Physician-Owned Implant Companies:

Evidence of Product Quality Deficiency

And/Or Overutlization At One Hospital

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*

	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.

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, recently 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." *See* Letter from Vicki L. Robinson, Chief, Industry Guidance Branch, OIG, to Stephen J. Ubl, President and Chief Executive Officer, AdvaMed (Oct. 6, 2006).

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 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.[1]

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:

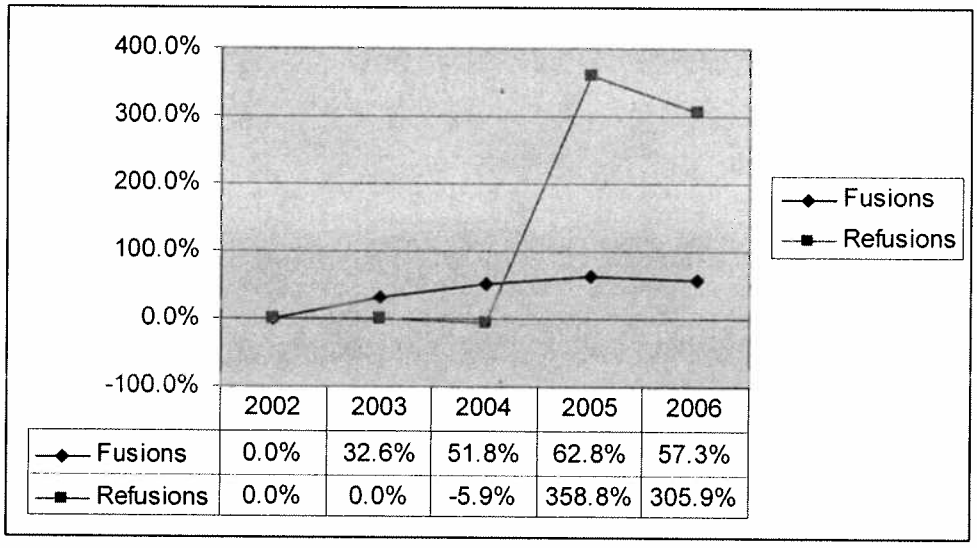
Spine Fusions and Refusions 2002-2006

	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%**

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:

[1]. 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.

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



	2002	2003	2004	2005	2006
Fusions	0.0%	32.6%	51.8%	62.8%	57.3%
Refusions	0.0%	0.0%	-5.9%	358.8%	305.9%

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 and in costs to public and commercial payors and patients.

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