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?

A wide range of commentators, including the Department of Justice, 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, highly compensated
speakers bureau participation for marketing of products, and surgeon “investments” in companies with little or no need for capital—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.

The Stark and anti-kickback statutes have some significant similarities but also differences which are frequently confounded.

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,\(^\text{7}\) 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,\(^\text{8}\) 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.\(^\text{9}\) 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,\(^\text{10}\) 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.\(^\text{11}\) Eventually the Ninth Circuit ruled, upholding
the viability of joint ventures under the law, finding that 
you were not, per se, violative of the anti-kickback statute 
and taking the position that there must be specific intent to 
vio late the law. The case had begun before the small in-
vestment 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 al-
low physician investment in entities to which they refer, pro-
vided there is proper disclosure to the patient.\textsuperscript{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 physi-
cian, 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.\textsuperscript{13} In the 
preface to the regulations, the example offered is owner-
ship by a group of urologists in a lithotripter that the hos-
pital 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.\textsuperscript{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 in-
vestors; 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 in-
vestors. 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 prod-
uct; the surgeons invest small amounts of money; their re-
turns are far higher than other comparable investments; 
and the business depends primarily on the use of its prod-
ucts by its shareholders. While such a company might event-
tually 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 in-
dividual use of the device, such arrangements may be de-
fensible. They are not, however, safe.

Frequently swept under the same rubric as the sce-
narios 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 problem-
atic\textsuperscript{15} under the long-standing policies of the OIG regard-
ing joint ventures.

Equally problematic is surgeon ownership in dis-
tributors of medical devices. Distributors of medical de-
vices 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 own-
ers 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 intro-
duce 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

The principles of safety that have long existed in the Medicare and Medicaid programs remain in effect today.

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 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.

REFERENCES

1. Medical device industry warned to expect more attention from the Department of Justice. BNA Health Care Fraud Report. 2007; 11:392-393.
7. 42 CFR §411.350 et seq.
8. 42 CFR §1001.951 et seq.
13. 42 CFR §411.354(b)(5), (c).