

Physician-Owned “Distributors” of Spinal Implants: The Impropriety of Physicians as Commissioned Sales Representatives

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“My idea was to form a limited liability company that consisted of approximately one hundred doctors who would also act as the company’s customer base.” (Affidavit by founder of physician-owned distributor, April 2006)

“Given the strong potential for improper inducements between and among physician investors, the entities, device vendors, and device purchasers . . . these ventures should be closely scrutinized under the fraud and abuse laws.” (OIG October 2006)

“These business ventures raise substantial concerns that a physician’s return on investment from the venture may influence the physician’s choice of device.” (OIG February 2008)

“We are concerned that some physician-owned organizations may 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.” (CMS April 2008)

“In many instances, the arrangement would not satisfy the requirements of the exception for indirect compensation arrangements in § 411.357(p), and would, therefore, run afoul of the physician self-referral [Stark] statute.” (CMS April 2008)

1. Executive Summary

A physician-owned “distributor,” or “POD,”¹ purports to act as an “independent” sales representative on behalf of any implantable medical device manufacturers that will participate in its scheme. In fact, the business model is simply to share with the physician-“investors” sales commissions that otherwise would be paid to the support personnel, whom the physician establishment call “industry employed allied professionals” (IEAPs), for the implantable medical devices ordered by the physicians themselves. The physician-investors in a POD, and the hospitals and implant manufacturers who deal with them, risk substantial liability under the

¹ PODs are a subset of a broader category of physician-owned companies or “POCs”, sometimes called “POIs” (physician-owned intermediaries) in recognition of their middleman status. *See infra* notes 8-9 and accompanying text.

Antikickback statute, the Stark Law, and the False Claims Act for participating in this business model.

Simply put, we do not believe that physician ownership of PODs reflects a legitimate investment, and the evidence is that government “fraud and abuse” enforcers share our view. Rather, paying a POD a commission every time the physician-owners order an implant for one of their patients is no different than paying the physicians for their collective referrals. Unlike legitimate independent sales agents, PODs present an obvious and unavoidable potential for the patient and program abuses that the federal Antikickback statute and the Stark law were specifically intended to prohibit. Moreover, we believe a close examination will reveal that most PODs essentially are shell entities, with no real infrastructure or capital investment, that exist simply for the unlawful purpose of directing remuneration to physicians for their ability to control the selection of surgical implants sold through the scheme. In particular, we have concerns that:

- Physician ownership of PODs creates an ethical conflict of interest that can distort medical decision making because it gives physicians an incentive to order the implants that will benefit them financially, rather than to choose the products that are best for their patients, as well as to perform more procedures than necessary in order to earn more commissions. For example, client representatives have reported to us that physician “investors” in PODs increasingly are engaging in revision spinal fusion procedures simply to replace implants with their own commission-based products.
- PODs have an unfair effect on competition because hospitals who want a physician-owner to perform procedures there, and manufacturers who want those physicians to use their products, will have little choice but to deal with a referring physician’s POD, even if it is more expensive to do so and even if the POD is not as well qualified as its legitimate competitors.
- PODs are likely to result in either increased cost or lower quality. Simple economics teaches that adding a new “mouth to feed” to the supply chain will add cost, and since the commission payment is a percentage of sale price, the POD has no incentive to negotiate a lower sale price. Moreover, in the prevalent scenario, where an existing distributor employing qualified IEAPs decides to form a “joint venture” POD with its physician customers as “investors,” the physician adds zero value to the transaction, and puts his or her product choices in the pocket of only those manufacturers who are willing to pay these sorts of distributors. The alternative – where physicians form a “new business” and bypass a qualified IEAP – obviously portends even more ominously for patient care. In either case, not only will the physician be receiving a straightforward payment per referral, but the quality of the procedure is destined to decline as the advent of more “investors” siphons commissions from their proper purpose of compensating the IEAP, and as financial self-interest limits the implant choices available to patients.

Both the Office of Inspector General of the Department of Health and Human Services (OIG), and the Centers for Medicare and Medicaid Services (CMS) have expressed serious legal and programmatic concerns with physician-owned entities, including PODs. In October 2006, OIG indicated it was “aware of an apparent proliferation” of physician-owned entities and stated that “[g]iven the strong potential for improper inducements between and among physician investors,

the entities, device vendors, and device purchasers,” the OIG believed “these ventures should be closely scrutinized under the fraud and abuse laws.”² More recently, OIG officials indicated in Congressional testimony that PODs and other physician-owned companies “raise substantial concerns that a physician’s return on investment from the venture may influence the physician’s choice of device.”³

Similarly, CMS has been critical of these entities, and has considered amending its Stark physician self-referral regulations to address PODs and like entities more specifically.⁴ Discussing PODs along with similar physician-owned entities, CMS has stated that these entities “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,”⁵ and that in many instances such physician-owned entities “would not satisfy the requirements of the exception for indirect compensation arrangements in [42 C.F.R.] § 411.357(p), and would, therefore, run afoul of the physician self-referral [Stark] statute.”⁶

Given these expressions of serious legal concern from OIG and CMS, it is only a matter of time before enforcement authorities, acting on their own or with the assistance of private relators suing under the *qui tam* provisions of the federal False Claims Act, bring enforcement actions against the physician-owners of PODs and the hospitals and medical device manufacturers who deal with them. Moreover, since violations of the Stark law prohibit Medicare payments for any hospital service referred by a physician with a prohibited financial relationship, and require refunds for payments already received, hospitals that accept referrals from physicians whom they know or should know are receiving commissions from a POD are subject to penalties and repayment obligations that increase with each new referral from a POD physician.

To better explain to stakeholders the inherent unlawfulness and legal liabilities associated with the POD business model, we have set forth below (1) a more detailed description of the supply chain for implantable medical devices and how the POD structure that our client representatives are

² Letter from Vicki Robinson, Chief, Industry Guidance Branch, HHS Office of Inspector General (Oct. 6, 2006), available at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20%282%29.pdf>.

³ Testimony of Gregory Demske, Assistant Inspector General for Legal Affairs, before the U.S. Senate Special Committee on Aging Examining the Relationship Between the Medical Device Industry and Physicians (Feb. 27, 2008), available at http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

⁴ Department of Health and Human Services, Centers for Medicare and Medicaid Services, Medicare Program; Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23528, 23695 (April 30, 2008) (“we are soliciting public comments as to whether our physician self referral rules should address POCs and similar physician owned companies more specifically”); *see also* Department of Health and Human Services, Centers for Medicare and Medicaid Services, Medicare Program; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 48434, 48727 (Aug. 19, 2008) (“we are not adopting the position that physician owned implant or other medical device companies necessarily ‘perform the DHS’ and are therefore an ‘entity’” under Stark, but “[w]e may decide to issue proposed rulemaking on this [POD] issue in the future”).

⁵ Centers for Medicare and Medicaid Services, Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23527, 23694 (April 30, 2008).

⁶ 73 Fed. Reg. 23695.

encountering disrupts that supply chain without adding any value, (2) the legal case for how these entities implicate, and most likely violate, the federal Antikickback statute and the Stark physician self-referral law, and provide a ready vehicle for whistleblower enforcement under the federal False Claims Act, and (3) the patient and program abuses that are part and parcel of the POD business model.

2. The Supply Chain for Implantable Medical Devices

Unlike pharmaceuticals, implantable medical devices are not sold to distributors for later resale into the marketplace. Rather, implantable medical devices are sold directly from the manufacturer to the end-user institution, usually a hospital (though sometimes an ambulatory surgery center). Implantable devices are physician preference items: the physician dictates to the hospital precisely the device he or she intends to implant surgically. The physicians do not actually buy the device; the hospital buys it based on the selection of the implanting surgeon. Hospitals may rely on group purchasing organizations (GPOs) to aggregate the buying power of hundreds of hospitals and negotiate lower prices, but the GPOs do not actually buy or sell the products. Hospitals may also rely on technology committees, staffed in part by hospital employees and in part by user physicians, to advise on which products should be “preferred” for hospital use, a function that heretofore has been performed by physicians who do not have a financial interest in which product is chosen.

Critical to the proper functioning of this product supply chain are the IEAPs, who advise physicians on product selection and use, arrange for immediate delivery, and often are present in the operating room to provide technical assistance to support the physician’s use of the selected implants and associated external instrumentation (the latter of which the IEAP typically carries and brings to the operating room himself or herself).⁷ While many IEAPs are employed by the implant manufacturers, others are employed by independent sales agencies, which the industry calls “distributors.” Both kinds of IEAPs typically are paid for their services based on a commission from the implant manufacturer.

This well-established supply chain support model – which insulates the ordering physician from the improper financial influence that arises when he or she has an interest in which implant is chosen – has worked well for the implant industry, physicians and hospitals. While implants are certainly not immune to the soaring costs of health care generally, open competition among implant manufacturers, none of whom controls the choice of implant, allows hospital purchasers to engage in robust price negotiation without fear that referring physicians will take their procedures elsewhere. Physicians have the freedom to select the implantable products and venue best suited

⁷ See, e.g., American Medical Association Council on Ethical and Judicial Affairs, Report on Industry Representatives in Clinical Settings (CEJA Report 2-A-07), available at <http://www.ama-assn.org/ama/pub/category/3840.html> (“Manufacturers of medical devices may facilitate their use through representatives . . . who can play an important role in patient safety by providing information about the proper use of the device or equipment as well as technical assistance to physicians”); see also American College of Surgeons, Statement on Health Care Industry Representatives in the Operating Room (ST-33, Revised September 2005), available at http://www.facs.org/fellows_info/statements/st-33.html (recommending hospitals adopt procedures to govern the conduct of “health care industry representatives” in the OR); Hayes et al., *The Role(s) of the Industry Employed Allied Professional*, 24 PACE 398 (March 2001).

to their patients' needs, and to receive appropriate compensation for their professional physician services from patients and payers (under Medicare, via the physician fee schedule), without the corrupting influence of a financial interest in choice of hospital or implant; the hospital provides the facilities for performance of the procedure, and is suitably compensated by patients and payers for its services and supplies, including the implant (under Medicare, via the DRG inpatient or APC outpatient payment system); and the implant manufacturer furnishes the product and the technical support of the IEAP, who is suitably compensated for his or her expertise and product support via the manufacturer's commission. *What makes a POD different, and probably unethically and unlawfully so, is that it is the ordering physician who gets the commission.*

3. The Advent of PODs

As physician reimbursement has declined, doctors have looked for ways to supplement their income from professional services. While many such efforts may represent legitimate expansions of the doctor's existing medical practice (such as consolidating additional doctor-supervised health care services within the physician's office), entrepreneurs have seen opportunities to entice physicians into a variety of more dubious schemes. The POD is a recent entry. Apparently encouraged by a poster abstract presented at the January 2009 annual meeting of the American Academy of Orthopaedic Surgeons (AAOS),⁸ PODs are the latest version of the proliferation of physician-owned companies (POCs) described by OIG and CMS as presenting serious risks of patient and program abuse. Other POCs purport to function as GPOs (though they lack any credible credentials or infrastructure to function as purchasing agents by aggregating buying power to offer lower prices for their hospital "members"), as implant resale distributors (most of which differ from PODs in that they do not receive a commission, but rather make their profit on the margin between their "purchase" of an implant and its "resale" to a hospital),⁹ or as implant manufacturers (which actually function more as resale distributors, although they claim title to the implants whose manufacturing they outsource). *While all of these POC models present the same*

⁸ Steinmann, et. al., *Surgeon Ownership in Medical Device Distribution: Economic Analysis of an Existing Model*. Interestingly, the model described in the AAOS abstract is not the commission sale scheme represented by a POD, but that of a purported "distributor" that buys and resells products. The abstract claimed that its distributor was in fact furnishing legitimate supply chain services, including hiring "staff with medical and orthopedic experience to support standard distribution functions," and was able to supply the implants at lower cost. These claims are dubious at best. As noted above, true buy-and-resell distributors are not a necessary or common feature of the implant supply chain, so it is unlikely that the model described in the abstract would really deliver value in the long run. Either hospital acquisition costs would go up as the "distributor" sought to protect its resale profit margin, or quality would go down as the transfer of compensation to the physician would constrain the choice of implant to those generating a commission (or worse, deprive the supply chain of a qualified IEAP). Moreover, the claim of reduced cost is a transparent case of comparing apples to oranges. The abstract purported to compare the hospital's pre-existing "average contract price" from implant manufacturers with the lower priced that the physician-owned "distributor" offered, but there is no suggestion that the manufacturers were offered the opportunity to bid against the distributor. If real competition had been allowed to take place, the manufacturers surely would have been able to meet any price offered by the distributor, since the manufacturer would not have the additional expense of the distributor's profit to cover. In any event, however, the buy-and-sell distributor model described in the abstract provides no support for the activities of a commission-sale POD, which is simply a vehicle for paying the referring doctor a commission on each implant he or she orders.

⁹ See *supra* note 8.

ethical and legal abuses, the POD is the most extreme example of impropriety, in that it is simply and obviously a way of giving a physician a piece of the sales commission on each implant he or she orders for a patient.

Since the medical device supply chain does not require middleman entities to acquire and take physical possession of implants, and since PODs do not do this, these arrangements require virtually no investment capital to get up and running. Moreover, in the prevailing situation, where a rogue IEAP offers to share his or her commissions with customer physicians via an “investment” in a “joint venture” POD, there is no “new business” that would require any capital at all. Even if some nominal investment were made, the effect of allowing physicians to invest in such entities is to turn them into commissioned sales representatives, with all of the potential abuses that such “white coat marketing” entails.¹⁰

Reports from client representatives indicate that POD interests are performing medically-unnecessary surgeries to make use of the products on which they earn a commission. For example, at several hospitals, representatives report an increase in revision spinal fusions simply to replace non-defective implants with commission-based products. This represents a continuation of a trend reported earlier, which showed a dramatic increase in revisions at one hospital after the physicians “invested” in a distributor.¹¹

4. How the POD Model Violates the Federal Antikickback and Stark Laws

The description above makes clear that the POD model presents a very significant flaw: PODs provide their physician-owners with a strong economic incentive to leverage their hospital admissions into implant purchases for their own patients based on the physicians’ financial interests in the implants, rather than the best interests of patients. As set forth more fully below, this flaw causes PODs to implicate, and most likely violate, both the federal Antikickback statute and the Stark physician self-referral law.

A. PODs Exist to Direct Prohibited Remuneration to Physicians in Violation of the Antikickback Statute

The federal Antikickback statute prohibits, among other things, giving or receiving any financial benefit or “remuneration” in exchange for, or to induce, the referral of any patients for, or the purchase, lease, order or recommendation of, any item or service for which payment may be made

¹⁰ See; 56 Fed. Reg. 35799, 35974 (July 29, 1991) (stating that marketing and advertising activities may warrant prosecution if “the individual or entity involved in these promotions is . . . involved in the delivery of health care [and therefore] in a position of public trust in the same manner as physicians or other health care professionals who recommend or order products and services for their patients.”); see also OIG Advisory Opinion No. 02-12 (Aug. 30, 2002) (stating that marketing by health care providers “is subject to closer [antikickback] scrutiny, since health care practitioners are in a position of trust and may exert undue influence when recommending” products); OIG Advisory Opinion No. 99-12 (Nov. 23, 1999) (“[m]arketing by physicians . . . is closely scrutinized under the anti-kickback statute . . . [physicians] are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services, especially when marketing to their patients”).

¹¹ See attached case study.

under Medicare or other federal health care programs.¹² Penalties for violation of the statute include substantial criminal fines, imprisonment, exclusion from participation in federal health care programs, and/or civil monetary penalties.¹³ Courts and administrative bodies interpreting the law have stated the broad rule that the statute is violated if even “one purpose” –as opposed to a sole or primary purpose – of a payment arrangement is to induce referrals for services or purchases of items reimbursable under a federal health care program.¹⁴ Of particular relevance here, where improper intent was present, courts have found unlawful remuneration in the giving of an opportunity to earn a profit¹⁵ and in earning a return on an investment.¹⁶

Thus, the Antikickback statute is implicated if one purpose of offering referring physicians an opportunity to invest in a POD is to induce those physicians to order implants for their patients through that POD. Likewise, hospital agreements to buy, and manufacturer agreements to sell, products through a POD could violate the Antikickback statute if one purpose were for the physicians’ profit-making opportunity offered by the POD to act as an inducement to perform procedures at a particular hospital, or to order a particular manufacturer’s products. The only real question is one of intent.

While the statute requires proof of parties’ state of mind in any individual transaction, the physician-owners of implant “distributors” have made no secret of their purpose. As the founder of one prominent physician-owned distributor baldly acknowledged in describing his own motivations, the essential business concept underlying these entities is “to form a limited liability company that consisted of approximately one hundred doctors who would also act as the company’s customer base.”¹⁷ But even without such an admission, in evaluating a business model that pays doctors a commission for each product order, it would defy common sense not to see unlawful intent as at least “one purpose.”

To begin with, every court to have considered the question has held a commission on the sale of a health care product to violate the Antikickback statute.¹⁸ While these cases generally have been

¹² 42 U.S.C. § 1320a-7b(b).

¹³ 42 U.S.C. § 1320a-7 (exclusion from Federal Health Care Programs); § 1320a-7a (civil monetary penalties of up to \$50,000 per act plus three times the remuneration); § 1320a-7b(b) (imprisonment of up to five years or criminal fines of \$25,000 or both); 18 U.S.C. § 3571 (augmenting penalties: \$250,000 per violation for individuals and \$500,000 per violation for entities).

¹⁴ See, e.g., *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

¹⁵ See *Bay State Ambulance and Hospital Rental Services, Inc.*, 874 F.2d 20, 29 (1st Cir. 1989) (“[g]iving a person an opportunity to earn money may well be an inducement to that person to channel Medicare payments toward a particular recipient”). See also OIG Advisory Opinion 08-10 (Aug. 26, 2008), *infra* note 28 and accompanying text.

¹⁶ See *Hanlester Network v. Shalala*, 51 F.3d 1390, 1401 (9th Cir. 1995) (affirming the finding of the Department of Health and Human Services Departmental Appeals Board that the opportunity for physician-investors to earn money from their investment in a laboratory partnership was remuneration for purposes of the Antikickback statute).

¹⁷ See, e.g., Declaration of Souhail Toubia in Support of Application for TRO, *Allez Medical Applications, Inc. v. Allez Spine*, Case No. 06CC0153, Cal. Sup. (April 17, 2006).

¹⁸ See, e.g., *Nursing Home Consultants, Inc. v. Quantum Health Serv., Inc.*, 926 F. Supp. 835, 844 (E.D. Ark. 1996) (consultant’s compensation was “directly pegged to the number of sales generated”), *aff’d per curiam* 112 F.3d 513 (8th Cir. 1997); *Medical Dev. Network, Inc. v. Professional Respiratory Care/Home Med. Equip. Serv., Inc.*, 673

civil contract avoidance disputes rather than enforcement actions, they have recognized that the purpose of a commission is to induce the recipient to sell the product.¹⁹ Where the commission is not to a seller, but to the person who actually *orders* the product, not only is the potential for abuse obviously much greater, the inference of improper intent becomes unavoidable.

Although the OIG does not regard commissions as *per se* violations of the Antikickback statute, it has established a framework for when a commission is sufficiently abusive to warrant Antikickback prosecution. Inarguably, the most important abuse is “the use of sales agents who are health care professionals or persons in a similar position to exert undue influence on purchasers or patients.”²⁰

The fact that it is the POD rather than the individual physician who receives the commission is of no importance. The POD’s only revenue comes from commissions paid when a hospital offers the physician that profit opportunity in return for the physician’s referrals. That the physician-owners might share these revenues via an “investment return” does nothing to break the connection between the profit opportunity, the product order, the hospital purchase, and the commission. Moreover, it appears that the POD business model involves most of the “questionable features” identified by the OIG in its 1989 *Special Fraud Alert* on fraudulent physician joint ventures,²¹ all of which are indicative of an unlawful intent to induce federal program business:

- Choice of Investors. Investment interests are offered exclusively or primarily to surgeons without any particular purchasing, distribution, or management expertise, but who are in a position to order implants for their own patients through the POD. As the OIG noted in the *Special Fraud Alert*, where physicians are specifically targeted as investors, a joint venture may be suspect as “intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals.”
- Little or no *Bona Fide* Business Risk. The physician-investors’ primary contribution to the POD is referrals, and because they order the implants for their own patients, the physician-investors determine the amount of business that is done with the POD through their own captive patient referrals. Since hospitals and product manufacturers who want the business of the physician-investors will have no choice but to deal with their POD, there is little doubt that the business will succeed as long as a sufficient number of referring physician-investors is recruited and sustained.

So.2d 565, 567 (Fla. Dist. Ct. App. 1996) (arrangement by which consultant is paid a percentage of the sales it generates violates the Antikickback statute).

¹⁹ *Nursing Home Consultants, Inc.* at 843 (stating that the sales commission arrangement was paid to plaintiff “for referring persons who needed Medicare-covered supplies . . . and this type of relationship falls squarely within the transactions prohibited by [the Antikickback statute]”).

²⁰ See *supra* note 10.

²¹ The 1989 Special Fraud Alert is available on the OIG’s website at <http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html>.

- Financing and Profit Distribution. Most PODs are simply “joint ventures” between existing distributor-IEAPs and their customer physicians. Thus, there is no need for any new investment capital. Moreover, because the physician investment vehicle is a shell that has little need for investment capital, the amount of capital invested by the physician-investors likely is disproportionately small and the returns on investment disproportionately large and occur much sooner when compared to a typical investment in a new business enterprise, and the amount of return surely would be extraordinary based on the minimal level of risk involved.
- Captive Referral Base. Since a POD earns its money only on commissions paid for products ordered by its physician-owners, it obviously serves only the physician-owners’ own patients and does business only with the hospitals where the physician-investors refer their patients. In this business model there is no need – or ability – to expand to new customers except by recruiting new physician-investors who also would self-refer.
- Scope of Services Provided by the POD. To the extent it purports to perform any real services at all, the POD offers services that are already offered without profit-sharing with the referring physicians. Either the POD adds no value (because there is no change in operation other than the existing distributor sharing its commission), or it impacts patient care negatively (because it replaces a qualified IEAP with a low-wage inventory management technician).

In sum, it is evident that physicians are sought as investors in PODs *not* for their capital *nor* for their business acumen, but because of their trusted authority over choice of product and choice of facility. Moreover, the fact that PODs are not credible competitors in the implant marketplace calls into question why anyone would deal with them *but for* their ability to return a portion of the sale commission to the referring physician-owners who have the ability to control implant ordering decisions at their hospital. Under these circumstances, it is difficult to take seriously any argument that “one purpose” of the remuneration a physician gains through a POD is *not* to induce the physician to use products that will generate commissions for the POD. In other words, even without in-depth investigation, the *prima facie* case for an Antikickback violation is a compelling one.

B. Safe Harbor Protection is Not Available for PODs

While a facial violation of the Antikickback statute can, in some cases, be avoided by structuring an arrangement in accordance with one of the regulatory safe harbors,²² such protection is not available in the case of physician ownership of PODs. The applicable safe harbor for investment interests in non-publicly traded entities contains an important condition that limits safe harbor protection to entities that derive no more than 40 percent of their gross revenues from referrals or business otherwise generated by investors, such as physicians.²³ We do not believe that any of the PODs of which we are aware can meet this standard: since hospitals would not deal with PODs but for the physician-owners’ referrals, virtually 100 percent of the POD’s business is generated

²² See 42 C.F.R. § 1001.952.

²³ *Id.* § 1001.952(a)(2)(v).

by interested physicians. This is not a mere technicality. As the OIG noted in its October 2006 letter regarding physician-owned entities, “the fact that a substantial portion of a venture’s gross revenues is derived from participant-driven referrals is a potential indicator of a problematic joint venture.”²⁴ In particular, in adopting the safe harbor regulations, the OIG observed that:

[E]ntities protected under this safe harbor provision should not exist by relying on their business coming from referrals from investing physicians. In our experience, a large number of joint ventures are formed with the intent to encourage investors to refer patients to the joint venture. In many cases, the referrals from investing physicians dominate the joint venture’s business so that it does not have to compete for outside business and that it cannot survive without such referrals from its investing physicians. *At that point, the business purpose of the joint venture becomes suspect.*²⁵

In addition, we suspect an investigation would reveal that many PODs do not meet a number of the other investment interest safe harbor conditions,²⁶ including requirements that (1) no more than 40 percent of the interests in each class may be held by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity (which, notably, includes interests held by a POD organizer who provides management services to the venture), (2) the terms on which interests are offered to referring physicians who are passive investors (i.e., not involved in day-to-day management of the entity) must be no different from the terms offered to other passive investors, (3) the terms on which interests are offered to referring physicians must not be related to the previous or expected volume of referrals from, or business generated by, the physician for the entity, and (4) there is no requirement that a physician who is a passive investor make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor, which may be violated by provisions requiring physicians to divest their interest if they retire or are no longer actively engaged in the practice of medicine in the markets served by the POD.

Although failure to qualify for a safe harbor does not necessarily mean that the Antikickback statute has been violated, arrangements outside of the safe harbors are subject to scrutiny and challenge.²⁷ As discussed above, PODs would fare poorly if subject to such scrutiny and challenge.

We also note that there is doubt whether even if the criteria were met, the safe harbor would protect the *opportunity* to profit arising when the hospital agrees to buy, and the manufacturer agrees to sell, through a POD. A little over a year ago, OIG issued an advisory opinion stating in highly analogous circumstances that the “opportunity to generate a fee” that would not otherwise exist may be unlawful remuneration, even if the payments are otherwise protected by safe harbors.²⁸ OIG declined to give favorable treatment to a radiation therapy treatment facility’s

²⁴ See *supra* note 2.

²⁵ 56 Fed. Reg. 35,970 (emphasis added).

²⁶ 42 C.F.R. § 1001.952(a)(2).

²⁷ 54 Fed. Reg. 3088, 3089 (1989); 56 Fed. Reg. 35,952, 35,954 (July 29, 1991).

²⁸ OIG Advisory Opinion 08-10 (Aug. 26, 2008).

offer to lease itself out to referring physician groups, thereby allowing the physicians in those groups to profit by billing the technical component of the radiation therapy services they would order for their own patients. OIG concluded that the arrangement posed “a significant risk that the Proposed Arrangement would be an improper contractual joint venture that would be used as a vehicle to reward the [referring physicians] for their referrals.”

Tellingly, OIG reached this conclusion even assuming that all of the specific payment arrangements proposed – leases of space, equipment, and services from the facility – could satisfy the criteria for an Antikickback safe harbor. OIG noted that “[b]y agreeing to provide services it could otherwise provide in its own right for less than the available reimbursement, the [facility] may provide the [referring physicians] with the opportunity to generate a fee and a profit. *The opportunity to generate a fee is itself remuneration that may implicate the Antikickback statute.*”²⁹

The proposition that the opportunity to earn a fee may constitute unlawful remuneration is not novel;³⁰ however, OIG’s application of that proposition to a circumstance where all of the individual payment relationships were safe harbored is a significant statement about what constitutes “remuneration,” and one that is highly relevant to the treatment of PODs under the fraud and abuse laws. OIG here recognizes a stream of remuneration from the opportunity to earn a fee that is separate and apart from the actual monies paid under the various leases. In effect, OIG is saying that if the facility *offers* the referring doctors an opportunity to profit that they otherwise would not have, *that* constitutes remuneration even if the payments between the parties are safe harbored.

Whether that is an appropriate conclusion in the context of leased services under the intent-based Antikickback statute may be questioned. However, if there is any context in which OIG’s reasoning from the advisory opinion clearly should apply, it is that of the naked sales commission sharing that is the POD business model.

C. PODs Create Financial Relationships Prohibited by the Stark Law

POD arrangements also create financial relationships between their physician-owners and their hospital customers that implicate the federal physician self-referral law, commonly known as the “Stark” law.³¹ More specifically, the Stark law prohibits physicians, subject to limited exceptions, from making referrals to an entity with which they have a financial relationship for certain designated health services (DHS) – including inpatient and outpatient hospital services – reimbursable by the Medicare program.³² Notably, the Stark law imposes conflict of interest restrictions that apply whenever a direct or indirect financial relationship exists between a hospital and a physician, without regard to any intent to induce referrals. Thus, if there is a financial

²⁹ *Id.* (emphasis added).

³⁰ See e.g. *United States v. Bay State Ambulance and Hosp. Rental Services, Inc.*, 874 F.2d 20 (1st Cir. 1989) (“[g]iving a person an *opportunity* to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient”) (emphasis added).

³¹ 42 U.S.C. § 1395nn.

³² 42 C.F.R. § 411.353(a).

relationship, the Stark law prohibits the physician from referring any Medicare patients to the hospital for any services, and the hospital may not bill Medicare for any such services, unless an exception applies. And unlike the Antikickback law safe harbors, full compliance with a Stark exception is required to permit referrals that otherwise would be prohibited by the Stark law.

In the case of POD arrangements, CMS has recognized that in many cases “an unbroken chain of financial relationships will connect the physician owner of a [POD] to a DHS entity [i.e., a hospital] to which the physician makes referrals,” thereby creating an indirect financial relationship under the Stark law.³³ Accordingly, any Medicare referrals to a POD hospital-customer from a physician-owner are prohibited unless the arrangement meets the requirements of the relevant Stark law exception for indirect compensation arrangements.³⁴ Among other things, that exception requires that the compensation paid to the POD by the implant seller must not take into account the volume or value of referrals generated by the referring physician to the hospital. CMS has also recognized that “[i]n many instances, the [financial] arrangement would not satisfy the requirements of the exception for indirect compensation arrangements . . . and would, therefore, run afoul of the physician self-referral statute.”³⁵ That seems obviously true here. It is difficult to see how a sales commission could satisfy this standard: a percentage of each sale varies based on both the volume and the value of the physician’s referrals.

The likelihood that CMS would find a Stark law violation seems enhanced after OIG’s analysis of the remunerative value of the *opportunity* to earn a profit in its recent advisory opinion. CMS has already recognized that the value a physician owner receives from his/her POD constitutes an indirect compensation arrangement with the hospital to which the physician refers an implant case.³⁶ That Stark “chain” of remuneration runs from the hospital (purchase of implant) to the manufacturer (pays commission) to the POD (receives commission) to the physician-owners (return on investment). Applying OIG’s logic, there would also be *direct* remuneration from the hospital to the physician in the form of the *opportunity* to profit. The hospital is in the same position as the facility in the advisory opinion, in that its agreement to purchase implants through the POD provides the physician owners of the POD with an *opportunity* to earn a fee arising from part of the hospital’s reimbursement from the implant procedure, to perform a job – arranging an implant purchase – that the hospital would otherwise perform for itself.³⁷ OIG found the conferring of the profit opportunity to be remuneration separate from the safe harbored lease arrangements in the advisory opinion.

³³ 73 Fed. Reg. 23528, 23695 (April 30, 2008). In the case of a POD, the relationship would run: hospital to manufacturer (purchase); manufacturer to POD (commission); POD to physician (opportunity and return on investment).

³⁴ 42 C.F.R. § 411.357(p).

³⁵ 73 Fed. Reg. 23695.

³⁶ See 73 Fed. Reg. 23695 (“[i]n many instances, the [POD] arrangement would not satisfy the requirements of the exception for indirect compensation arrangements . . . and would, therefore, run afoul of the physician self-referral statute.”).

³⁷ It is true that the hospital’s payment for the implant procedure would be reduced in any event by the cost to the hospital of the implant purchase. But that is equally true in the advisory opinion, where the hospital would have to incur the cost of equipment, labor and supplies to furnish the radiation therapy.

The OIG's theory of opportunity-as-remuneration is potentially very far-reaching, and it may reasonably be questioned whether that theory was correctly applied even in the circumstances of the advisory opinion. There may be many circumstances where the opportunity to profit should not be treated as unlawful remuneration, particularly under the intent-based Antikickback statute. However, if there is any context in which the opportunity to profit ought to be treated as remuneration, it is under the strict liability imposed by the Stark law when a hospital confers on a physician-owned supply chain company the sinecure of a POD commission, which the hospital would not have done but for the plain intent of locking up the physician's referrals. Whether viewed by CMS as direct or indirect, this remunerative opportunity plainly would be based on the volume or value of the doctor's referrals, and so would not satisfy any Stark law exception.³⁸

Violations of the Stark law are subject to substantial civil monetary penalties for submitting claims for a service referred by a physician with a prohibited relationship. In addition, hospitals are required to refund to Medicare any amounts so-paid, subject to additional penalties if they do not.³⁹ Thus, if a hospital is accepting referrals from a physician with knowledge that the physician is receiving unlawful remuneration through a POD, the hospital is subject to penalties if it submits claims and for more penalties if it does not do a review and refund payments already received.

D. Enforcement under the False Claims Act

Violations of both the Antikickback statute and the Stark law also create the potential for liability under the federal False Claims Act (FCA).⁴⁰ The FCA provides for treble damages and a civil penalty between \$5,500 and \$11,000 per violation for submitting, or causing the submission, of false or fraudulent claims to the federal government or its contractors.⁴¹ Private *qui tam* relators are empowered under the FCA to bring actions for violations in the name of the federal government, and are entitled to share in the government's recovery an amount up to 30% of all damages received in an action plus attorney fees and other costs.⁴² Courts have held that violations of the Antikickback statute and the Stark law are actionable under the FCA.⁴³ Hospitals submit claims to Medicare for the DHS furnished pursuant to the physician's referral, the physician causes those claims to be submitted by virtue of performing the procedure at the hospital, and if the manufacturer knows or should know of the physician's commission, it also could be said to have caused the inappropriate claims to be submitted.

³⁸ The special rule on compensation that treats fair market value unit-based compensation as not based on the volume or value of referrals, 42 C.F.R. § 411.354(d)(3), would not be available to a POD, both because neither a percentage commission nor the ongoing opportunity to profit is unit-based, and because sharing a commission with a referring doctor does not represent fair market value compensation for anything.

³⁹ 42 U.S.C. §§ 1395nn(g)(2) and (g)(3).

⁴⁰ 31 U.S.C. § 3729 *et. seq.*

⁴¹ *Id.* § 3729(a).

⁴² *Id.* § 3730.

⁴³ *See, e.g., United States v. Rogan*, 459 F.Supp. 2d 692, 717 (N.D. Ill. 2006) (citing *United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004)).

Further, apart from violations of the Antikickback or Stark laws themselves, where a physician performs a procedure of questionable medical necessity, such as when a POD physician-investor performs a repeat spinal procedure so that he or she can utilize POD-supplied products, the FCA is implicated notwithstanding any allegations of other statutory or regulatory violations. Where a physician-investor seeks to perform a procedure that would not otherwise be performed but for that physician's interest in the POD, then the procedure would not be medically necessary, and any resulting claim made to Medicare or Medicaid could implicate the FCA.⁴⁴ Because of the obvious financial incentive to overutilize with any POD, hospitals that allow a POD physician to perform procedures run the risk that they will be viewed as acting with "reckless disregard" or "deliberate ignorance" of unnecessary procedures being performed and billed.⁴⁵

Thus, in addition to the potential for direct enforcement by government officials under Stark, the Antikickback statute, and the FCA, PODs place physicians, hospitals, and implant manufacturers at risk for a *qui tam* lawsuit brought by disgruntled employees or competitors.

5. Significant Patient and Program Abuses are Inherent in the POD Business Model

Where, as here, all the elements of a legal violation are present and no statutory exception or regulatory safe harbor is available, the exercise of prosecutorial discretion to pursue an enforcement proceeding usually is driven by an assessment of the potential for program or patient abuse. In the case of PODs, those risks are inherent, significant, and ongoing – all of which points to a high potential for enforcement.

A. PODs Present an Ethical Conflict of Interest That Will Distort Medical Decision Making

The economics of the POD business model create what would seem to be almost irresistible incentives to order implants only from manufacturers who agree to pay them a commission, and to direct hospital admissions for implants exclusively to those facilities that agree to deal with the POD. Thus, the physician's mind is likely to be closed to, or at least prejudiced against, implants from other sources and hospitals that refuse to deal with the physician's POD. The likely result is that doctors are incentivized to put their own economic wellbeing ahead of patient interest, creating an ethical conflict of interest for the doctor.

The Council on Ethical and Judicial Affairs of the American Medical Association (CEJA) has cautioned against a physician prescribing medical devices if that physician is influenced in the prescription by a direct or indirect financial relationship with the supplier.⁴⁶ Further, in a separate opinion, the CEJA issued guidance about physicians selling products in their offices, stating that

⁴⁴ See 42 U.S.C. § 1396y(a)(1)(stating that "no payment may be made under part A or part B for . . . items and services . . . not reasonable and necessary for the diagnosis or treatment of illness or injury").

⁴⁵ 31 U.S.C. § 3729(b)(1)(A)(ii) – (iii)(a "knowing" violation of the FCA includes "deliberate ignorance" or "reckless disregard" of the truth or falsity of information).

⁴⁶ American Medical Association Council on Ethical and Judicial Affairs, Opinion E-8.06, *Prescribing and Dispensing Drugs and Devices*.

physicians should severely restrict their sale of items directly to patients because this “presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians to serve the interests of their patients before their own.”⁴⁷ CEJA’s concern over sales of products in physician offices correlates precisely to the concerns with physicians deciding which implant to use on their patients: not only is there potential that the financial incentive can cloud the physician’s judgment, but there is also a disturbing appearance of overreaching as relates to patients.

Thus, established medical ethics principles present a good starting point for analyzing POD investments by physicians. That starting point is overwhelmingly negative.

B. PODs Are Anti-Competitive

Because of the physician’s ability to control implant choice, PODs distort competition in the implant and implant procedure market. Hospitals must acquire the implants their referring physicians require or the physicians will perform their procedures at other hospitals that do; thus, PODs control both the supply and the demand for their products. In contrast, legitimate device manufacturers and sales agents do not have the advantage of controlling the demand for their products. Rather, they must compete against each other based on the cost and quality of their implantable products, their responsiveness to customer orders and service needs, and the like. Similarly, competitors to hospitals and manufacturers that have agreed to deal with a POD are at an impossible disadvantage; unless they offer the referring physician the same economic benefit, superior service, location, facilities and products will not be sufficient to attract the physician’s business. Not only is it unfair to these legitimate competitors for PODs to have this advantage, the competitive unfairness is likely to lead to all the evils traditionally associated with monopolies: higher costs, poorer product quality, and less innovation.

C. PODs Are Likely to Lead to Higher Implant Costs or Lower Quality Care

The ethical conflict of interest and unfair competition are reason enough for enforcement officials to challenge the POD business model, even if the implants obtained were to cost less. This risk becomes almost inevitable when coupled with the dilemma that furnishing implants through a POD must lead in the end either to increased costs or lower quality.

There is an obvious flaw in any claim that PODs can deliver the same quality implant services at lower cost. In a real competition based on price, it is ludicrous to suggest that the manufacturer itself, selling directly, could not offer a lower price than a middleman distributor with its extra costs. For example, the lower prices claimed to be offered by the physician-owned “distributor” in the abstract presented at this year’s AAOS meeting were *not* arrived at via competition with the manufacturers for direct sale; rather, the “distributor” simply took the previously negotiated manufacturer pricing and offered a lower price.⁴⁸ The manufacturer was not offered the opportunity to bid against this “competitor.” In the end, either the implant price offered by a POD

⁴⁷ American Medical Association Council on Ethical and Judicial Affairs, Opinion E-8.063, *Sale of Health-Related Products from Physicians’ Offices*.

⁴⁸ See *supra* note 8.

(or a buy-and-resell “distributor”) would have to be more expensive (because of the need to give the physician a profit margin on the product), or the quality of care furnished would have to be lower (because of the replacement of a qualified IEAP with a low-wage inventory-management employee, or the restriction to products on which the doctor can earn a commission). The POD is also likely to lead to overutilization, with physician-owners ordering procedures of questionable medical value in order to utilize more POD products, and/or to the substitution of inferior products. Our client representatives have already reported that surgeon “investors” in PODs are performing revision spinal fusion surgeries to replace implants with those on which they earn a commission through their PODs, and in some cases taking the occasion to replace even non-defective implants with the commission-based products.⁴⁹

6. Conclusion

At bottom, PODs are about creating opportunities for physicians to profit from their own referrals. The abuses inherent in the POD business model are currently occurring in the U.S. markets for spinal implants, presenting conflicts of interest that interfere with physician judgment about whether to perform a procedure, the best products to use, and where procedures are performed. This conflict of interest not only presents significant health and safety risks to patients, but also presents a significant risk to physicians, hospitals, and implant manufacturers of being prosecuted and otherwise penalized for violating federal and state fraud and abuse laws. The likelihood that such an obviously abusive arrangement will avoid law enforcement scrutiny is vanishingly small, and will be less than that if the model expands to other implantable products such as hips, knees, pacemakers, and defibrillators, all of which are used extensively in the Medicare population.

Thomas N. Bulleit
John A. Murphy, III

⁴⁹ See attached case study.

**Physician-Owned Implant Companies:
Evidence of Product Quality Deficiency
And/Or Overutilization At One Hospital ^{1/}**

Executive Summary

- Business arrangements involving physician ownership of medical device companies and distributorships are proliferating. These arrangements involve medical device companies formed to give physicians who control the choice of what medical devices they implant in patients a share in the profits generated by the sale of such devices. In addition, the physicians who own these device companies can use their ability to generate referrals for hospitals to induce the hospitals to buy devices from the physicians' companies.
- These types of arrangements appear likely to cause substandard quality of care for patients through the use of inferior devices, and to result in unnecessary, or unnecessarily device-intensive, procedures. Indeed, surgery statistics from at least one hospital reflect an extraordinary four-fold increase in spine refusion procedures when surgeons at the hospital became owners of a device company that sold devices used in those procedures to the hospital.

Spine Fusions and Refusions 2002-2006 at One Hospital*

	2002	2003	2004	2005	2006
Fusions	438	581	665	713	689
Refusions	17	17	16	78	69
Ratio Refusions/Fusions	4%	3%	2%	11%	10%
Increase in Refusions over 2002		0%	-6%	359%	306%

* Source: Verispan (de-identified spinal surgery statistics from a U.S. hospital purchasing from a POIC). Note that the annual data presented pertain to one-year periods ending on September 30th of each referenced year, rather than the calendar years.

^{1/} Information collected and prepared in 2007 by a member of the Quality Implant Coalition (QuIC).

I. Introduction

More and more medical device companies that manufacture or distribute implantable medical devices are creating passive investment vehicles to distribute profits to physicians who implant such devices in patients. While the structure of these arrangements may differ from company to company, the business model is that investment opportunities and the resulting financial rewards are being offered to surgeons or other proceduralist physicians because these doctors direct or prescribe the products and the hospitals at which they perform procedures. The resulting financial incentives may be invisible to patients, but they can clearly affect the treatment patients receive. These financial incentives create conflicts of interest for physicians who invest in these companies.

The Advanced Medical Technology Association (AdvaMed), the trade association that represents many companies in the medical device industry, has asked the HHS Office of Inspector General (OIG) to comment on these physician ownership schemes. In response, the OIG stated that “[g]iven the strong potential for improper inducements between and among the physician investors, [medical device and distribution] entities, device vendors, and device purchasers,” the OIG believes these types of ventures “should be closely scrutinized under the fraud and abuse laws.”^{2/} OIG recently restated in Congressional testimony that POICs “raise substantial concerns” under the anti-kickback law.^{3/}

The proliferation of physician-owned implant companies (POICs) is problematic for obvious reasons. When a physician selects a medical device to implant in a patient, is it in the patient’s best interests for the surgeon to be deciding between a product from which the surgeon makes a profit, and a product from which the physician makes nothing? When a hospital chooses what device companies to do business with, is it in the patient’s best interest for the hospital to be deciding between a company that controls referrals to the hospital, and a company that does not? The answer to both of these questions is clearly no. When a physician who profits from every use of a particular medical device is faced with a decision whether to select that device, a competing device, or perhaps no device at all, the physician’s financial interests corrupt the treatment decision. And when a hospital fears losing hospital business if it refuses to purchase devices from the POIC, the hospital’s financial interests taint the relationship between caregiver and patient, and place

^{2/} See Letter from Vicki L. Robinson, Chief, Industry Guidance Branch, OIG, to Stephen J. Ubl, President and Chief Executive Officer, AdvaMed (Oct. 6, 2006).

^{3/} Senate Special Committee on Aging, Hearing February 27, 2008 (Testimony of Gregory E. Demske, Office of Counsel of the Inspector General, U.S. Department of Health and Human Services) (“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.”)

the unknowing patient at risk if the physician's choice of his or her company's device is not the best decision for the patient.

Ideally, one would be able to point to specific cases where conflicts of interest had inappropriately influenced a physician's clinical judgment. However, due to health privacy rules and practices, standard corporate confidentiality measures, and the efforts that some of these companies make to obscure the financial relationships among themselves, their physician-owners, and the hospitals with which they do business, it can be difficult for independent parties to obtain information about such cases. Nonetheless, limited reports and de-identified aggregate information about at least one hospital's procedures reveal patterns and practices that appear suspect and demand explanation.

A. Typical Structure of a Physician-Owned Device Company

The typical genesis and structure of a POIC arrangement is as follows: A small group of founders, who may or may not themselves be physicians, establish a company to manufacture or distribute medical devices for implantation in orthopedic surgeries. The company is typically organized to sell what are essentially copycat devices based on designs that are already on the market and that can easily receive FDA 510(k) approval. Acting essentially as shells, these companies do not own manufacturing facilities, but outsource the manufacturing function to other companies. The operators of the company then seek investors in the company, limiting their search to physicians who can generate referrals that benefit the company. These physicians are offered "limited partnerships" or similar ownership interests in the company in return for relatively small amounts of money, and are promised the potential to earn returns far higher than the returns they could earn through traditional investment vehicles.

After the physicians invest in the company, they are inclined to choose their own company's devices rather than the devices they previously chose on their patients' behalf. However, because it is hospitals or other facilities that actually purchase the devices to be implanted in patients, POICs must solicit these facilities for their business. In this way, inappropriate financial incentives spread from the POIC to the facilities with which they do business. Obviously, when a hospital agrees to do business with a company owned by its referring physicians, one of its reasons for doing so is to "keep the physicians happy," i.e., to accede to the physicians' business proposition in order to retain the physicians' stream of referrals to the hospital.

Physicians, who are passive owners of device companies whose products they implant, and hospitals, who do business with such companies, have clear conflicts of interest. These conflicts can only lead to increased costs, reduced innovation, and lower quality. Unlike traditional physician collaboration with medical device companies, where the surgeon may actively direct or aid in developing or designing new technologies, the current proliferation of POICs is based on distributing passive

revenues to a large number of physicians who have not contributed to development of the product. They simply prescribe its use, and choose to perform the procedures at hospitals that agree to purchase from their companies. This structure means that the physicians have direct financial incentives to over-utilize and inappropriately utilize their own company's existing devices, and no incentives to fund research and development or to use innovative technologies that may be best for patients.

B. One Hospital's Refusion Rates

Spine surgery data from one hospital certainly raise alarm. Spinal fusion is a surgical technique that involves uniting two or more vertebrae of the spine to prevent them from moving independently. Various types of medical devices are used to achieve this fusion. For example, in a typical fusion, a surgeon embeds screws in each vertebra to be fused and threads a rod through the heads of the screws to form a fixed structure supporting the spine. A refusion surgery is a repeat surgery that redoes a previously performed initial fusion because the previous fusion failed in some way (e.g., the screws did not stay in place). Refusions generally present greater risks to patients than fusions.

When the spine surgeons at the hospital in question invested in a POIC, to sell devices used in their spinal fusion and refusion procedures, the annual numbers of refusion surgeries performed at the hospital increased dramatically. Given the fact that the number of initial fusion surgeries remained relatively flat or increased only gradually during this period, the drastic increase in the numbers of refusion surgeries, coupled with the fact that the physicians became owners of a company that could sell more devices with each such procedure, certainly raises the question of whether financial interests affected these physicians' decisions.^{4/}

Specifically, although the surgeons performed only an annual average of 17 refusion procedures in the three years before their company began to operate, the annual numbers of refusions jumped to 78 and 69 for this type of surgery in the following two years, as reflected in the following table:

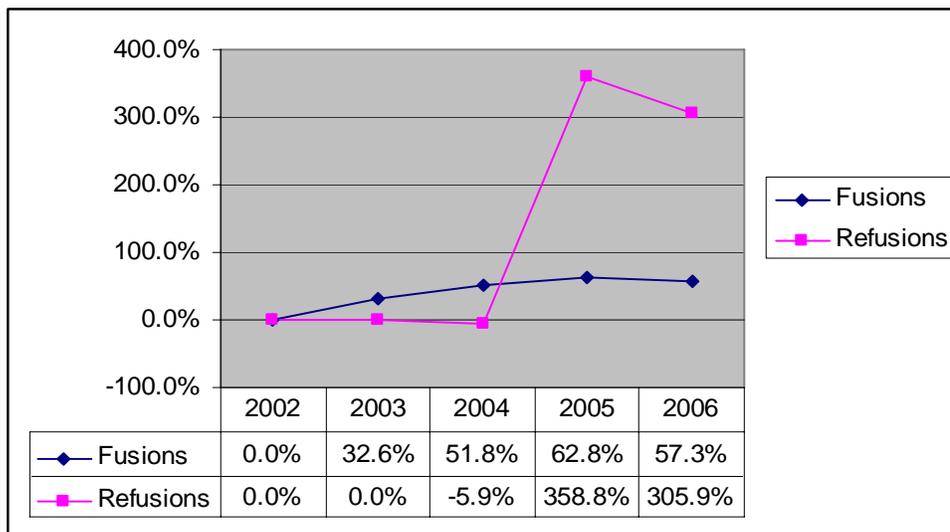
^{4/} Source: Verispan (de-identified spinal surgery statistics from a U.S. hospital). Note that the annual data presented pertain to one-year periods ending on September 30th of each referenced year, rather than the calendar years.

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This table reflects that the annual number of refusions at this hospital jumped from 16 to 78 when the surgeons at the hospital became owners of their own device company in 2005. Significantly, the jump cannot be explained as a function of an increase in initial fusion surgeries. First, the incidence of refusions remained constant until 2005 even though the number of fusions increased by 143 and 84 cases in 2003 and 2004, respectively. But in 2005, the rate of refusion procedures as a percentage of fusion procedures exploded from 2% to 11%. Second, the annual number of refusions more than quadrupled in 2005 and 2006 as compared to the annual figures for the prior three years. In essence, even though the number of fusions compared to 2002 increased by only approximately 60% for 2005 and 2006, the number of refusion procedures increased by approximately 359% and 306% in that same time frame, as shown in the following chart:

Comparison of 2003-2006 Increases in Fusions and Refusions Over 2002 at One Hospital



The increase in refusions at this hospital demands explanation. Without reviewing individual cases, it is impossible to state with certainty the reasons for a particular refusion surgery. Nonetheless, if the rate of refusion surgeries at a hospital increases dramatically as compared to the rate of fusion surgeries, and this dramatic increase takes place at the same time the surgeons in the hospital have

formed a POIC to sell devices used in their surgeries, two explanations appear to be likely.

One possible explanation is that the refusion surgeries are happening because the POIC's devices are resulting in an increased number of initial fusion failures, leading to a greater number of refusions. If so, this would appear to indicate that the surgeons' decisions to use their own devices have harmed patients because their devices are inferior to those that the surgeons had previously chosen for patients. Moreover, based upon the dramatic initial increase and continuing high incidence of refusions, it appears that the surgeons must have become aware that their own products were inferior, and nonetheless continued to use them.

Another possible explanation is that the refusion surgeries are not necessary. Because refusion surgery often involves replacing previously implanted devices, such as the screws and rods used in an initial fusion surgery, a refusion surgery presents an obvious opportunity to generate sales for the physician's company. This abuse could occur in two ways. First, surgeons are choosing to do unnecessary refusions in order to replace other manufacturers' devices with their own. The second may be occurring with patients that have already had a fusion, but need to have fusions in adjacent vertebrae. In these cases, the second fusion typically is a matter of adding additional rods, screws and other devices to those that are already in place. Because these devices are designed to work together, the best practice is typically to use devices from the same manufacturer as were used in the initial fusion. The implication raised by the above data is that surgeons are choosing to revise the first fusion with their own devices in order to use their own devices in the second fusion.

The sudden significant increase in refusions that occurred at this hospital is illustrative of the essential conflict-of-interest problem with POICs. At a minimum, these data raise serious questions of whether POICs pose an increase in risks to patients, and in costs to public and commercial payors and patients.

* * *