

January 13, 2009

Thomas N. Bulleit, Jr.
Partner
202-536-8276
TNBulleit@hhlaw.com

BY ELECTRONIC MAIL

Ms. LouAnn Stanton
Office of the General Counsel
Department of Public Health
250 Washington Street
Boston, MA 02108
Reg.Testimony@state.ma.us

Re: Testimony Concerning M.G.L. Chapter 111N, 105 CMR 970.000: "Pharmaceutical and Medical Device Manufacturer Conduct"

Dear Ms. Stanton:

Pursuant to the Department of Public Health's ("DPH") solicitation of testimony on the implementation of M.G.L. Chapter 111N, "Pharmaceutical and Medical Device Manufacturer Conduct," (the "Act") we submit this testimony on behalf of the Quality Implant Coalition (QuIC), a coalition of manufacturers of implantable medical devices formed to urge governmental action to preserve the quality and integrity of implantable medical devices.

QuIC's testimony focuses on suggested changes to the regulations DPH has proposed to implement the Act (the "Proposed Rule")¹. Specifically, QuIC proposes that the final version of the Proposed Rule (the "Final Rule") clarify that the Act's financial disclosure provisions require pharmaceutical and medical device manufacturers to disclose ownership interests and payments resulting from ownership interests along with all other forms of economic benefits. QuIC also suggests that, consistent with existing law affecting Federal health care programs and the laws of many states, including Massachusetts, DPH's Final Rule clarify that physician ownership in a medical device company is prohibited where such ownership is intended to induce the physician-investor to use, order, recommend, purchase, or arrange for the purchase or lease of any company products.

QuIC is a coalition of manufacturers of medical devices that is concerned with the potential for harm to patients, payors, and the general health care system that inevitably arises

¹105 CMR 970.000.

when a physician's choice of the implantable medical devices s/he will use in treating his or her own patients is influenced by that physician's financial interests in those devices. Our specific focus has been on the inherent conflict-of-interest resulting from physician-owned implant and other medical device companies, entities that the Federal Centers for Medicare and Medicaid Services ("CMS") have denominated "POCs" (physician-owned companies). Both CMS and the HHS Office of Inspector General ("OIG") have recognized the inherent conflict of interest and potential for harm presented by the self-referral to POCs of physician-investors.² QuIC has previously filed comments with CMS on POCs, copies of which are attached.³

Consistent with the Federal "sunshine" legislation proposed by Senator Grassley,⁴ a principal focus of the Act, as recognized in the Proposed Rule, is to ensure the transparency of physician financial relationships with medical device companies. QuIC members are fully supportive of this goal. While we believe that the descriptions of "fee, payment, subsidy, or other economic benefit" in the Act and the Proposed Rule already encompass ownership interests, QuIC recommends that the Final Rule clarify this point, and proposes regulatory language to that effect.⁵ Consistent with Federal "safe harbors" exempting from scrutiny ownership in companies sufficiently large that owner physicians cannot materially affect their own returns, the regulatory language would further clarify that ownership does not trigger a disclosure requirement in the case of such companies.

QuIC's other proposal is that the Final Rule clarify that physician ownership is unlawful where it is offered or received as an inducement to use the company's products. Such financial relationships are already unlawful under Federal⁶ and Massachusetts⁷ law, but the Final Rule affords an opportunity to bring regulatory clarity. We have also proposed regulatory language to this effect.⁸

QuIC's proposed regulatory language follows a more detailed discussion of the rationale for QuIC's proposals.

I. Background on QuIC Proposals

As discussed above, QuIC's primary focus as a coalition has been to petition governmental entities concerning ways to address the inherently abusive nature of physician self-referral to POCs. This section summarizes the experience of QuIC members with POCs and the nature of the threat to patients, payors, and the health care system presented by physician self-referral to these entities.

²See Letter from Vicki Robinson, Chief, Industry Guidance Branch, HHS Office of Inspector General (Oct. 6, 2006), available at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20%282%29.pdf>; see also Centers for Medicare and Medicaid Services, Proposed Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules, 73 Fed. Reg. 23527, 23694 (April 20, 2008) ("[w]e have recently become aware of an increase in physician investment in implant and other medical device manufacturing, distribution, and purchasing companies . . . [w]hen physicians profit from the referrals they make to hospitals through physician-owned implant and medical device companies ('POCs'), we are concerned about possible program or patient abuse").

³Attachment 1, we are happy to furnish copies of the attachments to our earlier comments if DPH would find that helpful.

⁴S. 2029, 110th Cong., Physician Payments Sunshine Act.

⁵See Appendix A.

⁶42 U.S.C. § 1320a-7b.

⁷M.G.L. c. 118E, S. 41 and M.G.L. c. 175H, s. 3.

⁸See Appendix A.

A. A Primer on POCs.

Both the OIG and CMS have expressed concern with POCs, indicating that physicians being able to profit from referrals they make to hospitals could lead to patient and health care program abuses.⁹ OIG has cautioned strongly against such ventures, arguing that “the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers” necessitates these arrangements being “closely scrutinized under the fraud and abuse laws.”¹⁰ CMS has opined that many POC arrangements violate the Federal Physician Self-Referral (“Stark”) Law,¹¹ and continues to consider regulatory changes that would more squarely prohibit all such arrangements.¹²

These substantial Federal concerns exist because POCs operate as a vehicle for physicians to insert themselves in the medical device supply chain with the opportunity to earn income from their investment. POCs generally take the form of medical device distributors, medical device manufacturers, and sometimes as small group purchasing organizations (“GPOs”), but more practically operate as superfluous middlemen who adversely affect device pricing and limit consumer choice. POCs flourish in the implantable device market due to the unique control surgeons have over product selection for their patients. Specifically, most implantable devices are physician-preference items, meaning that an individual surgeon can control the type and brand of device ordered by a hospital for his or her individual patient; often, despite any purchasing contracts or agreements the hospital already may have to the contrary.

Because of the physician’s unique ability to control device ordering for his or her patients, an investment in a POC can prove to be a lucrative endeavor, since the physician can more or less guarantee a certain level of income for the POC solely by directing his or her patient referrals there. In fact, many POCs have structured their investment mechanism solely to capture these physician orders and capitalize on the conflict of interest created by the physician’s investment. Indeed, as the founder of one prominent POC has acknowledged in describing his own motivations, the essential business concept underlying a POC is “to form a limited liability company that consisted of approximately one hundred doctors who would also serve as the company’s customer base.”¹³

This financial incentive for the physician creates an irreconcilable conflict of interest, pitting a physician’s own financial self-interest against a patient’s need to have the most

⁹ See *supra* note 2 and accompanying text.

¹⁰ Letter from Vicki Robinson, Chief, Industry Guidance Branch, HHS Office of Inspector General (Oct. 6, 2006), available at <http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20%282%29.pdf>; See also Testimony of Gregory E. Demske, Office of Counsel of the Inspector General, U.S. Department of Health and Human Services, before the U.S. Senate Special Committee on Aging Examining Relationships Between Medical Device Industry and Physicians (Feb. 27, 2008), available at http://www.oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf (“Demske Testimony”) (“[a]dditionally, physician ownership of medical device manufacturers and related businesses appears to be a growing trend in the medical device sector. These business ventures raise substantial concerns that a physician’s return on investment from the venture may influence the physician’s choice of device”).

¹¹ 42 U.S.C. § 1392nn; 73 Fed. Reg. 23695 (“[i]n many instances, the [POC] arrangement would not satisfy the requirements of the exception for indirect compensation arrangements . . . and would, therefore, run afoul of the physician self-referral statute”).

¹² See Centers for Medicare and Medicaid Services, Changes to the Hospital Inpatient Prospective Payment System and Fiscal Year 2009 Rates 72 Fed. Reg. 48434, 48727 (Aug. 19, 2008) (stating that ordinary product suppliers do not “perform” Stark Designated Health Services, but that POCs are different in that CMS does not currently consider them “necessarily” to perform DHS, and “[w]e may decide to issue propose rulemaking on this issue in the future”).

¹³ See, e.g., Declaration of Souhail Toubia in Support of Application for TRO, *Allez Medical Applications, Inc. v. Allez Spine*, Case No. 06CC0153, Cal. Sup. (April 17, 2006). [Attachment 2](#).

appropriate and safest device selected by the physician without regard to the device's distributor or maker. Despite this, POCs are proliferating throughout the country, and existing legal authorities have not succeeded adequately in deterring their growth. For example, there is little doubt that a physician's self-referral to his or her POC violates the Federal health care programs Antikickback Law ("AKL"), because such relationships provide the referring physician with remuneration, at least "one purpose" of which is to induce the doctor's referrals.¹⁴ Yet the AKL's requirement of establishing unlawful intent has proved an impediment to prosecution.¹⁵ Likewise, CMS has indicated that many POC arrangements violate the Stark Law; yet, as discussed above, has deferred developing regulatory guidance that would clearly prohibit all POC self-referral.¹⁶

Based on the first-hand experience of QuIC members, we have been able to gather information about the operation and structure of the most common kinds of POCs, and we include below a brief description of each.

1. Distributor POCs

In most instances of which QuIC members are aware, distributor POCs have arranged to buy implants from manufacturers and resell the implants to the hospitals where the physician-investors refer their patients for the implant procedure.¹⁷ While most prescription drug products are sold this way (through distributors that buy and resell) in the United States, sale through a distributor is uncommon in the medical device industry, and almost unheard of with implantable devices.¹⁸ Rather, implant manufacturers overwhelmingly sell direct to the hospitals and surgery centers where patient procedures are performed. Though some end users keep product on consignment, most sales are direct shipped from the manufacturer to the hospital in response to a specific order from the physician who plans to implant the product into his or her patient. This means that distributor POCs likely do not actually take physical possession of the devices. And unlike legitimate manufacturers and their independent sales agents, they do not offer the assistance of industry-employed allied health professionals.¹⁹ Rather, they have as their only substantive function procuring and entering into a contract for the sale of the devices with hospital customers. Moreover, by virtue of their physician owners being able to leverage their hospital admissions into POC contracts, the POCs are engaged in "white coat" sales, with all of

¹⁴See, e.g., *United States v. Greber*, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985) ("if one purpose of the payment was to induce future referrals, the medicare [Antikickback] statute has been violated").

¹⁵Demske Testimony at 8 ("Because the anti-kickback statute is a criminal, intent-based statute that requires a case-by-case analysis to determine whether the law has been violated, OIG's ability to issue general guidance about the statute is limited").

¹⁶See *supra* note 12.

¹⁷In some instances, the POCs might not even buy and resell, but instead might receive some sort of "commission." Either kind of POC presents the same basic fraud and abuse issues.

¹⁸Most medical device manufacturers contract to some extent with independent businesses to serve as commissioned sales representatives. While the term in the industry applied to these representatives agents is "distributors" they are not true distributors, in that they do not buy and resell. Sales still go directly from the manufacturer to the hospital. Representatives of these independent businesses function like manufacturer-employed allied health professionals, assisting with ordering and distribution, supplying instrumentation for use in procedures, and in many cases assisting physicians during procedures in the operating room. See, e.g., American Medical Association Council on Ethical and Judicial Affairs, Report on Industry Representatives in Clinical Settings (CEJA Report 2-A-07) ("Manufacturers of medical devices may facilitate their use through representatives . . . who can play an important role in patient safety by providing information about the proper use of the device or equipment as well as technical assistance to physicians"), <http://www.ama-assn.org/ama/pub/category/3840.html>.

¹⁹See *supra* note 18.

the abuses that entails,²⁰ and can generate business for themselves (via owner referrals for procedures involving POC-provided products).

2. *Purported Manufacturer POCs*

Some POCs use a business model in which they purport to be implant manufacturers. In most of the instances of which QuIC members are aware, these purported manufacturers are in fact nothing more than distributors, outsourcing all of the key manufacturing functions. In comments filed last year with CMS, counsel to a POC operating in California acknowledged, somewhat euphemistically, that his client was engaged in “competitive outsourced manufacturing.”²¹ Thus, like the POCs that acknowledge their distributor status, such purported manufacturer POCs add no value other than their mark-up on the outsourced implant product.

3. *POC GPOs*

Some POCs have organized themselves in an attempt to take advantage of the AKL “safe harbor” for group purchasing organizations (GPOs).²² Under the safe harbor, product manufacturers are permitted to pay administrative fees to GPOs acting on behalf of their hospital members. These fees are always based on the volume or value of purchases made through the GPO, and, in the case of POC GPOs, always based on the volume of referrals made by the POC’s physician investors.

A true GPO can add value for its hospital members by aggregating the buying power of a large number of members to negotiate lower prices from a wide variety of manufacturers. Like true GPOs, POC GPOs have an incentive to increase utilization of the product on which they receive GPO fees. However, unlike a true GPO, a POC GPO, through its physician owners, can increase utilization of the GPO’s product lines as the physicians require the hospitals where they perform their procedures to order POC implants for those procedures, and even to order other items furnished through the POC that are not physician preference items. Both the value of his or her investment interest and any return on investment is based on the size of the GPO fees paid by the manufacturer; thus, the more products ordered, and the more expensive those products, the more the physician earns from ownership in the POC GPO. There is no counterbalancing incentive to acquire lower cost items, because the physicians ordering the products are not the purchasers – they have no money at stake in the transaction.

In addition, the GPO marketplace for medical device purchasing is dominated by a small number of large, national companies that by virtue of their large membership have substantial

²⁰See HHS Office of the Inspector General, Advisory Opinion No. 02-12 (Aug. 30, 2002); *see also* HHS Office of the Inspector General, Advisory Opinion No. 99-12 (Nov. 23, 1999).

²¹Letter from W. Bradley Tully to CMS dated August 29, 2007 at 3. [Attachment 3](#).

²²42 C.F.R. § 1001.952(j); 42 U.S.C. § 1320a-7b(b). The GPO safe harbor protects only fees paid to an entity “acting as a purchasing agent” on behalf of the hospital principal. Although it is fundamental agency law that the agent’s duty to its principal prohibits it from converting the principal’s business opportunities to the agent’s benefit, it is evident that such conversion is exactly what physician-owned GPOs are intended to achieve. As such, the physician-owned GPO does not qualify as legitimately “acting as a purchasing agent” and the safe harbor does not protect vendor fees to POC-GPOs. Moreover, the GPO safe harbor protects only fees paid to the GPO, not the financial return the physician receives from owning the GPO. And the safe harbor for small investments will never be available, in part because no POC will satisfy the requirements that 60% of its business come from purchases not referred by the physician-owner and other active investors. 42 C.F.R. 1001.952(d). Even if the POC traffics in other hospital items besides implants, all of that business will have been generated by the referring physician-investors, because there would be no other reason for a hospital to change its purchasing habits but for the physicians’ express or implied threats to take their procedures elsewhere if the hospital will not buy through their POC.

buying power.²³ Thus, there is little if any reason to believe that a new POC GPO would be able to generate the volume of membership that would give it bargaining leverage on price equal to that of current GPO players. In other words, one could reasonably expect that the prices that a POC GPO would be able to negotiate would be *higher*, or at least not lower, than a hospital could receive through the current market leaders. And of course, even if a POC GPO did manage to deliver lower pricing to a hospital member, that would not change the fact that the product selection would be driven inappropriately by the doctor's economic interests.

In essence, while a true GPO is engaged in the business of aggregating the purchasing power of a large number of members in order to negotiate lower purchase prices, a POC organized as a purported GPO performs no function for its members. Rather, operating on behalf of its physician investors, it simply arranges for the distribution to its "members" of the investor-physician's preferred products. As such, like a purported manufacturer or distributor POC (but unlike a true GPO), a purported GPO POC is a "pharmaceutical or medical device manufacturing company" subject to the provisions of the Proposed Rule.²⁴

4. Summary

In sum, although POCs assume various guises, they all have the same essential flaw: they provide the physician with a strong economic incentive to leverage his or her hospital admissions into implant purchases for his or her own patients based on the physician's economic interest rather than the patient's best interests.

B. The Inherent Abuses in POC Self-Referral.

In addition to not being what they purport to be, the POC business model presents substantial, and inevitable, potential for patient and program abuse.

1. POCs Present Medical Ethics Concerns

To begin with, physician-investment in a POC through which the physician orders implants for his or her own hospital admissions generally is unethical. The Council on Ethical and Judicial Affairs of the American Medical Association has cautioned against a physician prescribing drugs, devices, or appliances if that physician is otherwise influenced in the prescription by a direct or indirect financial relationship with the supplier.²⁵ Physician-investors in POCs surely believe their choices are not influenced by the financial interest; yet it is difficult to believe that anyone's judgment could fail to be affected by the powerful economic incentive that is created when the hospital agrees to acquire implants from the physician's POC. Further, in a separate opinion, the AMA Council issued guidance about physicians selling products in their offices, stating that physicians should limit the sale of items directly to patients in their offices because this "presents a financial conflict of interest, risks placing undue pressure on the patient, and threatens to erode patient trust and undermine the primary obligation of physicians

²³The Government Accountability Office has estimated that the seven largest GPOs account for over 85% of all hospital purchases through GPOs. See GAO Report No. 03-998T, *Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products* (July 16, 2003).

²⁴ See 105 CMR 970.004 (a "pharmaceutical or medical device manufacturing company [is] any entity that . . . is engaged in the . . . distribution of prescription drugs, biologics, or medical devices").

²⁵American Medical Association Council on Ethical and Judicial Affairs, Opinion E-8.06, *Prescribing and Dispensing Drugs and Devices*.

to serve the interests of their patients before their own.”²⁶ The concern the AMA Council has with sales of products in a physician’s office correlates precisely to the concerns with a physician deciding which implant to use on a patient: the financial incentive can cloud the physician’s judgment.

2. POCs Are Likely to Lead to Overutilization or Inappropriate Utilization of Health Care Services

The conflict of interest that inheres in the POC business model creates what would seem to be almost irresistible incentives to limit hospital admissions for implants to those facilities that agree to provide the physician-investor with an economic return by acquiring implants through his or her POC. Thus, the physician’s mind is likely to be closed to, or at least prejudiced against, implants from other sources and hospitals that refuse to deal with the physician’s POC. The likely result is that inappropriate implant choices will be made.

The same conflict of interest may even lead to overutilization, with physician-investors ordering procedures of questionable medical value in order to utilize more POC product. There is evidence to this effect. Data on spinal fusions²⁷ at one hospital from 2002-2006 shows that fusions increased dramatically when the spine surgeons at the hospital in question invested in a POC. Specifically, although surgeons performed only an annual average of 17 fusion procedures in the three years before their company began to operate, the annual number of fusions jumped to 78 and 69 in the following two years – over a 300% increase.²⁸ This data suggests that, for at least one hospital where the surgeons were involved in a POC, substantially more fusion procedures were ordered once a physician stood to benefit from the implant ordering decision.

3. POCs Are Likely to Lead to Higher Implant Costs

Not only will product choice inevitably be affected, but there is every reason to assume the end result of implant procedure choices made through POCs will be higher costs for such procedures. As discussed above, devices such as spinal implants (and hip/knee implants) are physician-preference items, so each physician-investor not only can minimize the risk of his or her investment, but also increase its value and contribute to return on investment by requiring the hospital to purchase the implants sold through the POC in which he or she has invested. Since physicians can control the venue for their implant procedures, they are in a position to insist that hospitals buy through their POCs.²⁹ And since physicians have this control over hospital implant purchasing, hospitals will have little ability to negotiate for lower implant prices as they will have lost the leverage to turn to other implant suppliers. Similarly, once physician-investors convince a hospital to purchase from their POC, the POC will have the power to raise prices almost at will, since the hospital that declines a price increase is likely to see the POC-investor physicians take their procedures to another hospital.

²⁶American Medical Association Council on Ethical and Judicial Affairs, Opinion E-8.063, *Sale of Health-Related Products from Physicians’ Offices*.

²⁷A repeat surgery that redoes a previously performed initial spinal fusion because the previous fusion failed in some way.

²⁸See [Attachment 4](#).

²⁹In discussing the buying power forces in the orthopedic industry, an analyst report characterizes orthopedic-market purchasing as a market where “healthcare facilities [are] buyers, assuming that their buying choices experience strong pull-through from the clinicians who use these products.” DataMonitor, *Orthopedics in the United States*, Industry Profile at 12 (July 2007).

4. POCs Are Anti-Competitive

Because of the physician's ability to control implant purchasing by the hospital in favor of his or her POC, POCs distort competition in the implant and implant procedure market. Hospitals must acquire the implants their referring physicians require or the physicians will perform their procedures at other hospitals that do; thus, POCs control both the supply and the demand for their products. In contrast, legitimate device manufacturers do not also have the advantage of controlling the demand for their products. Rather, they must compete against each other based on the cost and quality of their implantable products, their responsiveness to customer orders and service needs, the strength of their warranties, and the like. Similarly, competitors to hospitals that have agreed to deal with a POC are at an impossible disadvantage; unless they offer the referring doctor the same economic benefit as the POC, superior service, location, and facilities will not be able to attract the doctor's procedures. Not only is it unfair to these legitimate competitors for POCs to have this advantage, the competitive unfairness is likely to lead to all the evils traditionally associated with monopolies: higher costs, poorer product quality, and less innovation.

5. POCs Can Lead to Substandard Patient Care

Finally, though perhaps most importantly, POCs present risks to patient care. We have already noted that the conflict of interest that inheres in POCs is likely to have a profound effect on procedure venue, physician product choice, and implant utilization. Such incentives cannot be good for patients.

6. Summary

In sum, POC investment poses a myriad of risks to both patients and to the Massachusetts and other government-sponsored health care programs. Since Massachusetts is a benchmark state in medical innovation and treatment, the continued proliferation of POCs could have a disproportionate impact on medical costs and patient care. DPH's adoption of QuIC's regulatory proposals would temper the proliferation of these arrangements in addition to bolstering quality of care and improving device pricing in Massachusetts.

II. Clarification That Ownership by Physicians is an Economic Benefit that must be Disclosed

The Act requires, and the Proposed Rule recognizes, that any "fee, payment, subsidy or other economic benefit" from a medical device company to a health care practitioner "in connection with the company's sales and marketing activities" is subject to annual disclosure requirements. Plainly, a physician's ownership interest in a company that sells implants that the physician orders for his or her own patients is an "economic benefit" from the company, thus triggering the proposed § 970.009 reporting requirement. QuIC's proposed regulatory language clarifies this point.³⁰ Our proposed regulatory language also clarifies that publicly traded stock, and the stock of privately held companies that meet the same size requirements as the Federal "safe harbor" regulations for investment interests, would be exempt from the disclosure requirement. In the case of such companies, a physician's ordering practices cannot affect his or

³⁰Appendix A.

her return on investment, and so should not be viewed as “in connection with” sales or marketing activities. This approach is similar to the reporting exception found in the pending Federal Physician Payments Sunshine Act.³¹

III. Clarification that Ownership to Induce Referrals is Prohibited

While QuIC’s members are strongly supportive of the salutary effects of disclosure as a mechanism to address some of the evils of POC self-referral, we believe equally strongly that this method is not strong enough to fully protect patients and the larger health care system. POC advocates and physician-investors argue that disclosure to the patient regarding a physician’s financial interest in a device will allow the patient to make a more informed choice about the procedure and ultimately negate any influence underlying the physician’s own product choice. However, one can only imagine that any physician making a disclosure about a financial interest in a product would assure the patient that his or her financial interest was immaterial to the decision to perform the procedure or the choice of implant. Most patients will not be sufficiently skeptical of their own doctors to be able to make meaningful use of such information.³² Besides, the implant market is not one where consumer choice even operates in a very meaningful way. Procedural physicians tend to use the implantable products that they prefer and a patient’s only choice if he or she prefers a different product typically would be to change physicians. Unlike, for example, a disclosure by an ophthalmologist that the patient may buy eyeglasses from him/her or take the prescription elsewhere, physicians do not present their patients with a choice of implants, and even if they did, patients are not in a position to evaluate whether one is better than another.

Accordingly, in addition to clarifying the disclosure requirement of § 970.009, QuIC urges DPH to clarify that the financial relationship prohibitions set forth in Proposed § 970.008(1)(d) apply to ownership interests that are offered or received as an inducement to use the company’s products. Federal and Massachusetts law already incorporate this prohibition, but it is important that this regulation not provide the proponents of POCs with ammunition for an argument that the Final Rule creates a “safe harbor” for ownership by omitting a specific statement about ownership. We have proposed a minor modification to § 970.009(1)(d), which would clarify this point.³³

IV. Conclusion

By implementing these narrowly-tailored proposals, Massachusetts and DPH can go a long way toward putting a stop to the abuse of self-referral to POCs without disrupting the important role that physicians play in the development and improvement of implantable medical

³¹S. 2029, 110th Cong.

³²There is ample social science evidence that disclosure of financial conflict-of-interest is not a meaningful protection, and in fact has the perverse effect of lending credibility to the message of the discloser rather than breeding skepticism. *See, e.g.,* Diana and Lowenstein, “A Social Science Perspective on Gifts to Physicians from Industry,” 290 JAMA 252 (2003) (“Disclosure can only be effective if those informed can rationally update their beliefs – discount the advice they receive from physicians who disclose financial conflicts of interest – in light of the disclosure. However, most patients would have little idea about, for example, how much to discount their physician’s recommendation to participate in a clinical trial if they were informed that their physician would benefit financially from their participation.”).

³³*See Appendix A.*

Ms. LouAnn Stanton

January 13, 2009

Page 10

devices, or unfairly impacting legitimate physician ventures. We hope that DPH will take these steps to put a stop to this type of serious abuse.

Very Truly Yours,

Thomas N. Bulleit, Jr.

John A. Murphy, III

Appendix A

Quality Implant Coalition, Proposed Regulatory Language to Address Physician-Owned Companies

We propose adding a new definition to § 970.004 that would clarify the requirement of disclosure of ownership and other investment interests held by covered recipients in a pharmaceutical or medical device manufacturing company:

“Fee, payment, subsidy or other economic benefit” shall include any ownership, investment or equity interest, including any stock, stock option grant, limited liability interest, or other ownership interest (other than any ownership, investment, or equity interest in a publicly traded security or mutual fund, or in any company with stockholder equity exceeding \$75 million at the end of that company’s recent fiscal year) held by a covered recipient in a pharmaceutical or medical device manufacturing company during the preceding year, and any dividend, profit distribution, or other payment resulting therefrom.

We also propose amending § 970.008(1)(d) to clarify that ownership or other equity interests held by a covered recipient when offered or received as an inducement to use a company’s products are prohibited:

d. any other payment or remuneration, in cash or in kind, directly or indirectly, including any fee, payment, subsidy or other economic benefit, as defined in 105 CMR 970.004, offered or received as an improper inducement to use a company’s products or services, or to refer or arrange for referral of any person for services involving use of a company’s products or services, or any rebate or “kickback” that is prohibited under applicable federal or state “fraud and abuse” laws or regulations including the federal “Anti-Kickback Statute” (42 U.S.C. 1320a-7b) and equivalent Massachusetts laws such as M.G.L. c. 118E, s. 41 and M.G.L. c. 175H, s.3.