DEPARTMENT OF HEALTH & HUMAN SERVICES **Office of Inspector General**

Washington, D.C. 20201

October 6, 2006

[Name and Address Redacted]

RE: Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries

Dear [Name redacted]:

We are in receipt of your letter dated September 6, 2006, requesting further guidance from the Office of the Inspector General ("OIG") regarding certain physician investments in medical device manufacturers and distributors. Specifically, you have requested: (1) confirmation that the 1989 Special Fraud Alert on Joint Ventures and various other guidance on physician investment issued by OIG apply to medical device and distribution entities; (2) clarification with respect to certain factors relevant to analyzing a joint venture under the fraud and abuse law; and (3) publication of additional OIG guidance regarding physician investment in medical device and distribution entities.

We appreciate the concerns expressed in your letter. We are aware of an apparent proliferation of physician investments in medical device and distribution entities, including group purchasing organizations. Given the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers, we believe these ventures should be closely scrutinized under the fraud and abuse laws.

With respect to your first request, we confirm that the guidance addressing physician investment posted on OIG's website at oig.hhs.gov is current guidance. We believe all industry stakeholders involved in joint ventures with physicians, including medical device manufacturing and distribution entities, are well-advised to pay close attention to such guidance. Most of our guidance about joint ventures is not sector specific and applies equally to all physician joint ventures. Thus, principles set forth in the 1989 Special Fraud Alert on Joint Ventures and our other joint venture guidance would be applicable to physician investments in medical device manufacturing and distribution entities (as well as group purchasing agents). It is important to note that the characteristics of a suspect venture enumerated in the Special Fraud Alert and other guidance are illustrative, not exhaustive, and other characteristics may also indicate potential unlawful conduct. Because the anti-kickback statute is an intent-based statute, every arrangement is evaluated on a case-by-case basis.

We interpret your second request as seeking clarification with respect to whether the amount of revenues generated directly or indirectly by a physician investor is a relevant factor in analyzing a joint venture under the anti-kickback statute. We confirm that it is. For example, the small entity investments safe harbor at 42 C.F.R. 1001.952(a) includes a condition that limits safe harbor protection to entities that derive no more than 40% of their gross revenues from investors, such as physicians. While safe harbor protection requires strict compliance with all safe harbor conditions, the conditions listed in the safe harbors are relevant to the analysis of physician and other joint ventures under the fraud and abuse laws. As noted in the discussion of joint ventures in our Supplemental Compliance Guidance for Hospitals (equally relevant to medical device manufacturers, distributors, and others), 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. See 70 Fed. Reg. 4858, 4865 (Jan. 31, 2005).

Finally, you have requested that OIG publish additional guidance specific to the manufacturing and distribution entities. We will take your views on the matters raised in your letter into consideration as we contemplate future OIG guidance projects.

Thank you for sharing your views on physician investments in medical device manufacturers and distributors. OIG appreciates information from concerned stakeholders in the health care industry.

Very truly yours,

Vicki L. Robinson
Chief, Industry Guidance Branch