



**Statement of Scott Lederhaus, M.D.
President, Association for Medical Ethics**

**Hearing on Physician Owned Distributors:
Are They Harmful to Patients and Payers?**

**United States Senate Committee on Finance
November 17, 2015**

Introduction

Chairman Hatch and committee members, it is an honor to be invited to testify before the Senate Committee on Finance's hearing on "Physician Owned Distributors: Are They Harmful to Patients and Payers?" As a neurosurgeon, spine surgeon and President of the Association for Medical Ethics, I have spent the last several years speaking out about the pervasive effect Physician Owned Distributorships of implantable medical devices, also known as PODs, on the medical community to my colleagues, patients and the media.

The Association for Medical Ethics is a grass roots group that was established by Ms. Gemma Cunningham and Dr. Charles Rosen at University of California, Irvine. The group formed in 2005 due to concerns regarding excessive and unnecessary spinal surgery being done in the United States. Initially consisting of orthopedic surgeons and neurosurgeons, the Association is now a national group and has expanded to include a variety of medical and surgical specialties. The members believe there is a need to address the rampant physician financial conflicts of interest contributing to the overuse and misuse of spine surgery in America. Dr. Charles Rosen was the only physician who testified in 2007 before Senate hearings about these abuses, which helped push through the Sunshine Act. Our current efforts have been directed towards the abuses and conflicts of interest with Physician Owned Distributors. I have been a member since 2007, a board member and now president of the group in 2014 and 2015.

In my testimony for the committee, I will define how PODs are affecting patients, physicians and the American medical community.

Understanding Physician Owned Distributors (PODs)

There are approximately 13.6 million patient visits for neck or low back conditions per year costing about \$950 per patient per year. Between 49% and 70% of all adults will experience back pain during their lifetime and 12-30% of all adults have an active back problem. Back pain is the second most common reason adults consult a primary care provider and it is estimated that the total cost of spine related problems is approximately \$90 billion per year with \$10 to \$20 billion in economic losses each year. Low back pain is the number one cause of disability in the United States and worldwide. Spinal fusion surgery is one of the most common surgical procedures done in the United States, roughly 500,000 operations per year. These 500,000 operations a year are where the opportunity arose for many spine surgeons to exploit the American medical system and endanger their patients.

Extensive spinal fusion surgery in the United States has exploded over the last decade often without indication and for no reason other than to enhance the income of some greedy and misguided spine surgeons. Outcomes are often poor. This behavior by some spine surgeons borders on criminal behavior, yet is largely ignored by most physicians and generally unrecognized by the public. The development of all types of spinal implants has dramatically increased over the last decade, enabling these spine surgeons to run amok by performing unindicated multilevel spinal fusion operations. Due to the vast array of spinal implants now available – and the large amount of money to be made - spine surgeons have consciously and subconsciously loosened their "indications" for the use of these new implants. When you have a

hammer, everything looks like a nail. The profit from the “sale” of these screws, rods, and cages to the hospital is often more money to the surgeon than received for the surgical fee.

At present there are more types, shapes, sizes, materials and ways of putting implants into the spine from almost any direction; front, back or side, than ever before. The signature turn of the further explosion of operative spine procedures occurred when spine surgeons began performing operations to treat low back pain. Low back pain became the key ingredient for spinal fusion operations that initially seemed to make sense with limited and specific indications. However, over time the “surgical candidate” became anyone with a backache. Due to the evolution of thought processes regarding the treatment of back disorders, the spinal surgeon can now simply rationalize almost any back complaint as a surgical indication by grossly expanding the accepted criteria. Some patients may benefit by this shotgun approach, but the improvement may be more on the basis of luck than following evidenced-based medicine and good surgical guidelines.

Another reason for the surgical aggressiveness can be attributed to the continued financial cuts to a physician’s income. Any cut in payments from Medicare directly translates into cuts in commercial insurance across the board. In order to maintain the same level of income, many doctors have made a conscious effort to see more patients and do more surgery, and some have become more “aggressive” with their surgical indications. The stage was set for some spine surgeons to enhance their income by increasing the numbers and levels of spine fusion procedures with the plethora of spinal implants available, particularly with the loosening of indications for spinal surgery.

With the further advent of PODs around 2003, doctors could now enhance their income far beyond what was imaginable prior to being involved in a POD. A POD is an entity whereby the physician purchases an ownership in an implant company. The POD buys the implants wholesale and then sells those implants to the hospital at retail. The surgeon inserts the POD implants into their patients and the doctor and POD organizers pocket the difference. Thus, the POD-docs can make additional income on each and every implant inserted in their patients creating obvious conflicts of interest. This has resulted in thousands of patients being treated by some overly aggressive spine surgeons, which have resulted in many un-indicated, multilevel spinal fusion operations, many of whom have suffered injuries, horrific infections and even death.

As a result of what my partners and I witnessed for years, we felt something had to be done. I was compelled to notify the appropriate authorities and have some resolution to the horrible acts of neglect and malpractice that my partners and I witnessed on a regular basis. However, going after these individuals legally is a quagmire of issues, which is bogged down and largely impotent. The peer review (hospital physician oversight) process is generally useless and powerless. Too often, doctors who sit on peer review committees may choose to look the other way to avoid being tied up in legal proceedings. Hospital administrators often close their eyes to the abuses since the extensive spinal fusion operations bring huge profits into the hospital. The State Medical Boards have done little to protect the public.

What are the positions of our surgical societies and the American Medical Association on investing in PODs and conflicts of interest?

American Medical Association (AMA)

(<http://www.amednews.com/article/20130408/government/130409964/7/>). The American Medical Association (AMA) Code of Ethics, Opinion 8.06 issued in 2002 under Prescribing and Dispensing Drugs and Devices on the AMA website states: “Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products.” “Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or re-packer of the products involved.” (<http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion806.page>).

North American Spine Society (NASS): Ethical Stance on Industry and PODS

According to the North American Spine Society (NASS) Code of Ethics (<http://www.spine.org/Pages/PracticePolicy/EthicsProfConduct/CodeofEthics.aspx>) revised March 2012 states “A NASS member should not enter into any academic or consulting relationship with industry that might influence his or her care of patients. If a conflict or apparent conflict develops between the physician’s financial interest and the physician’s responsibilities to the patient, the conflict must be resolved to the patient’s benefit. A NASS member must disclose to colleagues and patients, in a professional context, any financial relationships that he or she has with industry. A NASS member who fails to disclose financial or other significant relationships with industry in accordance with NASS' current Disclosure Policy is in violation of this Code of Ethics. NASS does not prevent or restrict its members from participating in a POD, but requires POD owners to disclose their ownership to their patients. Level 1 compliance for all NASS committee chairs and board members cannot have any POD involvement.”

American Academy of Orthopedic Surgeons (AAOS): Ethical Stance on Industry

According to the American Academy of Orthopedic Surgeons (AAOS) Code of Ethics, revised 2011, section IIIC: (<http://www.aaos.org/about/papers/ethics.asp>). “When an orthopedic surgeon receives anything of value including royalties, from a manufacturer, the orthopedic surgeon must disclose this fact to the patient. It is unethical for an orthopedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular device or product. Fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable.”

American Association of Neurological Surgeons (AANS): Ethical Stance on Industry

The American Association of Neurological Surgeons Position Statement: 2008 May 05 (http://www.aans.org/~/link.aspx?_id=360DCEF0D6464BA3A086EF32819B1DD6&_z=z) Guidelines on Neurosurgeon-Industry Conflicts of Interest, Article 51297 states in their 2008 Code of Ethics: “It is unethical for a neurosurgeon to receive compensation of any kind from industry in exchange for using a particular device or medication in clinical practice. A neurosurgeon who has influence in selecting a particular product or service for an entity

(organization, institution) shall disclose any relationship with industry to colleagues, the institution and other affected entities. A "conflict of interest" occurs when a neurosurgeon or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with industry that could be perceived as influencing the neurosurgeon's obligation to act in the best interest of the patient."

California Association of Neurological Surgeons (CANS): California Association of Neurological Surgeons Newsletter, Volume 40, number 3, March 2013 and Volume 40, number 4, April 2013.

The California Association of Neurological Surgeons (CANS) in 2012 requested of "the AANS and the Congress of Neurological Surgeons (CNS) a Conflict of Interest Statement to include Physician Owned Distributorships (PODs)." CANS requested that the position statement should affirm that the neurosurgeon should disclose to the patient of his or her financial interest that is related to any aspect of the patient's evaluation and care related to the use of POD products.

AANS: Code of Ethics: Revised November 22, 2014

<http://www.aans.org/en/About%20AANS/~media/4A6862BB037742FF99B833D609D23B1E.ashx>

The AANS finally included Physician Owned "Enterprise" in their updated Code of Ethics. "The AANS Member who has influence in selecting a particular device, product or service for an entity shall disclose any relationship(s) with industry to colleagues, the institution and other affected entities prior to the entity's selection or purchase of the device, product or service. If a AANS Member has a financial or ownership interest in a **physician-owned enterprise**, or any other entity that sells, or arranges to sell, implantable medical devices, and/or in a durable medical goods provider, imaging center, surgery center or other health care facility where the neurological surgeon's financial interest is not immediately obvious, the AANS Member **must disclose that financial interest to the patient and the institution where the patient is being treated**. The financial or ownership interest must be disclosed on a timely basis so as to allow the patient to take the interest(s) into account when making his or her health care decisions. The AANS Member has an obligation to be aware of the applicable laws regarding physician ownership, compensation and control of these entities. Disclosure of professionally-related commercial interests and any other interests that may influence clinical decision-making is required in communications to patients, the public and colleagues."

Dr. Gerald Rodts, 2010 Congress of Neurological Surgeon (CNS) President stated in his 2010 CNS Presidential Address: "**Findings of disk dehydration or degeneration at greater than or equal to 3 levels in a patient without deformity and only back pain do not justify a 3- or 4-level fusion. Without any medical evidence to support such extensive fusions, it is unethical to perform them. We all have a responsibility in our own practices, in our own hospitals and in our own communities to police ourselves. We need to get the issue out in the open and discuss it openly and honestly at regional or national neurosurgery meetings. It can no longer be the 800 pound gorilla in the room that everyone is ignoring.**"

Dr. Gerald E. Rodts, M.D. 2010 CNS Presidential Address. Neurosurgical Pioneers: Foundation for Future Innovation. Clinical Neurosurgery, Volume 58, 2011. https://www.cns.org/sites/default/files/clinical_neuro/Chapter1_0.pdf

Summary of Ethical Problems with PODs

Every reputable physician association states that physicians must not be influenced in their choice of medical product by a financial interest. But it is difficult to believe that even physicians with the best of intentions could avoid being influenced in their choice of product and procedure by POD ownership. This conflict of interest is not the same as the financial incentive that exists in all fee-for-service medicine: its additive, and it's also qualitatively different. Not only is there potentially a lot more money involved for the physician-owners, but, the doctor's financial interest is likely to overwhelm any ability the hospital might otherwise have to exercise quality control. As Dr. James R. Bean, a former President of the American College of Neurosurgeons has said, "PODs invite an abuse that can neither be regulated nor prevented." Bean, "Are Physician-Owned Distributorships (PODs) Ethical," AANS Neurosurgeon, Volume 21, No. 2, 2012. And while disclosure to patients of such a conflict-of-interest is an ethical requirement, it is not sufficient. Relying on sound social science evidence, the HHS Office of Inspector General (OIG) has noted that patients often will perceive disclosure as a testimonial in favor of the procedure or product, Special Fraud Alert on Physician-Owned Entities (2013) http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf; e.g.

It has been my experience that patients have no idea what an implant looks like, where they are made, what they are made of, what kind of quality they may be or what would be best for them. That decision is left to the spine surgeon. As a result patients are blindly willing to accept whatever implant the surgeon would decide to use regardless of the quality of those implants or where they are made. A patient has no idea what a POD is or how a POD might affect their treatment or outcome. So a disclosure by the physician of the POD implants to be used is nothing more than the physician telling their patients what they will be inserting into their spines.

Unfair competition, predatory pricing, and market distortion

In addition to the severe ethical problems posed by PODs, they adversely affect competition and distort the true price of healthcare services. On the basic question of competition, PODs eliminate it. Because implants are physician preference items, once physicians invest in a POD, the hospitals and ASCs where they perform their procedures either buy from the POD, or the physicians will take their cases elsewhere. Direct sale from an implant manufacturer to the facility is eliminated.

Moreover, through what might be described as "**Predatory Pricing**," PODs prevent the non-POD doctors from being able to compete on a level playing field when it comes to contract negotiations with insurance groups. Physicians whose income is supplemented by their self-referral earnings from a POD can agree to what would otherwise be unrealistically low insurance reimbursement rates for their physician services. Thus, the physicians who are members of a POD can simply eliminate competition between the POD and non-POD physicians by signing ridiculously low reimbursement healthcare contracts. This rewards the POD physicians, stifles competition and has nothing to do with good or competitive care, but only about money. It can

only hurt the market for health care services when inappropriate financial incentives hide the true costs that should be the basis for reimbursement rates and policies.

The OIG and PODs

I am not a lawyer, and fortunately the committee has not asked me here today to give legal advice. But you don't have to be a lawyer to understand something is illegal when the OIG describes self-referral to PODs as "inherently suspect" under the Federal health care programs anti-kickback law. According to OIG, the law is that if one purpose of offering a physician an opportunity to earn a return from a POD investment is to induce that doctor to order products from the POD, the law is violated. Can anyone seriously believe that there is any physician anywhere who has a POD ownership interest without at least "one purpose" being the financial reward from ordering POD products for his or her own patients?

I'm also not an economist. But you don't have to be an economist to understand that PODs don't save money when the OIG reports that from a study of almost 600 hospitals and almost 1,000 spinal fusion cases. *Physician-Owned Distributors of Spinal Devices: Overview of Prevalence and Utilization*, October 2013 <https://oig.hhs.gov/oei/reports/oei-01-11-00660.asp>. The OIG reported that the cost of implants purchased from PODs was not less, and in some cases was more, than from the purchase of non-POD devices. Also not surprising was the fact that the rate of growth of spinal surgeries at POD-purchasing hospitals was three times the rate at non-POD hospitals. POD Hospitals also performed 28% more surgeries than non-POD hospitals. If PODs present a serious conflict of interest, are "inherently suspect" under the anti-kickback law, don't save money and do lead to overutilization of medical services, it is hard to understand why any of them are still in business.

PODs in the real world

The poor judgment and extensive surgeries are not just theoretical. Physicians with ownership in PODs have caused real harm to patients. I have personally seen patients in consultation who have been the brunt of a POD surgeon. Examples are numerous: The 85-year-old man who has back pain undergoes a T8 to S1 (10 spinal levels) fusion with pedicle screws and rods up and down the spine to treat the back pain. Needless to say this not indicated or supported in the literature, but in most instances detrimental and can be lethal. The 45-year-old woman who has a single level herniated disc in her back with radiating leg pain who may benefit by a one hour, limited lumbar discectomy, but undergoes a two level lumbar fusion operation. The patient who has a multilevel lumbar fusion for suspected nerve root pain who does not improve only to find out the POD doctor did not examine their arthritic hips, which was the actual source of the pain. The patient who presents with carpal tunnel syndrome in the hand, yet gets a multiple level fusion in the neck. The patient who has mild spinal canal narrowing in the neck without any spinal cord compression, but is told they need a multilevel neck fusion to avoid becoming paralyzed. The patient with back pain who undergoes a three level lumbar fusion operation, which does not help the pain, undergoes additional levels of fusion with still no improvement, who then undergoes a sacro-iliac joint fusion, still without resolution of the pain, only then to be referred to a pain management physician who puts in a spinal cord stimulator to help with the pain.

Mr. John Carreyrou authored an article for the Wall Street Journal about Dr. Aria Sabit, a neurosurgeon in Ventura, Calif., who used Apex Medical implants through Reliance Medical. The same Reliance Medical implants from Mr. Bret Berry and Mr. Adam Pike who claimed they had no financial dealings with the doctors. According to the **Wall Street Journal articles by Mr. John Carreyrou on 7/25/13 (“Surgeons Eyed Over Deals With Medical-Device Makers”)** and **7/27/13, (“Does my Surgeon Profit From My Implants?”)**, the Reliance Medical network of Mr. Pike and Mr. Berry eventually grew to comprise at least 11 PODs operating in six states: Utah, California, Texas, Louisiana, Florida and South Carolina. Thus, further evidence that Reliance Medical is a group of PODs that utilize one of their 26 LLC’s for distribution purposes of the POD implants. Dr. Sabit worked in Ventura, Calif., for 17 months and somehow managed to acquire 30 malpractice lawsuits against him. It just so happened that in many of his cases he used Apex Medical Implants, which are Reliance Medical implants supplied by Mr. Pike, Mr. Berry and Mr. Hoffman (the owners and salesperson for Reliance Medical implants). The profits from Apex Medical POD included 20% of the proceeds each going to Mr. Adam Pike, Mr. Bret Berry, Mr. John Hoffman, Dr. Sean Xie (a neurosurgeon in Los Angeles who apparently trained with Dr. Sabit, as a co-owner in Apex POD) and Dr. Aria Sabit. Dr. Sabit’s surgeries, often without indication and very extensive spine fusion procedures, caused injury to many patients including nerve root damage, spinal fluid leaks, failed fusions and life threatening infections to mention a few complications. Dr. Sabit reportedly was paid \$400,000 in just over a year for the use of the Apex POD implants. These issues were discussed in the articles by Mr. Carreyrou. Thankfully, the Department of Justice has brought cases against Dr. Sabit and against Reliance, bringing both criminal charges and claims under the False Claims Act. E.g., United States District Court for the Eastern District of Michigan, United States of America v Aria O. Sabit” Filed 2/7/14 page 32 and 33, http://projects.scpr.org/longreads/selling-the-spine/docs/doj_investigation.pdf. The USA vs Reliance Medical Systems, Mr. Adam Pike, Mr. Brett Berry, Mr. John Hoffman and Dr. Aria Sabit is the first test case against a POD. However, what is really remarkable is that although OIG’s report estimated that 20% of the spinal fusion operations done in America were done with POD implants in 2011, there currently do not appear to be any other enforcement cases.

Hospital systems react to POD controversy

Overtime, many hospital systems have recognized that PODs represent additional liability exposure and perhaps increased abuse, expense and inherent conflicts of interest. Especially following the OIG’s 2013 Special Fraud Alert, many hospitals have taken the opinion that PODs are too risky and have eliminated them from their facilities. Some of the hospitals that no longer allow PODs are:

- Catholic Healthcare West, now Dignity Health (40 Hospitals)
- Scripps Hospital System in San Diego
- Martin Memorial Health System (Florida)
- Providence Health & Services (28 Hospitals)
- Loma Linda University
- University of California, Irvine
- The Memorial Care Health System in Orange County (6 Hospitals)
- Tenet Health Care (77 Hospitals in 14 states)
- Ascension Health (70 Hospitals, largest Catholic non-profit)
- Intermountain Healthcare (22 hospitals in Utah and Idaho)
- Hospital Corporation of America (HCA, 165 hospitals, 115 ASC’s)

- Baylor Scott & White Health (43 hospitals in Texas)

It is encouraging that the private sector is stepping up to push back on PODs to fill the gap left by the absence of law enforcement. But there are still way too many hospitals that are dealing with PODs. The private sector alone is not enough to protect patients and the health care system.

Can there be an “Ethical POD?”

In a word, “no.” Surgery involving implantable medical devices is one of the great medical innovations of the 20th Century. Millions of patients have received life-changing and life-prolonging relief from disabilities that crippled or killed previous generations. Physicians who provide this kind of care are justifiably proud of what they do. After long years of training to become specialists in these fields, many of the physicians in this country have been frustrated to watch as a health care system tries to “bend the cost curve” which continues to devalue their services. That the physicians of this country are looking for an alternative should then be of no surprise.

But PODs cannot be the answer. Giving physicians a financial interest in the implants they order for their own patients creates a conflict of interest that is quantitatively greater and qualitatively different from the choice of whether to treat a patient in the first place. Medical ethics largely places the decision of whether an inappropriate financial interest exists in the hands of the physician. However, it is difficult to believe that any physician could fail to be influenced in choice of products based on the financial interest involved, or choice of facility based on whether the facility will deal with the POD. PODs adversely affect competition and distort the true cost of health care products and services. And while decreased health care costs and better controlled utilization of health care services would not eliminate the conflict interest, unfair competition, or market distortion, the OIG’s research demonstrates that PODs fail to deliver even on these.

Conclusion

In conclusion, my experience as a neurosurgeon these past 30+ years, and my observations of the world around me from my position as President of the Association for Medical Ethics, leads me to believe that physicians should not be permitted to profit from the implants they order for their own patients by investment in a POD. PODs present doctors with an ethical conflict that realistically can’t be overcome. They create unfair competition among implant sellers, hospitals, and physicians. They distort the true cost of medical products and services. And even if they did so in the transparent light of day, the potential for harm to patients and the integrity of the physician-patient relationship can’t be put at risk in this way. The only answer in my opinion is that PODs cannot be allowed.

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Supporting Addendum One

Physician-Owned Distributors: The Wave of the Future or the End of the Model?

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ABSTRACT: New business entities called physician-owned distributors (PODs) have sprung up around the country. PODs are business entities that enhance the income of physicians who are investors via the recovery of money paid out for the implantation of medical devices in their patients. There have been a varying opinions among attorney groups and the Office of Inspector General as to their legality and what may constitute a legal entity. The legal opinion of attorneys employed by the major implant companies is that the PODs are illegal, whereas the legal opinion of those physicians setting up a POD is that the PODs are legal when properly and “legally” constructed. The Office of Inspector General has been watching these businesses as possible violations of the Stark Laws and kickbacks being paid out to the physician owners in the PODs. Some hospital groups have been prohibiting PODs from doing business in their hospitals because of fear of the excessive use of implants and possible kickback violations. These are confusing issues and as of this time there is no clear and concise model that can be considered legal, yet the PODs persist and are becoming more prevalent.

KEY WORDS: physician-owned distributors, PODs, OIG, kickbacks, Stark, safe harbors, alliance surgical distributors, omega solutions, implants, Sunshine Act, predatory pricing, False Claims Act, civil monetary penalty.

I. DEFINITION

Physician-owned distributors (PODs) are sometimes called physician-owned intermediaries or physician-owned companies by virtue of their place in the supply chain. PODs are groups of physicians, usually surgeons, who enter into a business relationship with a business entity that purchases implanted devices such as total joint prostheses or spinal hardware (i.e., pedicle screws, cages, and rods that the owner physician ordered for their cases). The physicians in the POD profit financially by participating in the sale of medical devices intended for implantation in their own patients, thus creating the opportunity for them to profit from their own referrals and implants.

II. INTENT AND DESIGN MODEL

Probably in large part because of the continued decline in reimbursement from Medicare and private payers, PODs have become increasingly widespread throughout the United States in an effort to increase physician income.¹ The design with which the PODs achieve their goal varies. The simplest model involves the POD business being set up by an entrepreneur, who could be a physician or nonphysician. The developer of this model then seeks investors who implant devices such as spinal implants, joint replacement,

cardiac pacemakers, and spinal cord stimulators. The initial financial contribution to be an investor may vary, but it could exceed \$50,000. The investor may own their implants, a percentage of the POD, or both. The hospital at which the surgery takes place pays the POD for the product after the investor implants the devices. The POD includes a shell—a second corporation or entity—that is used to facilitate payment to the investors, thus avoiding direct payment from the POD which then sells its products to the physician investors. The investor may be involved as a solo physician in his own investment group or possibly could be involved in a small group of physicians who all share in the profits; both of these models are considered mini-PODs. Therefore, in most of these models there is a direct payment per implant to the POD.

III. CONFLICTS OF INTEREST

The Office of Inspector General (OIG) along with the Stark legislation have examined PODs as a source of kickbacks and conflicts of interest.^{2,3} Kickbacks can be in the form of direct financial payments, consulting and royalty agreements, trips for doctors and their families, or consulting meetings. The conflict of interest is borne out in that an investor in a POD stands to make large sums of money for the implants used. The more extensive the surgery the higher the reimbursement, which may be a set up for egregious acts on the part of the surgeon. Unfortunately, all too often, greed becomes the determining factor in the extent of surgery and issues surrounding minimal or no indication for surgery.

IV. EXISTING LEGISLATION AGAINST THE POD MODEL

According to a OIG/Department of Health Services (DHS) Fraud and Abuse Alert from January 23, 1989,² noted that Congress did not intend to bar absolutely any investment by physicians in other health care entities but has included a “safe harbor” for investment interests in large public corporations. The OIG and DHS have done this to ensure that the companies are sufficiently large enough so that the return on investment is, at most, tangentially related to any referrals of items or services made by a shareholder. Therefore, under the proposed rule, referrals by physicians to entities in which they have any kind of investment interest (other than in large corporations available to the general public), such as limited partnerships, would be subject to prosecution.

Safe harbors’ protection of medical business entities makes it possible that certain business arrangements might violate the antikickback laws. Thus, if the business qualifies as a safe harbor then the doctors involved do not have to worry about being accused of making money from referrals. To be a “legal” POD entity under the safe harbor regulations a number of legal issues would need to be satisfied to avoid being held accountable under antikickback regulations.

Safe harbor regulations allow for certain arrangements when the business entity, a POD in this case, is not publicly traded, derives less than 40% income from physician investors, be no more than 40% physician owned, receive no referrals from investing physicians, have terms for passive investors that are no different than those for physician

investors, and require payments to physicians that are not directly related to volume of referrals. Passive physician owners are not required to make referrals to the POD and physicians are not required to divest their interest if they retire or are no longer actively engaged in the practice of medicine in the POD market. It is doubtful if any of the PODs today would qualify as safe harbors because a large, publicly traded company does not fit the POD model. In general, then, safe harbor protection would not apply to a POD.

If the safe harbor classification does not apply, then the Ethics in Patient Referral Act (Stark law against self referrals) may apply. The theory behind the Stark law is to control unnecessary spending that arises from improper financial relationships with Federal programs. The statute applies to anyone who is connected financially under any federally funded health care program, not just Medicare or Medicaid. A physician is prohibited from referring Medicare-funded inpatient or outpatient services when the physician or anyone in their immediate family has a financial relationship with the associated hospital unless the relationship meets a Stark exception, for example, a possible indirect financial relationship.⁴ To violate Stark laws, the *intent* to violate does not matter, whereas with antikickback regulations, *intent* to violate is critical.

Under the Stark law, anyone who fulfils either of the following criteria is potentially liable for prosecution:

A physician who has a "financial relationship," which is defined as (a) ownership of an entity, or (b) a compensation arrangement between physicians and the entity, including family members.

The entity cannot make a claim to Medicare for a prohibited referral. This is done to prevent physicians from making referrals based on financial gain, thus preventing overutilization, which increases health care costs.

Because PODs do not qualify as safe harbors, they must follow antikickback regulations and potentially Stark laws. A member of a POD then has to be concerned about whether the POD is a legal entity and if, as an investor, they would be potentially at fault for breaking these laws. The Stark laws prohibit Medicare payments for any hospital services *referred* by a physician with a prohibited financial relationship or who requires refunds are subject to penalties that increase with each new referral. This is especially true when the physician knows or should have known they are an investor in a POD. The Centers for Medicare and Medicaid Services has recognized the physician-POD-hospital connection and believe this is a *indirect financial relationship* under the Stark laws and would run afoul of the physician self-referral statute.⁵ The Federal Register⁵ reported that there is concern about possible program or patient abuse when physicians profit from the referrals they make to hospitals through physician-owned companies. In the *Federal Register* it is noted that many cases the physician investors bear little, if any, economic risk with respect to the medical devices. It is felt that some PODs serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician investors use on their own patients. "The financial incentives paid to the phy-

sicians may foster an anticompetitive climate, raise quality of care concerns, and lead to overutilization of the device or other products to which the physician is linked.”^{5,6}

If the Stark restrictions are not enough, the False Claims Act (FCA) can also be a legal avenue against a investor. The FCA is the Federal government’s primary civil enforcement tool for addressing health care fraud. Under the False Claims Act the government may enforce significant penalties against any person who *knowingly* submits a false claim for *unnecessary* medical services. Whistleblowers can report those violators who have defrauded the government, and many of the individuals who file these lawsuits are employees or former employees of the companies that committed the fraud. If there are violations of the antikickback or Stark laws, then there is a potential for a violation of the FCA, which is implicated in cases of the questionable medical necessity of procedures. In February 2008, Gregory Demske of the OIG stated that, “[PODs] will be closely scrutinized due to potential for abuse. These groups can be prosecuted under the Federal False Claims Act, Federal antikickback statute, or civil monitories penalty law.”⁷ The Civil Monetary Penalty (CMP) refers to device manufacturers paying a physician to recommend the specific device for use in hospital procedures. Therefore, a physician owner in a POD is walking a tight rope with respect to believing they can navigate the potential laws designed to punish those involved in health care fraud and abuse.

V. GOVERNMENT LEGAL ISSUES

A June 2011 inquiry by the Senate Finance Committee provided an overview of key issues and potential areas for congressional oversight. This investigative report noted that PODs began developing around 2003 and have branched out from orthopedics to spinal implants, cardiac pacemakers, and other implants.^{8,9} It was noted that that there are multiple PODs in at least 20 states, with as many as 40 PODs in California alone.¹ On June 9, 2011, letters were sent to the US Department of Health and Human Services and the CMS, both of which were authored by Senator Orrin Hatch (ranking member of the Finance Committee), Senator Herb Kohl (chairman of the Special Committee on Aging), Senator Charles Grassley (ranking member of the Judiciary Committee), Senator Max Baucus (chairman of the Finance Committee), and Senator Bob Corker (ranking member of the Special Committee on Aging). The authors requested that PODs be included in the Sunshine Act as far as making public the payments made to physicians through these POD groups. In addition, the letters requested that the DHS and CMS address potential loopholes in the POD model that may relate to the upcoming accountable care organizations and any potential conflicts of interest, safety concerns, and the impact on health care, all of which are considered “troubling issues about PODs.”⁸

VI. GETTING AROUND THE GOVERNMENT LEGAL ISSUES

Bill Lockyer, Attorney General for the State of California, issued a opinion letter in February 2006.¹⁰ He stated that a physician may prescribe a medical device distributed by a

company in which a physician has an ownership provided that the return on investment is based on the physician's proportional ownership share and that the requisite disclosures are made. He goes on to point out that the company's profits are not dependent on the number of referrals that the physician has made if the physician complied with relevant patient disclosure requirements. The opinion mentions the Department of Health and Human Services regulations defining "financial interests" subject to the federal antikickback statute and that interest offered to passive investors would be no different than that offered to other investors. He states that the investment would be required to be lawful under the federal antikickback statute and implemented regulations. Regarding the Unfair Competition Law, which governs anticompetitive business practices as well as injuries to consumers, he notes that, "a business practice can be unfair if it offends and established public policy or is immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers."¹¹ The terms of financial interest, proportional return on investment, and passive investors are vague and not well defined in Lockyer's opinion letter. Despite his opinion, the Attorney General of the State of California has no jurisdiction over the federal laws regarding fraud and abuse, antikickback regulations, or the Stark laws.

Many of the attorney groups that argue that PODs are illegal generally have some connection to the medical device companies and thus argue in favor of the illegal nature of PODs.¹²⁻¹⁴ No different are the attorney groups that argue that PODs are legal.^{15,16} Thus, there seems to be no unbiased opinion when it comes to the legal views on either side of the argument. Hooper, Lundy & Bookman, a law firm in California that has worked with PODs, including Alliance Surgical Distributors, a POD owned by Dr. John Steinmann in Redlands, California; Omega Solutions, a POD in Fresno, California; and Atlas Medical in Southern California. Hooper, Lundy & Bookman have stated and recognize that a POD may be impacted by antikickback statutes and they point out that the OIG recognizes that these PODs are vulnerable to violations of antikickback laws, and the firm also states that, "following these guidelines does not guarantee the POD is lawful."¹⁴ In an attempt to avoid the need for safe harbors, Hooper, Lundy & Bookman claim to have set up a potentially legal POD by using *indirect compensation* as an exception to the Stark self-referral laws: the products are sold at fair market value, and pricing competes with that of other companies. As reported by Orthopedics This Week,¹⁷ the firm has established a 19 requirements that must be met for a POD to be considered a legal entity; these requirements will in effect make the POD as legal because it can meet the current restrictive federal laws. The Indirect Compensation Agreement is a Stark exception but is not relevant to the kickback laws. Therefore, the kickback laws can still be applied even with a Stark exception. Dr. Steinmann, owner of the POD Alliance Surgical Distributors, has opined that his model is a win-win for the doctor and hospital because he is able to supply the hospital with competitively priced implants and enable the physician members of the POD to enhance their income by using his model and his implants. His model does not take into account the surgeon who uses the POD implants and "saves the hospital money" but in actuality would increase costs by performing

extensive surgery that may not be needed. According to Hooper, Lundy & Bookman, using the 19 provisions, PODs can be as legal as possible although they still could be violating the antikickback laws.

The 19 steps for the formation of a POD¹⁸ as required by Hooper, Lundy & Bookman include the following:

1. The company will hire and employ its own personnel.
2. The company will purchase products directly from manufacturers/distributors under its own contracts.
3. The company will sell products directly to its own customers such as hospitals or surgery centers under its own contracts.
4. The company will manage its own inventory.
5. The company will have its own distinct office and warehouse space for the operation of its own business.
6. Products will be shipped to the company by the manufacturer/distributor and will be separately warehoused by the company before resale to hospitals or surgery centers.
7. The company will hold any and all licenses or governmental approvals necessary for the operation of its business.
8. The investment price offered to physicians will not be based on the projected referrals from the physicians, nor will the amount being offered to physicians reflect the anticipated referrals generated from the physicians procedures.
9. No physician's investment interest will be subject to repurchase for failure to use the company's devices in their surgeries.
10. The investing physicians will not be pressured in any way to utilize the company's devices in their surgeries.
11. The investing physicians will not exert pressure on the hospitals or surgery centers to purchase the devices from the company.
12. The company will be adequately capitalized for its operations through the initial capital contributions of its members and the physician investments will not be nominal. The members' capital contributions will not come from the manufacturers or distributors that sell devices to the company, nor will the managers or its affiliates loan funds to the physician investor for their capital contributions.
13. The use of the devices will at all times be medically necessary.
14. The company will not bill patients or payers (including Medicare and Medi-Cal) for the devices.

15. The company will have written agreements with the manufacturers/distributors for purchase of the devices.
16. The company will have written agreements with the purchasers, hospitals, or surgery centers for the sale of the devices.
17. The purchasers, hospitals, or surgery centers will be charged a fixed price based on negotiations, which will not increase with the use of more devices.
18. The company will generally have a fixed list of prices that will be generally available to all purchasers, hospitals, or surgery centers.
19. However, the company may be willing to accept lower pricing if the purchaser dictates lower fixed pricing. The payments by the purchasers will not be higher than fair market value for the devices.

Omega Solutions was the distributor used by Dr. Vishal Makker, who was exposed by the *Wall Street Journal* in March,¹⁷ April,¹⁹ and June 2011¹¹; the *Journal* highlighted that Makker was using implants from a POD and allegedly was performing multiple repeat surgeries while receiving \$500,000 per year from Omega Solutions. As well, Makker's girlfriend was an Omega product representative. Omega Solutions closed its doors after the *Wall Street Journal* articles because the instrument manufacturers declined to do business with Omega any longer. Since the exposition of Dr. Makker the Oregon's Providence Health & Services Hospital, the Providence Health & Services have eliminated PODs from their 28 hospital system, which was implemented by John Koster, M.D. and President/CEO on February 9, 2012.

Regarding physician ownership in light of the OIG opinion mentioned earlier, Paul Hastings,²⁰ an attorney employed by Medtronic-Sofamore Danek, stated that, "this could be considered a 'referral,' which is applicable to the antikickback statutes. Return on investment to a physician from a medical device company to which the physician refers must be based solely on the value of the investment. The physician with a ownership must disclose the financial interest in writing to the patient at the time the referral is made. These referral companies may be permissible, but should not be considered a blanket permission to engage in such activities." Hastings concluding the following: (1) the physician must disclose ownership interest in writing to the patient; (2) physicians should remember that they must comply with the most restrictive federal laws, which may carry significant criminal penalties; (3) the return on investment must be solely on the value of the investment; (4) the attorney general seems to view solicitation by medical device companies of physicians as investors to be a potential violation of the California Unfair Competition Law (hospitals have to use the physician implants); and (5) the physician should be careful not to commit in any way to using a company's products or to enter into an arrangement that guarantees return based on the volume of referrals.

Thomas Bulleit,^{17,21} an attorney in a firm that represents some large spinal implant companies, noted that PODs are entrepreneur-driven opportunities where doctors are

seduced into kicking in a “little bit of money” in exchange for shares of the company. “There is no purpose for these companies but to give the doctor’s a return. ... The anti-kickback statute is violated if one purpose of the financial reward to a doctor is to get him to order a particular product or refer patients to a particular hospital.”

Mr. Kevin McAnaney,²² a attorney who specializes in healthcare fraud, claims physician ownership of medical device companies is legal providing that the physicians are buying their shares at fair market value and that their profits are based on their percentage of ownership of interest and not on the volume of business they generate for the company. The problem would arise if the money made is directly tied to his usage of the product.

VII. THE STANCE OF GOVERNMENT TODAY

Advanced Medical Technology, an organization representing the code of ethics of interaction with health care professionals, headed by Stephen Ubl, requested clarification from the OIG regarding guidance for certain physician investments in medical device manufacturers and distributors.²³ The OIG has taken the stance of closely scrutinizing PODs under the fraud and abuse laws (Dept HHS, Oct 6, 2006). The OIG considers these arrangements ripe for potential violations of fraud and abuse and that these models will be observed closely. More recently the Senate Finance Committees¹² have strongly requested clarification on PODs to draw a line in the sand so everyone can understand what is “legal.” “You can’t possibly think this is OK,” said Tom Scully, senior counsel at the law firm Alston & Bird who headed the Medicare program from 2001 to 2004. “I understand that the docs feel squeezed and want to make more money, but they’re racing toward a cliff. This can’t possibly hold up.”¹⁸

In September 2011, Daniel Levinson, Inspector General of the OIG, gave the following response²⁴:

We expect that our study will produce important information about PODs. We will consider this information in determining whether to issue additional guidance addressing physician-owned entities, including PODs. However, as we have discussed a wide variety of POD models are being utilized, and different POD models can raise varying levels of legal concern; thus, the answers to many of the important legal questions posed about PODs depend on the specific facts of the case. The Federal Anti-Kickback Statute is a criminal, intent-based statute that plays a central role in addressing improprieties in physician–industry relationships. The legality of any individual physician-owned entity under the Federal Anti-Kickback Statute is highly dependent on each entity’s particular characteristics, including the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. For these reasons, the OIG’s ability to issue guidance about the application of these business structures is limited.

It has been OIG's longstanding view that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute an illegal inducement under the Federal Anti-Kickback Statute. When evaluating the legality of a such an investment, OIG would consider, among other factors, the terms under which a physician may invest in the entity and, conversely, the terms under which a physician owner may be required to divest his or her ownership interest; the actual return or projected return on the physician's investment; and the amount of revenues generated for the entity by its physician investors. OIG has repeatedly expressed this view, and listed these factors, in various guidance documents, including Special Fraud Alerts, advisory opinions, and published letters to the industry.

It is clear from Levinson's response that there is no formal decision as to what constitutes a legal POD or whether a POD even can be legal. The "wait and watch," noncommittal attitude of the OIG continues to confuse proponents on either side.

VII.A. The Sunshine Act

The Sunshine Act, introduced in 2009 by Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI),²⁵ requires manufacturers and group purchasing organizations to report a wide variety of payments to physicians and physician-owned entities. Penalties for not reporting include fines from \$1,000 to \$10,000 for each payment not reported, with a cap of \$150,000 per year. For intentional failure to report, the penalties will be steeper, with fines of \$10,000 to \$100,000 for each payment not reported, with a cap of \$1 million per year. For PODs, the Sunshine Act requires reporting physicians' ownership interests in private companies, including the dollar amount(s) invested, the current value, and any payment or transfer of value to the owner, including dividends or other payments. The information is to be published in a searchable website in 2013. The Sunshine Act alone does not imply that the PODs are illegal, only that items such as the dividends and payments are to be made public.

VII.B. The Stance of Some Hospital Groups

The Martin Memorial Health Systems in Stuart, Florida, have decided to stop doing business with PODs because in their opinion PODs are "inconsistent with the spirit and intent of the federal antikickback statute."²⁶ Other hospital groups are requiring their physician members to sign financial relationships with their suppliers to avoid antikickback and self-referral laws. The Scripps Hospital system in San Diego, California, has eliminated the use of PODs in their hospitals. According to Daniel Roach, Vice President of Compliance, except for very limited use the Catholic Healthcare West Hospital systems have eliminated PODs from their system of 40 hospitals throughout California, Arizona, and Nevada (Roach D, personal communication). As well, the 28-hospital

Providence Health & Services have eliminated PODs where Dr. Makker had performed surgery.

VIII. OTHER POD ISSUES NOT PREVIOUSLY CONSIDERED

VIII.A. Predatory Pricing

If one considers health plan contracts including capitated payment issues to the physicians who are investors in a POD, the POD physicians cannot be competed with. Over the years, physicians have been competing to the point of who will accept the bottom dollar on a contract. Now, with the POD model available, one can consider predatory pricing when it comes to contract negotiations. Without the monies paid from a POD, a non-POD physician has little or no power to compete with a physician or group of physicians who utilize a POD model. In theory, the POD physicians could survive without being paid any fees for services or capitated money to provide care for their patients from their contracted insurance groups. The POD physicians can generate more income than would be possible with any insurance payment plan. Thus, the POD physician essentially could work without compensation when it comes to the insurers and could dominate their local provider market. How could anyone who is not part of a POD compete with this model? This could be considered a violation California's unfair business practice under the Unfair Competition Law, section 17200.^{20,27} The antitrust laws were enacted to promote competition. Now we have gone to the other extreme to eliminate competition by reducing payments to amounts so low as to consider the POD model being almost free services to insurers. Although this is a new concept, it is occurring. This essentially promotes those physicians who may egregiously perform extensive and nonindicated operations for the sake of enhancing income solely on the implants used. Gone are the days of lumbar discectomies when a multilevel fusion can be done instead. Thus, predatory pricing rewards those unscrupulous surgeons who have no sense of ethics or doing what is best for the patient.

VIII.B. Who Loses?

In a POD situation, if a surgeon performs more than that which needs to be done, the hospital loses because the costs of the implants generally are paid directly by the hospital. In some instances the costs may be paid by the health maintenance organization or insurance company, depending on the contracts the hospital may have with the insurer. In the instance of Medicare, the hospital loses because patients are admitted on a diagnosis-related group basis, multiple implants would be paid for by the hospital and Medicare would only pay based on the admitting diagnosis-related group. The other loser in this model is the patient, who unknowingly has submitted to a extensive operation with little or no indication for the treatment.

VIII.C. What Can Be Done?

It is doubtful that all physicians can be trusted enough to perform operations or provide services for only those patients who need surgery and do only what is best for their patients. There are too many financial enticements to keep those marginally ethical docs on the straight and narrow. It will be up to the hospitals to be proactive in their stance regarding PODs. At a minimum, hospitals should develop a conflict of interest statement that all physicians should sign. If a hospital's opinion is that the PODs do not coincide with the intent of the law, then it would be up to the individual hospital to decide whether or not PODs should be allowed at their facility. These efforts likely would eliminate the PODs ability to develop or gain a foothold at any given hospital.

VIII.D. Can a POD be Legal?

With the controversy regarding the legality of PODs, one must decide if sitting on the fence waiting for the federal government to formally declare PODs illegal or legal or if the risks of joining a POD are worth it. With time there may be more openly prosecuted cases involving PODs undergoing OIG investigations for fraud and abuse with surgeons performing egregious nonindicated, multilevel procedures.

It would seem that a POD cannot qualify for protection as a safe harbor. Thus, a indirect payment model, as a potential Stark exception, would be necessary, as outlined in part by Dr. Steinmann's 19-point compliance, with several important additions and differences.

1. The POD investors could only own a fixed, small percentage of the company and eliminate multiple small and individual or mini-PODs.
2. Reimbursement from a POD can be based only on the percentage ownership of a individual POD and not by individual use of a product.
3. A POD must have a large number of physician owners, perhaps 25 or more, all with equal percentages of ownership, who locally work in a close geographic area, so that one cannot construe that payment is based on volume as it would be in a smaller POD and an investor cannot choose heavy users throughout a large geographic area.
4. Any implant company potentially could compete for the business at any hospital from the POD.
5. The physician owners would not purchase specific implants because purchasing a implant would force a physician to use only one particular product that may be of inferior quality or not what would be best for the patient.
6. The POD would not accrue implants but would purchase implants from the most cost-conscious and quality options manufactured by any of the small or large implant companies.

7. Implants purchased by the hospital through any vendor would be no more expensive with a POD; a POD could not charge higher fees than other implant companies.
8. Each hospital that allows PODs must have a conflict of interest statement that each physician member of that hospital signs.
9. If any physician is egregiously performing nonindicated, multilevel operations (which would have to be monitored via a peer-review process and conflict of interest declaration at each hospital), those individuals would be eliminated from the POD and potentially reported for possible fraud and abuse prosecution.
10. The POD owner would have to declare in writing to their patients that they have a financial interest in the company.
11. There would be no need for passive investors because the POD models would not qualify as safe harbors.
12. Physician investors who retire or move out of the area of a particular POD would sell their interests back to the POD.
13. POD investors who care for non–federally funded insurance, including workers compensation, should follow these same guidelines to avoid egregious acts and kickbacks.

IX. CONCLUSION

The POD model as described by John Steinmann and others has been looked at legally by Hooper, Lundy & Bookman in California. Nevertheless, even this legal team, despite all efforts to develop a legal entity that complies with the most stringent federal legislation, recognizes and acknowledges that their efforts to make a legal POD still could be considered illegal under scrutiny by the federal government. It should be remembered that a legal opinion from an attorney or group of attorneys does not have legal jurisdiction over the OIG/DHS and the federally funded patients. It is ultimately up to the OIG and Fraud and Abuse to determine what is considered legal and what is deemed illegal and worthy of prosecution. For these reasons, one should be exceedingly careful when becoming involved in a POD. Only after a POD investor loses his license to practice medicine, incurs heavy fines, or faces potential prison time for egregious acts will these POD groups collapse, as they did in the case of the Omega Solutions group and Dr. Makker. Perhaps all hospitals should consider what the Stuart, Florida–based Martin Memorial Health Systems decided this year: stop doing business with such entities. Martin Memorial Health Systems told its staff that PODs are “inconsistent with the spirit and intent of the federal antikick-back statute.” If a legal POD could be devised with stringent guidelines then perhaps there is a place in the market for such a model. Without strict guidelines the POD model will be poorly defined and lead to fragmentation of structure, and we will be back to our current

dilemma of forming semilegal or entirely illegal PODs and dealing with predatory pricing and kickbacks. Continuing on as we are is not acceptable and will eventually require the OIG to take a firm stance for or against PODs. It is up to physicians to practice responsible, ethical surgery for the benefit of their patients. However, if a legal POD entity can be developed that satisfies all the stringent federal laws and restrictions it also could be a revenue source for physicians in these difficult economic times.

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Supporting Addendum Two

T10-S1 fusion for low back pain and bilateral Sacro-iliac fusion



Shown is an extensive POD fusion to treat low back pain. Unfortunately, despite a total of four operations, the patient is in worse pain than prior to the surgeries. This is not a unique case.