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September 6, 2006

Vicki Robinson, Esq.  
Chief, Industry Guidance Branch  
Office of Counsel to the Inspector General  
Department of Health and Human Services  
330 Independence Avenue, SW  
Washington, DC 20201

RE: Request for Guidance Regarding Certain Physician Investments in  
Medical Device Manufacturers and Distributors

Dear Ms. Robinson:

The Advanced Medical Technology Association (AdvaMed) is the world's largest medical technology association, representing medical device manufacturers, makers of medical equipment, medical software, and medical technology. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent purchased annually around the world. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

AdvaMed has made a substantial commitment to promoting principles of lawful and ethical conduct among its members. In the last few years, AdvaMed has made a particular effort to encourage companies to comply with AdvaMed's *Code of Ethics on Interactions with Health Care Professionals* to ensure ethical collaboration between companies and health care professionals vital to the advancement of medical innovation and technology, and to facilitate compliance with the principles of the Anti-Kickback Statute<sup>1</sup> (Statute) and guidance issued by the Office of the Inspector General (OIG).

An important recent development in the device industry is the formation of companies in which physicians both have an equity ownership interest and generate a substantial portion of the companies' revenues (e.g., >40%) through ordering (or influencing orders

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<sup>1</sup> 42 U.S.C. §1320a-7b.

for) devices sold or manufactured by the company. As we explain below, AdvaMed recognizes the important and beneficial role that physician investment in device companies may have. On the other hand, the emergence of companies with equity investments by physicians who are also major revenue generators for the companies, raises important legal and policy issues relating to the potential effect on clinical decisions by physicians that may be inconsistent with the goals of the Statute. Although OIG has made a number of statements about the application of the Statute to physician investments in entities to which they refer patients or business,<sup>2</sup> and has even promulgated a regulatory safe harbor for certain of such arrangements, there remain areas in which further guidance regarding the applicability of the Statute to such investments would be beneficial to our members. Accordingly, we identify below areas in which further guidance would be useful.

## I. BACKGROUND

Robust physician-industry collaboration is essential for the continued advancement of medical technology. Indeed, many beneficial medical technologies available today are the product of physician innovators and entrepreneurs. The medical technology industry relies heavily on collaboration with physicians for innovation and product development. In return for their services, physicians receive compensation for their efforts. Such compensation may be in the form of equity, consulting fees, royalties, or other forms. The touchstone of these appropriate arrangements is that the payment received by the physician is for valuable *bona fide* services rendered to the company. As a result, many of these collaborations may satisfy the requirements of the personal services safe harbor.<sup>3</sup> Even if an arrangement cannot fit squarely within the personal services safe harbor, a *bona fide* fair market value exchange of services for payment is unlikely to be deemed to violate the Statute.

Recently, the device industry has seen the emergence of device companies and distributors that offer substantial equity positions to physicians apparently, in some cases, selected because collectively they are in a position to generate a substantial amount of business for the entities (e.g., more than 40% of total revenues) through ordering (or influencing orders for) devices sold or manufactured by the company. These arrangements satisfy neither the safe harbor for investment in publicly held companies,<sup>4</sup> nor the safe harbor for investment interests in small entities (small entity safe harbor).<sup>5</sup>

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<sup>2</sup> See, *infra*, fns 6-10, and the accompanying text.

<sup>3</sup> 42 C.F.R. §1001.952(d).

<sup>4</sup> 42 C.F.R. §1001.952(a) (1).

<sup>5</sup> 42 C.F.R. §1001.952(a) (2).

## II. REQUEST FOR FURTHER GUIDANCE

In furtherance of AdvaMed's efforts to assist its member companies to comply with the highest principles of lawful and ethical conduct, AdvaMed would appreciate the Office of the Inspector General's guidance in the following areas<sup>6</sup> related to physician investment in medical device manufacturers and distributors.

A. Confirmation that the 1989 Special Fraud Alert and Other Guidance on Physician Investment Applies to Medical Device Manufacturing and Distributor Entities.

In 1989, OIG issued a Special Fraud Alert (SFA) addressing the application of the Statute to certain joint venture arrangements.<sup>7</sup> According to the SFA, a joint venture may be suspect when physicians are both investors in the joint venture and also in a position to refer to the joint venture. Such ventures would be especially scrutinized with respect to: (i) the manner in which investors are selected and retained; (ii) the business structure of the venture; and (iii) the financing and profit distributions of the venture. According to the SFA, the OIG is concerned that the ventures are using profit distributions to disguise payments to the investing physicians for their referrals of patients or business to the venture.

With respect to the first area of concern – the manner in which physician-investors are selected and retained – the OIG noted six suspicious characteristics of these ventures.

- Investors selected because they are in a position to refer;
- Physician-investors that are in a position to refer more patients are offered greater participation;
- Active encouragement of investors to refer to venture;
- Active encouragement of low referrers to divest;
- Tracking referrals by investors and distributing the information to all investors; or

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<sup>6</sup> We emphasize that these areas and suggested interpretations do not constitute a code of conduct for AdvaMed members or a statement of how any individual AdvaMed member interprets the law. In fact, each AdvaMed member must make its own decision as to how to apply the law based on advice from its own legal counsel. Nevertheless, we believe it is useful to suggest interpretations of the Statute in order to assist OIG in its analysis and to illustrate more clearly the areas where we believe clarification would be particularly helpful.

<sup>7</sup> See Special Fraud Alert, "Joint Venture Arrangements" (OIG-89-4), *reprinted in* 59 Fed. Reg. 65373 (December 19, 1994).

- Restrictions on transfers of ownership interests (e.g., mandatory buyouts if physician retires or leaves area).

With respect to the second element – the business structure of the venture – OIG noted the following suspicious characteristics:

- One investor, typically the general partner or manager of the venture, already provides the same services as the venture (e.g., a syndicator of such ventures); or
- The venture outsources substantially all its operations to that investor (“shell ventures”).

With respect to the third area of concern – the financing and profit structure – OIG stated that it would look at the following characteristics:

- The physicians’ capital investment is small and their return on investment is disproportionately large;
- Nominal capital investments; or
- High returns for low risk.

In addition to identifying the characteristics of suspect physician joint ventures, OIG promulgated a regulatory “safe harbor” that protects certain physician investments in businesses to which they refer. Ventures that comply with the small entity safe harbor are immune from prosecution under the Statute. The key element of this safe harbor is that investors that refer to, or can otherwise generate business for, the venture or that provide services or supplies to the venture cannot generate more than 40% of the revenues of the venture; or own more than 40% of the venture. Simply put, the venture cannot depend on the referring physicians as its customer base; it must do the majority of its business with independent third parties. The other conditions in the small entity safe harbor largely address the concerns identified in the 1989 SFA.<sup>8</sup>

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<sup>8</sup> OIG has questioned whether arrangements that link several different safe harbors to protect discrete steps or aspects of a larger arrangement will qualify for protection in the absence of strict compliance with all elements of all safe harbors, or whether they might protect the remuneration to one party in the transaction, but not other parties. See OIG Special Advisory Bulletin on “Contractual Joint Ventures,” 68 Fed. Reg. 23148 (April 30, 2003):

To qualify for safe harbor protection, an arrangement must fit squarely in one of these safe harbor provisions. Some parties attempt to carve otherwise problematic contracting arrangements into several different contracts for discrete items or services (e.g., a management contract, a vendor contract, and a staffing contract), and then qualify each

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OIG has repeatedly emphasized its concern with these types of ventures – most recently in the OIG Supplemental Compliance Program Guidance for Hospitals,<sup>9</sup> and in the OIG Special Advisory Bulletin on Contractual Joint Ventures.<sup>10</sup> In addition, there have been several enforcement actions regarding suspect joint ventures involving physician investments in entities to which they refer.<sup>11</sup>

Based on the policy considerations underlying the Statute and OIG's statements in this area, it is reasonable to assume that OIG's various guidance on physician joint ventures, including the 1989 Special Fraud Alert, the small entity investment safe harbor, and the advisory opinions and other informal guidance documents referenced herein, apply to physician investments in device and distribution companies, even though these authorities do not expressly reference physician investment in medical device manufacturing and distribution entities. However, OIG has never expressly stated this principle. It would be helpful if OIG would confirm their applicability publicly.

#### B. Additional Indicators of Potentially Unlawful Arrangements.

Next, AdvaMed is concerned that at least some of the physician equity investments in device manufacturing or distribution entities for which physicians generate substantial revenues (e.g., >40%) have the potential to: (i) reduce quality of care; (ii) create conflicts of interest between physicians' responsibility to provide the best care and physicians' equity interests which may compromise (or appear to compromise) the physician-patient

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separate contract for protection under a "safe harbor." Such efforts may be ineffectual and leave the parties subject to prosecution. . . .

See also, OIG Advisory Opinion 06-02 (proposed arrangement between a DME manufacturer/supplier and physicians could generate prohibited remuneration notwithstanding certification of compliance with safe harbors); OIG Advisory Opinion 04-08 (physician practice's proposed non-exclusive leasing arrangement of physical therapy center to other physicians could generate prohibited remuneration notwithstanding ostensible compliance with safe harbors).

<sup>9</sup> 70 Fed. Reg. 4858, 4865-4866 (January 31, 2005)

<sup>10</sup> *Supra*, fn. 8.

<sup>11</sup> See, U.S. Department of Justice ("DOJ") June 2003 press release of settlement in U.S. ex rel. Thompson v. Columbia HCA, et al., (Columbia HCA paid \$225.5 million for alleged false claims arising from kickbacks to physicians, including physician investments in Columbia HCA facilities) at: [http://www.usdoj.gov/opa/pr/2003/June/03\\_civ\\_386.htm](http://www.usdoj.gov/opa/pr/2003/June/03_civ_386.htm); OIG CMP settlement with Inland Empire Lithotripsy, LLC for violations of the Anti-Kickback Statute involving termination of physician investors for insufficient referrals, reported at: <http://oig.hhs.gov/fraud/enforcement/administrative/cmp/cmpitems.html#3>

relationship; (iii) increase the cost of health care; and (iv) restrict patient access to the most appropriate medical technologies.

Hence, in furtherance of AdvaMed's requests above, and in addition to the factors identified in the SFA as "indicators of potentially unlawful activity," AdvaMed requests specific clarification and guidance by OIG whether the following situation also provides, in OIG's view, potential evidence of a linkage between an investment opportunity and referrals that could trigger scrutiny:

- After an entity's initial start-up phase, a substantial portion of the entity's revenues (i.e., >40%) are derived from business generated directly or indirectly by physician investors.

As with the other indicators identified by OIG in the SFA, any ultimate determination of a violation would require an analysis of the entirety of the facts and circumstances surrounding the investment.

C. Publication of Additional Indicators of Potentially Unlawful Arrangements Identified By OIG as Applicable to Medical Device Manufacturing and Distributor Entities.

Finally, AdvaMed understands that, regardless of the presence or absence of the characteristics identified by OIG in the SFA, there are no *per se* violations of the Statute; rather, the Statute is an intent-based statute and requires proof of not only what the parties did, but also why they did it. In that regard, OIG has occasionally and publicly identified fact patterns that suggest that there is an improper linkage between remuneration offered or paid and the referral of federal health care program business.

AdvaMed believes it would be helpful to the medical device industry and others, if OIG would publicly identify any factors or characteristics relative to physician investment in medical device manufacturing and distribution entities specifically, in addition to the factors identified in the SFA, which OIG views as "indicators of potentially unlawful activity."

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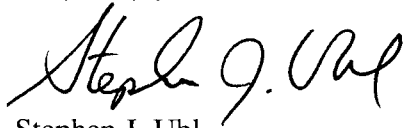
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AdvaMed is committed to educating its members with regard to strict compliance with the federal fraud and abuse statutes, and to encouraging the highest level of ethical conduct by its members. We believe the requested guidance would help accomplish that goal.

Thank you for your attention to this request.

Very truly yours,

A handwritten signature in black ink that reads "Stephen J. Ubl". The signature is written in a cursive, flowing style.

Stephen J. Ubl  
President and Chief Executive Officer

cc: Christopher L. White, Esq., Executive Vice President,  
General Counsel, and Assistant Secretary