Physician Investment in Startup Device Companies: Debunking the Myths

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Physician entrepreneurship is on the rise; and investment by physicians in startup device companies is one manifestation of it. At the same time, there is increasing concern about potential conflicts of interest in physician business interests, given their fiduciary responsibility to their patients. There are multiple forms such investment can take. The Stark and anti-kickback statutes are relevant to investment in companies that do business with the federal programs. Many physicians are confused about the distinctions between these two statutes and their different requirements. This article elucidates these distinctions, describes a continuum of safety associated with such investment, and offers some practical tips for those considering or involved in such arrangements.

Key words: Investment; device, Stark, conflicts of interest, anti-kickback, safe harbor.

From drug-eluting stents, to gender-specific artificial knees, to polyethylene and ceramic artificial hips, to a wide variety of laparoscopic surgeries, advances in the development and manufacturing of high-tech medical devices have exploded in recent years, resulting in numerous clinical benefits and ultimately a better quality of life for patients. Small, nimble startup companies have been at the forefront of these technological advancements, often resulting in either the purchase of these companies by their larger competitors or lucrative IPO's (initial public offerings). The promise of attractive financial returns for investors has not only captured the attention of Wall Street, it has garnered direct investment by physicians.

Who better understands the clinical benefits of these developments than the surgeons and physicians treating the patients whose lives these devices will prolong and whose quality of life they will improve? Furthermore, practicing surgeons have contributed to substantive enhancements in the design and functionality of these devices. This has been particularly true in the orthopaedic implant industry where the number of startup companies has multiplied in recent years.

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A wide range of commentators, including the Department of Justice,[1] have called into question the financial relationships between these practicing surgeons and the companies whose products they use. From consulting contracts, to clinical study participation, to surgeon investments in device makers, these developments in the world of orthopaedic devices have been criticized as improper conflicts of interest, if not illegal.

There is no question that conflicts of interest can be real. They are further exacerbated under the Stark and anti-kickback statutes, which define the fraud and abuse environment for providers in Medicare and Medicaid. Certainly, where abuses occur—such as consultants being paid inflated rates for little work,[2] highly compensated

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speakers bureau participation for marketing of products, and surgeon "investments" in companies with little or no need for capital[3]—there is legitimate cause for concern. That said, however, there is a significant body of mythology emerging regarding what constitutes potentially illegal behavior (or true conflicts of interest) by surgeon investors and what is legitimate, healthy capitalism. This article will elucidate and clarify these distinctions, debunking the myth that any ownership by surgeons in medical device companies is suspect.

PHYSICIANS AS INVESTORS

Physician entrepreneurship in the healthcare environment is on the rise.[4] As payors have reduced reimbursement, physician practice expenses—particularly malpractice insurance premiums—have increased disproportionately. Many physicians are looking for new revenue streams and opportunities to supplement their cash flow in a significantly constrained financial environment. They have launched specialty hospitals and ambulatory surgery centers that they own and at which they also render services to patients. They have expanded the range of diagnostic services they offer. They have even begun to dispense drugs as well as add "medical spa" services to their offerings.

The surgeons who invest in healthcare companies may well be responding to the same financial pressures, but their investment in startup device manufacturers usually reflects several other factors. Based on the "Peter Lynch principle"—invest in what you know—surgeons who use these devices daily are in a unique position to evaluate and appreciate the potential value that new technology or new companies might bring to patients.

Surgeons also represent an attractive investor base for startups, because their specific expertise puts them in a better position to assess the risks and opportunities facing the startup, compared with more traditional sources of capital. Their knowledge base typically includes such matters as gaps in the current product mix, the clinical application of the devices, and the utility new products will add to the market. In addition, as high-net-worth individuals, surgeons not only have significant funds available to invest, but they also qualify as "accredited investors" under Rule 501(a) of Regulation D under the Securities Act of 1933.

Surgeons' intimate knowledge of the industry and products puts them in a very different position regarding their perception of potential risk and reward in these investments, particularly as compared with typical financial investors, such as venture capitalists. Their more positive and knowledgeable assessment of the specific application of these startups' products translates into more attractive terms for the startup: better valuations, greater management control, fewer oversight requirements, and a shareholder base that is in tune with the fundamental business, facilitating communications.

THE HOSPITAL PAYMENT NEXUS

Under the Medicare program and in many commercial payor contracts, hospitals are paid on a fixed rate, frequently a diagnosis related group (DRG) payment that encompasses all of the resources the hospital will bring to bear to meet the patients' needs regardless of length of stay. Consequently, with a finite amount of money available to provide services, hospitals have an incentive to be efficient and cut costs. Standardization of processes has been demonstrated repeatedly to improve quality. Standardization of devices can contribute to increased familiarity with the devices to be used, which is good for quality. By the same token, though, standardization of devices has been criticized as impeding quality by limiting access, solely in the interests of generating short-term profits.[5] Even so, hospitals often narrow the varieties of devices that they will make available because they can garner a better price by channeling more business to specific preferred vendors. It is this phenomenon that has spawned most "gainsharing" programs.

These gainsharing programs are a direct recognition of the fact that it is the physicians' orders and preferences that drive the bulk of what the hospital provides to patients. A combination of factors influence which device a physician will choose for a particular case, including: perceived clinical efficacy; implantation efficiency, which reduces surgical time and enables more consistent application of surgical techniques, resulting in fewer complications; access to technical support; and, above all, availability of the device at the hospital. Some commentators claim that physician financial relationships with vendors improperly corrupt these choices.[6] How hospitals make the decision as to which products they will use is a subject of fierce debate within the industry; and the Stark and anti-kickback statutes are often cited for a range of propositions both in support of and to challenge specific approaches. Understanding the distinctions between these two laws—which are not even in the same Titles of the Social Security Act—is the beginning of elucidating the confusion surrounding their impact in the surgeon investment context.

STARK AND ANTI-KICKBACK IN CONTEXT

The anti-kickback statute has been on the books in one form or another since 1972. Although initially adopted to prevent what anyone would understand as kickbacks and bribes in Medicare and Medicaid, as the world of healthcare has become more complex, especially in the business relationships among parties who can make money from the publicly financed programs, the breadth of the statute has been inexorably expanded by Congress. Ultimately, the theory behind the statute is to control unnecessary expenditures that arise from improper financial relationships within the federal programs. The anti-kickback

statute affects everybody who is in the revenue stream of any federally funded healthcare program, not just Medicare or Medicaid.

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By contrast, the Stark statute is narrowly directed only to physicians, and then only with respect to referral for specific "designated healthcare services," and then only referrals of Medicare patients for those services. Among the designated health services are all inpatient and outpatient hospital services. Consequently, it is prohibited for a physician to refer a patient for Medicare-funded inpatient or outpatient hospital services when the physician or an immediate family member has a financial relationship with that hospital, unless the relationship meets a Stark exception.

The Stark and anti-kickback statutes have some significant similarities but also differences which are frequently confounded. Stark offers flat prohibitions: you either comply or you do not. To violate Stark, intent does not matter; whereas in assessing a potential violation of the anti-kickback statute, intent is critical. Regulations significantly clarified the meaning of the Stark statute,[7] which otherwise has internal inconsistencies of language and overreaching provisions and is generally hard to understand, even by the most sophisticated health lawyers in the country.

The anti-kickback statute offers safe harbors in regulations,[8] but failure to comply with a safe harbor does not mean that the transaction violates the law. Rather, the arrangement will be evaluated using prosecutorial discretion taking into account the specific facts and circumstances. If you conform explicitly with the safe harbors, you are completely safe. The safe harbor regulations exist to protect transactions that may tend to induce referrals but will not be seen as violating the statute.

Both Stark and the anti-kickback statute offer protection for certain kinds of financial transactions that involve physicians using the devices manufactured by companies in which they have invested. Under the anti-kickback statute, this is the small investment safe harbor, and under Stark it is the indirect compensation provisions.

THE SMALL INVESTMENT SAFE HARBOR

There is a specific safe harbor for physician investment in small companies (as distinct from publicly traded companies) that establishes some relatively straightforward rules that would be expected.[9] For example, the return on investment to the physicians must be commensurate with the capital they provided and have no relationship to the volume or value of their referrals or usage of the products. The entity in which the physicians are investing may not lend money to the physicians to buy-in; and those buying shares in the company must do so on the same financial terms as any other stockholders, without preference because of anticipated or existing referrals.

Two other aspects of the safe harbor are intended to validate the business as a truly viable company with economic value apart from the referrals from its shareholders. The so called "forty-forty" rules stand for the proposition that to be safe, no more than 40% of the value of any class of shares may be held by those who refer, are in a position to refer, or do business with the entity in any way. Similarly, no more than 40% of the gross revenues of the business may be generated by those who are investors. By the application of these criteria, a company that complies would have demonstrated its bona fides and the value of its products apart from its investors. For a compliant company, there is an independent, disinterested market for its goods. "Interested" investors generating less than 40% of its revenues imply that these interested investors are not essential to its ability to succeed as a business. It should be noted that there has never been a reported enforcement or settlement under this "safe harbor," nor a court case construing it. This is because what makes an investment safe is clear. Prosecution will not arise because of failure to comply in every respect with the safe harbor, but only when the financial relationships established by the defendants go well beyond safety into violative realms.

Interestingly, prior to the safe harbors being published in final form, the government took an early aggressive enforcement position on the issue of joint ventures, by moving to exclude from Medicare a purported clinical laboratory physician joint venture and the entrepreneurs who marketed and set up the arrangements, and were doing so with multiple groups of physicians. By using the tactic of exclusion, the government did not need to go to court and prove a criminal violation of the law in accordance with the very high criminal burden of proof—beyond a reasonable doubt. Under the Office of the Inspector General's (OIG's) administrative authority, the government can exclude from the federal programs individuals and entities that violate the law, without having to prove anything in court to do so. In the *Hanlester* case,[10] the OIG took the position that the laboratory joint venture was little more than a vehicle for SmithKline to provide services to small physician-owned entities, in essence kicking back money to them merely for referring to their own joint venture company, which SmithKline would service. The investments were small, and the joint venture companies had little capital and performed few services themselves. The case took years to prosecute and then appeal.

Well before the final appeals were resolved, the OIG issued a Fraud Alert specifically outlining its views on joint ventures.[11] Eventually the Ninth Circuit ruled, upholding

the viability of joint ventures under the law, finding that they were not, per se, violative of the anti-kickback statute and taking the position that there must be specific intent to violate the law. The case had begun before the small investment safe harbor had even been published. Today, more than a dozen years later, despite the enactment of many state laws mirroring the Stark and anti-kickback statute, many states, including California and Pennsylvania, specifically allow physician investment in entities to which they refer, provided there is proper disclosure to the patient.[12]

THE INDIRECT COMPENSATION EXCEPTION

The Stark regulations by contrast, do not offer a small investment safe harbor as above, but rather acknowledge that if a hospital in which a physician operates enters into a transaction with a company owned by the operating physician, an exception is allowed. As long as the payments made by the hospital to the physician-owned entity for its goods or services are fair market value, calculated irrespective of the volume or value of the physician's referrals, then the transaction is not one that implicates investment, but rather is considered indirect compensation because of the payment by the hospital to the physician-owned vendor.[13] In the preface to the regulations, the example offered is ownership by a group of urologists in a lithotripter that the hospital leases from the physician-owned entity, where the urologists are the only physicians who would ever use such a device at the hospital. Not only is this legitimate under the statute, as of this writing the hospital could even pay the physician-owned entity on a "per-click" or per-use basis.[14] The key is that the entity itself may not pay its profits from the hospital payment to the referring physician investors based on their volume of referrals.

So physician investment in small companies that do business with the hospitals where they practice and where the physicians will use the very products made by the companies whose shares they hold do *not* violate the statutes or regulations, when the arrangements are proper.

FORMS OF PHYSICIAN INVESTMENT: A CONTINUUM OF SAFETY

Surgeon investment in companies that manufacture devices that the surgeons will implant in their patients can be completely safe under the safe harbors. The company is safe if it has many investors beyond the using physicians (at least 60%); the physicians purchased their shares for significant dollars and on the same terms as other investors; and the company has more business than that generated from the surgeon investors. Companies that meet these standards can rest assured they will have no problems from the OIG.

Not safe are companies in which physicians who use and refer the products represent the vast majority of investors. These companies are typically characterized by the following features: a small group of founders limit their search for investors only to surgeons who will use the product; the surgeons invest small amounts of money; their returns are far higher than other comparable investments; and the business depends primarily on the use of its products by its shareholders. While such a company might eventually evolve into a situation that falls under the protection of the safe harbors, it is clearly not safe at the outset. At the same time, it cannot be said to flatly violate the law either. In fact, if the hospital purchasing the devices complies with the indirect compensation rules, and the owning physicians do not get paid profits that reflect the volume of their individual use of the device, such arrangements may be defensible. They are not, however, safe.

Frequently swept under the same rubric as the scenarios above is something which is quite different, hotly discussed in the industry, and far more suspect: in essence, a company formed and owned by practicing surgeons to purchase devices as a group purchasing organization (GPO). This newly created GPO then contracts with the hospitals where the surgeons operate to make the preferred devices available and receives payment of a percentage of the sales of these devices from the manufacturer. Since these GPOs have virtually no need for capital, the surgeon owners make nominal "investments" but receive outsized returns based on the volume of products they use. These types of schemes have been severely criticized as problematic[15] under the long-standing policies of the OIG regarding joint ventures.

Equally problematic is surgeon ownership in distributors of medical devices. Distributors of medical devices are typically agents of the manufacturers, who receive a commission for sales of the devices and provide consulting to operating room personnel in the use of the devices. Again, these entities have little to no real capital requirements, and the returns available to surgeon owners are highly correlated with their product usage.

The common characteristic of surgeon ownership in the problematic structures (GPOs and distributorships) is the absence of legitimate capital requirements and the perceived lack of value created by the entities. This is quite different from startup device manufacturers that introduce new products, the development of which requires the investment of capital and other resources. The GPOs and distributorships merely provide an ownership interest for a nominal investment by the surgeons in a company that functions as a conduit to funnel money back to the surgeons as a direct result of their product usage.

The issues associated with these models have been so controversial that AdvaMed, the device industry lobbying organization, entered the fray by requesting from the OIG Office of Legal Counsel explicit guidance regarding the

OIG's position on these types of intermediary entities—themselves not manufacturers, but middlemen, permitting physicians to make profit from their restriction of the availability of devices in their hospitals to the ones which they use and select. In October 2006, Vickie Robinson, chief of the OIG's Advisory Opinion branch, took the opportunity to make it clear that the OIG has not deviated in anyway whatsoever from its 1994 Joint Venture alert.[16]

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In essence, despite new forms of entrepreneurship in today's world, the principles of safety that have long existed in the Medicare and Medicaid programs remain in effect today and offer assurances both to investing physicians and to hospitals who would do business with their companies that they represent legitimate, viable, valid, and valuable additions to a fast-developing industry.

PRACTICAL GUIDANCE

Against this backdrop, there are practical issues for the range of actors involved with surgeon investment in startup device companies: (1) potential investors; (2) surgeons who are already invested; and (3) hospitals, surgery centers, and others who would do business with surgeon-invested device companies.

For those contemplating investment, being aware of the safe harbor regulations in the first instance is important. Legal advice from experienced healthcare counsel to evaluate the potential risks associated with an investment would be important given the volatile nature of the current environment.

For physicians who are already invested, the American Academy of Orthopaedic Surgeons Ethical Guidelines set forth in very straightforward terms the principle of disclosure, which mirrors the increasing emphasis on transparency throughout the healthcare industry.[17] Physicians who have invested in companies whose products they use should disclose that ownership to their patients when they recommend that the patients be treated using products of the companies with which the physicians hold an interest. The OIG's safe harbors offer safety for those who meet them; and it is fair for potential customers to ask whether the arrangement is safe under the safe harbors. It is not necessary for a company with physician investors to obtain an OIG Advisory Opinion for something that can meet the boundaries of published safe harbors. That is the point of publishing the safe harbors in the first place.

In addition, a company may start out as "not safe," but become "safe" over time, as the characteristics of the business change. Thus not being strictly safe does not mean that a company is violating the law. In fact, startup device makers often have a core group of early adopters who have been intimately involved in the creation of the new technology who may also own equity. This group may represent a majority of the surgeons using the products early in the development; however, over time, as the clinical benefits of the technology are demonstrated and the company develops broader distribution capability, the base of surgeon users expands and the core group diminishes in proportion, enabling the company to fall within the safe harbor guidelines.

Some models of physician investment are safe and preferable, others may give one pause for concern, and still others appear to be problematic.

For hospitals and surgi-centers considering doing business with surgeon-invested device companies, there is nothing that prohibits them from doing business with a company in which surgeons on staff are invested, as long as the basic parameters of safety are met and the indirect compensation rules are followed. It is legitimate to ask if the company has a "clean opinion" from healthcare counsel as to the safety of the arrangements under the safe harbors. The company likely will not share the opinion, but if the investments are safe, it can say so. For all parties, ensuring surgeon disclosure of ownership when clinical recommendations include products made by companies owned by surgeons is fair, transparent, and prudent.

CONCLUSION

The device-manufacturing segment of the healthcare industry is dynamic and expanding—creating value and improving lives. Surgeons and other physicians have become increasingly interested in participating in this dynamic environment as equity owners. As in many other components of the healthcare delivery system, there is a continuum of compliance with respect to acceptable arrangements. Some models of physician investment are safe and preferable, others may give one pause for concern, and still others appear to be problematic. For physicians who invest in and hospitals that purchase the devices of the companies that have physician investment, the key is to ask the right questions. ■

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