REPORT OF THE VIRGINIA
DEPARTMENT OF HEALTH PROFESSIONS

Report on Issues Related to the Use of Implantable Medical Devices Pursuant to Chapter 351 (2014)

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 15

COMMONWEALTH OF VIRGINIA
RICHMOND
2014

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Preface

Pursuant to Chapter 351 of the Virginia Acts of Assembly for the 2014 Session (HB1235/Senate Bill 536),* the Virginia Department of Health Professions solicited public comment on the issues related to the use of implantable medical devices distributed by distributors in which a physician has an ownership interest (PODs). The Board of Health Professions Regulatory Research Committee aided the Department through convening a public hearing on May 20, 2014 and receiving written comment until June 20, 2014.

This report provides a compilation of the public comment received during this period, including an overall summary, copies of the transcript, and the full written comments. The report also incorporates by reference the full Office of Inspector General (OIG) report: Levinson, D.R. (2013, October). Spinal devices supplied by physician-owned distributors: Overview of prevalence and use. OEI-01-11-00660. U.S. Dept. of Health and Human Services Office of Inspector General, Washington, D.C. Available at: https://oig.hhs.gov/oei/reports/oei-01-11-00660.asp.

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CHAPTER 351

An Act to require the Department of Health Professions to consider issues related to use of implantable medical devices distributed by physician-owned distributorships in the Commonwealth.

[H 1235]
Approved March 27, 2014

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Department of Health Professions shall consider any issues related to the use of implantable medical devices distributed by medical device distributors in which a physician has an ownership interest in the Commonwealth, including any existing federal or state laws or regulations and findings of the Office of the Inspector General of the U.S. Department of Health and Human Services, and actively involve and include any information provided by interested stakeholders, and shall report its findings and recommendations to the Governor and the General Assembly by November 1, 2014.*

Findings and Recommendations

In 2013, the U.S. Department of Health and Human Services Office of Inspector General (OIG) explored issues related to the use of implantable medical devices distributed by physician-owned distributors with results published in the two reports detailed as follows.

In March, the OIG issued a "Special Fraud Alert: Physician Owned Entities." The Alert references the "anti-kickback" provisions of Section 1128B(b) of the federal *Social Security Act* [1] which hold as criminal knowingly and willfully offering, paying, soliciting, or receiving any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. The Alert notes that the OIG is concerned about the proliferation of PODs, reiterates their position that the potential for illegal remuneration from PODs exists. What OIG deems as questionable kickback-related features of POD arrangements are listed in the document and relate generally to limiting selection of investors to those in a position to generate substantial business for the entity, barring investors who do not practice in the service area, and attaining returns on investment far exceeding the level of risk involved. OIG posits that corruption of medical judgment, overutilization, increased costs, and unfair competition may result.

No actual instances of questionable PODs were provided in the Alert. The Alert indicated that the OIG Advisory Opinion process remains available to PODs or actual or potential physician-owners with questions about the structure of a particular POD arrangement (see http://oig.hhs.gov/faqs.advisory-opinions-faq.asp for information about the process).

In October 2013, the OIG issued the report entitled, "Spinal Devices Supplied by Physician-Owned Distributors: Overview of Prevalence and Use" (OE1-01-11-00660), in response to congressional request to determine the extent of physician-owned distributorships (PODs) for spinal implantable medical devices. Critics of PODs had expressed concern that physicians who perform surgeries to implant such devices and who derive revenue from those devices are faced with a conflict of interest that may affect their clinical decision-making. PODs had indicated that their devices cost less than those provided by other types of companies. OIG selected a sample of 1,000 claims billed to Medicare in FY 2011 that included spinal fusion surgery and asked the associated hospitals to report on the implants used in the sample cases and on their knowledge of physician ownership of the spinal device suppliers.

In the Medicare billing sample, PODs supplied nearly one-fifth of the implanted devices and POD surgeries used fewer devices but did not have a lower per surgery device cost than the others. Approximately one-third of hospitals in the sample purchased implanted devices from PODs, and when those hospitals began buying from PODs, their spinal surgery rates increased faster than the rate for hospitals overall. Also, in FY2012, surgeons performed more spinal surgeries at the hospitals in the sample that purchased from PODS than those that did not. The OIG concluded that PODs constitute a "substantial presence in the spinal device market" and questioned the claim of lower costs from PODs due to the finding of no lower per surgery cost and concomitant increases in rates and volume of spinal surgeries at POD supplied hospitals. The report projected potential increased costs to Medicare for spinal surgeries over time. It also concluded that the ability of hospitals and patients to identify potential conflict of interest issues was hampered due to the fact that the sample hospitals varied in their requirements for disclosure of ownership interest. Recent Centers for Medicare and Medicaid Services (CMS) regulations promulgated under the *Physician Payment Sunshine Act* [2] require applicable manufacturer and group purchasing organizations to report annually to CMS about their financial relationships with physicians and hospitals. The 2013 OIG report indicates that group purchasing

[1] http://www.ssa.gov/OP_Home/ssact/title11/1128B.htm

[2] Ref. P. L. 111-148 §6002, Social Security Act, § 1128G and 42 CFR §403.900 *et seq.*

organizations include PODS but that CMS may determine on a case-by-case basis whether a particular POD arrangement falls under the rule.

Empirically validated data is not available as to the prevalence of medical implant device PODs in Virginia or the implications of PODs on utilization or cost in the Commonwealth. Public comment was solicited in response to HB 1235 and the aforementioned OIG report through a public hearing held of the Regulatory Research Committee of the Board of Health Professions on May 20, 2014. Additional written comment was accepted until June 30, 2014. The evidence presented was inconclusive and divided as follows:

- Commenters in support of restricting physician ownership cited the concerns expressed in the OIG report and the 2013 Fraud Alert relating to the inherent conflict of interest posed by PODs, their proliferation, and concomitant increases in implant surgeries. They hold that disclosure to patients is not sufficient to address the conflict of interest issue.

- Those in opposition to restrictions on PODs pointed to the American Association of Surgical Distributors Standards of Conduct, which includes disclosure of the surgeon's relationship with the distributor. They pointed to the anticompetitive effect of outright bans on PODs, including the potential restriction on innovations and increased prices when large companies maintain control over product sales.

- The Medical Society of Virginia (MSV) and Virginia Orthopaedic Society offered that outright prohibition of PODs would stifle innovation and could preclude the selection by the surgeon of the best device for the patient. MSV noted that existing *Code of Virginia* statutes could be amended to include PODs into the types of arrangements that must be disclosed:

    - §54.1-2914 (B) - prohibits a physician from selling articles to his own patients for his own convenience or to supplement income.
    - §54.1-2964 – requires physicians to disclose any material financial interest in a facility when referring patients for health related services, including devices.

Given the lack of definitive data relative to PODs in Virginia, the lack of evidence of harm, and the evenly divided public comment, the Department recommends no action at this time.

Summary of Public Comment

On behalf of the Department, the Board of Health Professions held a public hearing on May 20, 2014 to receive comment pursuant to HB1235/SB536 (2014). Additionally, written comment was solicited until June 20, 2014. The following provides a summary of the responses during the Public Hearing and subsequent written comments. The transcript of the Public Hearing and written comments in their entirety are available by contacting the Director's office.[1]

PUBLIC HEARING

John Steinmann, Orthopedic Surgeon – spoke in favor of physician ownership in medical device manufacturing and distribution, noted 23 years of practice, and expressed concern about what he considered to be the anticompetitive aspects of the restricting physician ownership including dampening of innovation.

Charles Edwards, Orthopedic Spine Surgeon – was in favor of physician ownership and noted that his company purchases FDA approved domestically manufactured spinal implants and sells them to the hospital at 40% below major manufacturer's price. He noted concern about reducing competition from small businesses if physician ownership were prohibited and the resulting advantages for a small number of larger companies.

Kathleen McDermott of Morgan, Lew & Bockius, LLP, Washington, D.C. – was against physician ownership. She stated that she has many years of experience in the private sector focusing on fraud and abuse issues and urges regulation or prohibition of physician ownership. She cited a need to emphasize ethical concerns over cost considerations. Full presentation, entitled "Physician-Owned Distributorships: History & OIG Concern, May 20, 2014," is included.

Senator Steve Martin, 11th Senate District – spoke against physician ownership. He referenced his 27 year service to the Commonwealth with a focus in healthcare and stated that physician owned distributorships (PODS) are a conflict of interest simply because they exist, causing harm to credibility and integrity. He commented that our laws are designed to prevent victims and that PODS practice should not be permitted in the Commonwealth of Virginia.

Thomas Tremble, VP, State Government Affairs, Advance Medical Technology Association – indicated that his organization is the national trade association of medical technology manufacturers and includes manufacturers of implantable orthopedic devices. He stated that PODS are "inherently suspect" as the HHS Office of Inspector General cited, are subject to conflict of interest because their success is based on referrals by their investors, and can threaten patient safety by performing a higher rate of surgeries and increase healthcare costs. He stated that he does not mean to question the integrity of the many Virginia physicians acting in the best interest of their patients but expressed concern that health care decisions are being made for economic reasons as opposed to what is in the best interest of the patient. Mr. Tremble urged consideration of the finding of the HHS office of Inspector General's Special Fraud Alert and its strong admonition that "PODs are inherently suspect under the anti-kickback statute" and concern about their proliferation.

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[1] Virginia Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 300 Henrico, Virginia 23233-1463,Phone (804) 367-4400, Fax: (804) 527-4475 or by e-mail to Laura.Rothrock@dhp.virginia.gov.

WRITTEN COMMENT

James Pickral, Alliance Surgical Distributors – noted concern over negative consequences of HB1235 had it passed in its original form. He further indicated that his client is part of the American Association of Surgical Distributors, a group that sets standards for surgeon distributors. Drs. John Steinmann and Charles Edwards Public Hearing written comments were attached to his correspondence and are summarized below.

John Steinman – Orthopedic Surgeon

- Seeks to protect surgeons' and companies' rights to bring innovation, competition, and cost savings to the U.S. healthcare system; Notes concern for U.S. citizens and businesses with relative high healthcare costs, and further speaks to difficulties companies face to remain in the U.S.
- Opines that cost-savings and innovations cannot depend upon existing, large business interests. States that price reduction occurs when demand decreases or competition is introduced; since demand will likely increase, competition is required.
- States surgeons, not general public, have the expertise to evaluate the costs and benefits of specific spinal fixation and joint replacement products available and PODS bring competition through bulk purchase negotiations for hospitals. References Alliance Surgical Distributors model and reports savings over 35%. Advocates for model expansion claiming it would save "tens of billions of dollars
- References the following two studies and the American Association of Surgeon Distributors' conduct standards, membership criteria and fact sheet outlining benefits of member PODS to hospitals and patients[2]:
    - Steinmann, J.C., Edwards, C., Eickmann, T. & Carlson, A. Surgeon ownership in medical device distribution: An analysis of cost saving.[3]
    - Steinmann, J.C., Edwards, C., Eickmann, T. & Carlson, A. Surgeon ownership in medical device distribution: Does this model influence utilization?
- Additionally references two white papers on the benefits of a new medical device company, Renovis Surgical Technologies, ("Renovis E-MAX ™ Highly Crosslinked Polyethylene: Technology Overview" and "Renovis Tesera Trabecular Technology ™).

Charles Edwards – Orthopedic Spine Surgeon

- Notes earning engineering undergraduate degree prior to medical school provided.
- States concerns related to healthcare financial crisis and cost of surgical implants.
- Provides personal example of request for bulk purchase implants from a generic manufacturer at substantial cost savings, but was declined by hospital which cited lack of expertise in implant selection and service.
- Reports establishing a POD for spine implants 5 years ago, with "full disclosure and respect for all federal and state regulations." Indicates purchase of only FDA approved and domestically manufactured implants and 40% discounted sale, estimates saving to hospital is over $2M/yr.
- References resulting lower prices and improved services with competition when monopolies and trusts were broken up last century. Reiterates concern about the original, proposed legislation as limiting competition and strengthen a few large surgical implant companies.

Kathleen McDermott—Partner, Morgan, Lewis & Bockius, L.L.P, Washington, D.C. (Counselors at Law)

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[2] Also available from the American Association of Surgeon Distributors website: http://aasdonline.org/.

[3] Also available from the Alliance Surgical Distributor website: http://www.alliancesurg.com/alliancesurg.com/Portals/0/Docs/SurgeonOwnershipinMedicalDeviceDistribution_%20final%20March%202013.pdf.

- References her white paper in strong opposition to PODs and Public Hearing slides
    - McDermott, K. Harper, J.J. (2013, March). Anti-fraud concerns for physician-owned distributors for medical device products: What's new is old. We won't be fooled again. Washington, D.C.[4]
    - "Physician-owned distributorships: History & OIG concern, May 20, 2014"
- The following list provides the outlined topics extensively explored in the 22 page white paper:
    - PODs as a "Pandora's Box"
    - PODS undermining physicians' role as gatekeeper to medical utilization
    - The Legal Question: PODS are Okay if Carefully Crafted…?
    - OIG Advisory Opinions on Anti-Kickback Compliance Do Not Support POD Models
    - Physician Self-Referral Prohibitions Apply to PODS? Yes, They Do
    - A Survey of Hospital Policies Show a Steady and Growing Concern Over PODS
    - PODS by the Numbers: What Does the Data Really Show Us?

  She concludes that physician-owned entities in the medical products arena are affected by conflict of interest and opines that the purpose of PODS is not to improve costs. Sites concern that public interest at risk is greater than the implant cost debate. Cites concerns for hospitals risk management issues and notes the need for clearer guidance from the OIG than in the 2013 report in light of new business model development under the Affordable Care Act.
- The slide presentation
    - Defines "POD" and notes conflict between proponents claiming lower costs and opponents claiming conflict of interest, lists hospitals (some in Virginia) "beginning to regulate or ban PODs."
    - Expresses concern over potential legal issues relating to conflict of interest, cites California's 2012 law prohibiting billing for medical devices in worker's cases if the physician has ownership interest in the device's manufactured or distribution.
    - Frames the impetus for the October 2013 Office of Inspector General (OIG) report[5] (i.e., growth of PODS, 2011 U.S. Senate Finance Committee report, and Special Fraud Alert published in May 2013[6]).
    - Describes OIG POD findings on device utilization for Medicaid-paid spinal surgery cases (20%) in 2011; During 2010-2012, PODS serviced half of hospitals. In 2011, 16% of sampled surgeries used PODS in Virginia.
    - Notes average cost reported by OIG was the same for POD and non-POD suppliers, but for spinal plate devices, the POD cost was $845 more per unit, on average. Also reports rate of spinal surgery in PODs supplied hospitals grew three times faster than the overall growth rate for spinal surgery.
    - Indicates OIG found hospital policy required disclosure from PODS physicians, but patients were not required to be informed.
    - Cites OIG concerns about findings of greater surgery rate, no lower cost, and inconsistent disclosure to patients
    - She closes with the observation that OIG's focus was on utilization and cost but not the potential patient harm from unnecessary or excessive surgery. She further indicates the OIG's study did not address compliance with existing anti-kickback statutes or legal and ethical concerns not addressed sufficiently through patient disclosure.

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[4] Also available on the AvaMed website: http://advamed.org/res.download/288.

[5] Reference: Levinson, D.R. (2013, October). Spinal devices supplied by physician-owned distributors: Overview of prevalence and use. OEI-01-11-00660. U.S. Dept. of Health and Human Services Office of Inspector General, Washington, D.C. Available at: https://oig.hhs.gov/oei/reports/oei-01-11-00660.asp.

[6] Reference: U.S. Dept. of Health and Human Services Office of Inspector General, "Special Fraud Alert: Physician-Owned Entities:" Available at: http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.

Thomas Tremble, Vice President, State Government Affairs – Advanced Medical Technology Association, Washington, DC

- Notes his association, also referred to as "AvaMed," represents 400 member medical technology manufacturing companies including those that manufacture medical implants.
- States the following:
  - "PODs are 'inherently suspect' as the HHS Office of Inspector General cited."
  - "PODs have an inherent conflict of interest because due to success based on referrals by their investors."
  - "HHS studies have shown that PODs can threaten patient safety by performing a higher rate of surgeries and increase health care costs."
  - "As the OIG has advised, it is not possible to create a good POD where the purpose of the investment is inducing or rewarding referrals."
- Describes collaborative device development as companies working with physicians or physicians creating a company to develop their ideas for new medical devices or obtaining royalties on their innovations. States he supports the physician innovators' ability to develop and bring their ideas to market and their ability to invest in innovative device manufacturing companies – without the self-referral aspect.
- Also cites benefits of small and start-up firms and large firms as incubators on innovation to save lives and reduce costs.
- Cites AdvaMed Code of Ethics on Interactions with Health Professionals' requirement to disclose relationships between companies and physicians. However, he holds that disclosure is not sufficient for physician relationships involving self-referral and references the aim of federal and state laws aiming to prevent or eliminate conflict of interest.
- Speaks to physician-investor business arrangements (i.e., physician-owned companies and physician-owned distributors) and their proliferation in recent years. Notes the arrangements are designed to leverage device purchasing into income generating opportunities for the physician-investor and that the PODs tend to sell devices to hospitals at which the physician-investor treats patients.
- Notes the March 2013 Special Fraud Alert referenced earlier and lists the OIG's points of concern:
  - Selecting investors because they are able to generate substantial business for the entity;
  - The size of investment offered to physicians varies with the expected or actual volume of POD devices used by the physician;
  - Physician-owners conditioning their referrals to hospitals on their purchase of the POD's devices through coercion or promises;
  - Requiring investors who stop practicing in the service area to divest ownership interest; and
  - Distributing extraordinary returns on investment compared to the level of risks involved.
  - PODs exhibiting these or other questionable features raise kickback concerns: corruption of medical judgment, overutilization, increased costs to federal health programs and beneficiaries, and unfair competition. Of special concern are arrangements involving implantable devices, because the surgeon often determines the brand of device the hospital purchases in deference to the "physician's preference."
  - The Alert holds that disclosure to a patient of the physician's financial interest in the POD is insufficient to address the above concerns, and cautions that the criteria delineated in the Alert are not intended to serve as a blueprint for how to structure a lawful POD because even if an entity does not exhibit any of the above issues, the arrangements may still not be lawful.
- Describes the October 2013 OIG report and highlights the points made in Ms. McDermott's slide presentation detailed previously.
- States no intention to question the integrity of the many Virginia physicians acting in the best interests of their patients but reiterates the Special Fraud Alert's position that "PODS are inherently suspect under the anti-kickback statute" and that they are concerned about their proliferation.

Sterling N. Ransone, Jr., M.D., F.A.A.F.P., President, Medical Society of Virginia (MSV)

- Reports that MSV represents over 11,000 physicians, resident and medical student members of all medical specialties across the Commonwealth.
- Opposes a ban on PODs in Virginia as unwarranted given its potential to stifle innovation and research that could positively advance patient care and a strict prohibition on PODs would discount a potential for the best device for the patient being one developed and provided via a POD.
- References existing Virginia statutes:
    - §54.1-2914 (B) - prohibits a physician from selling articles to his own patients for his own convenience or to supplement income.
    - §54.1-2964 – requires physicians to disclose any material financial interest in a facility when referring patients for health related services, including devices.
- Recommends extending existing statutes to include PODs into the types of arrangements that must be disclosed rather than banning PODs.
- Supports transparency in the health care delivery system and initiatives to promote patient safety and satisfaction. Holds that while complying with state and federal requirements and ethical guidelines and disclosing such relationships to patients, physicians should be free to pursue research and business arrangements to provide the best patient care.

Mark J. Romness, M.D., President, Virginia Orthopaedic Society (VOS)

- Reports VOS advocates for highest quality musculoskeletal care and physician and patient interests.
- Notes that since fall 2013, VOS has engaged in discussions with interested parties about PODS.
- States VOS expects members to adhere to all professional ethical guidelines and federal and state regulations and statute and would oppose financial arrangements where the physician's medical judgment would be compromised or financial incentives exist to promote utilization inconsistent with standards of care.
- States that:

    . . .there is little evidence that PODs exist or are prevalent in Virginia and no concrete information that orthopaedist medical judgment is being influenced or patient safety and quality care are at risk because of PODs
- Rejects the conclusion that physician ownership and provision of services or products ancillary to care is "inherently bad." Rather, views them as "promoting integrated and coordinated care, patient convenience and satisfaction, expedited delivery, and innovation."
- Holds that federal and state laws currently regulate "self-referral" to protect patients and the public health system dollars and that VOS supports such laws and specific exceptions that permit ancillary services as a vital component of the diagnostic and treatment regimens.
- States that VOS works with physician organizations, hospitals, academic medical centers, and industry to learn about PODs as a business model, determine their existence and prevalence in Virginia and measure the impact they may have on patient care and public healthcare dollars.
- Concludes VOS would be willing to strengthen or otherwise clarify existing self-referral laws to promote transparency and disclosure, but rejects POD ban or restriction of "legal arrangements that can contribute to innovation, market competition, and quality products and services for patients."

Jackson, Laura (DHP)

From: Carter, Elizabeth A. (DHP)
Sent: Monday, May 19, 2014 3:30 PM
To: Jackson, Laura (DHP)
Subject: Fw: BHP Regulatory Research Committee Hearing Tomorrow
Attachments: AASD Backgrounder.pdf; AASD Standards.pdf; Edwards VA Testimony_Final.docx; EMAX Development White Paper.pdf; HB 1235 Steinmann testimony-2[1]_Final.doc; SurgeonOwnershipinMedicalDeviceDistribution_ final March 2013[1].pdf; T3 Development White Paper.docx; Utilization Study Paper.pdf

Please see the attachments.

Thank you,

Liz

From: James Pickral [mailto:james@pickralconsulting.com]
Sent: Monday, May 19, 2014 03:21 PM Eastern Standard Time
To: Carter, Elizabeth A. (DHP)
Subject: BHP Regulatory Research Committee Hearing Tomorrow

Dr. Carter,

I hope all is well with you. I am representing Alliance Surgical Distributors and have some materials we would like to offer to help educate the committee on the negative impacts that would have resulted from the passage of HB 1235 in its original form. My client is part of the American Association of Surgeon Distributors which is a group that sets standards for surgeon distributors. We will have two physicians testifying before the committee tomorrow. I have attached their testimony and some background materials we hope you will find useful. Please let me know if you have any questions.

James A Pickral Jr.
Principal

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Honorable Members of the Board of Health Professions' Regulatory Research Committee:

Good morning and thank you for the opportunity to speak before the committee and to provide you my experience as it relates to HB 1235. My name is John Steinmann. I am an orthopedic surgeon, in practice for 23 years, and stand before you today representing surgeons and companies that desire to protect their right to bring much-needed innovation, competition and cost savings to the U.S. healthcare system.

We have a problem facing American citizens and American businesses – where individuals and businesses are forced to pay twice as much for healthcare in this country than the next most expensive country. Every year, this leads to thousands of medical bankruptcies, loss of jobs, and businesses that leave our country. Those businesses that stay here find it increasingly difficult to complete globally.

We MUST address this problem and yet we also MUST realize that we cannot depend on the existing, large business interests responsible for these costs to drive necessary, cost-savings innovation. The best evidence and example of this is the primary force behind the very issue we are addressing today is an incumbent device company intent on suppressing any innovation or competition that might serve to reduce healthcare costs.

Companies only reduce pricing when there is a decrease in demand or the introduction of competition. Since there is no anticipated reduction in demand, we must look to and support competitive forces that create cost savings.

The issue under consideration by this committee relates to physician ownership in medical device manufacturing and/or distribution. It is my desire, in the next few minutes, to share insight as to why we must retain the ability for physicians to develop and implement innovative methods to improve the value of the medical devices we utilize in this country.

Did you know that a total hip replacement device manufactured by any of the large U.S. device companies sells for more than $6,000 here in the U.S. and for $3,000 in Europe? We don't pay twice as much for the same blue jeans or Chevrolet's than they do in Europe; so why should we accept to pay double for medical device(s)?

In the area of medical devices, there is vast commoditization of products whereby many spinal fixation devices and joint replacement products share the very same features with no clear benefit of one over another. The American public needs purchasing decisions, therefore, to be made based on value - and the surgeon is in the best possible position to do this.

I am personally involved with three entities that have fostered a spirit of innovation in establishing models that bring sensible, competitive forces to bear on the medical device industry. These entities are directly responsible for tens of millions of dollars in annual healthcare savings for the communities they serve. And, there exists the potential for ***tens of billions in savings*** if these types of models were expanded nationally.

Surgeons are the most qualified individuals to assess technologies and features, and to help bring effective competition to the medical device industry. In the properly constructed physician-owned distribution company, the surgeon group carefully evaluates a number of competitive products that meet their design criteria and negotiate bulk purchases for the implants they have historically required for the treatment of their patients.

Alliance Surgical Distributors has developed a model that allows surgeons to pool their collective purchasing power, derive a collective consensus on the most valuable product choice, and to negotiate with medical device companies for the purchase of large quantities of the medical devices they will use throughout the year. The features of competitive bidding and bulk purchasing combine to result in savings that exceed 35%. You have before you two studies that demonstrate this cost savings.

This model requires surgeons to invest considerable amounts of capital in inventory and to hire and manage service representatives. Can physicians make a profit with this model? Yes, as should be the case for taking risks providing expertise and oversight that results in a better solution to the market that benefits everyone.

The incumbent device company responsible the amendment before you will try and argue that physicians cannot be trusted to manage the conflict of interest that results from participation in the purchasing and selling of products that they choose to use in surgery. They will profile a few clearly "bad apples" that have a long history of unethical behavior and will then ask you to conclude that it is their participation in a medical device distributorship made these individuals act improperly. While we fully understand that there is an abuse potential and that strict standards (such as those developed by the American Association of Surgical Distributors) are necessary to prevent abuse, we have shown that this conflict is easily managed through transparency that ensure proper intent and cost savings. Surgeon ownership in ambulatory surgery centers is a well-established model that has brought the American public considerable improvements in patient satisfaction and outcomes at a 40% savings over hospital-based outpatient surgery centers. This model is supported by a sensible set of standards that ensure conduct always remains in patient's and society's best interest.

Physician ownership in medical device distribution or manufacturing offers the same remarkable benefits for patients and society as surgeon-ownership in ambulatory surgery centers, yet must be conducted under a set of standards that promotes

transparency and cost savings.

The American Association of Surgeon Distributors (AASD) has published a set of 12 standards governing proper conduct when surgeons are in a position of ownership in medical distribution companies. You have been provided background information on this Association as well as the Standards and Policies that define membership. I would ask that instead of supporting the anticompetitive tactics of the incumbent device industry, that you instead support the strict standards developed by the AASD and the much-needed competition and cost savings resulting from surgeon ownership in medical device distribution.

Renovis Surgical Technologies represents the story of an up and coming medical device company that is developing industry-leading technologies while simultaneously developing delivery models that allow the American public to obtain the benefits of these products and technologies at considerably lower pricing.

Renovis has both surgeon and non-surgeon ownership and is therefore targeted by the anticompetitive nature of the amendment before you. You have been provided two white papers that identify two very important technologies developed by this fine company. The first represents the innovative use of additive manufacturing to produce a surface coating (Tesera) that appears to be ideal in every measurable respect – taking this technology an evolutionary step forward. The second paper you have been provided profiles the development of possibly the industry's best bearing surface for total joint replacement. This product (E-MAX) was developed in conjunction with the renowned polymer scientists at Harvard's Massachusetts General Hospital and provides a combination of strength and wear resistance not previously made possible.

Surgeons have a long history of developing most of the important advances we have seen in medical devices. It cannot be in society or patients' best interest to restrict their innovative potential.

In conclusion, I have taken two days out of my practice and traveled across the country to stand before you because I am concerned by the anticompetitive behavior behind HB 1235.

You can see that there has been a great deal of honorable work performed by many outstanding individuals representing outstanding companies that have demonstrated a dedication to bringing change that is vital to our national healthcare system. We cannot allow the interests of those profiting from this overly expensive system to suppress the innovation and competition that our system so badly needs.

I hope to offer you a resource today and in the future as you address the issues surrounding physician ownership in medical device manufacturing and distribution.

Thank you for your consideration and for weighing the case for innovation, cost savings and value.

My Best,

John Steinmann, DO

Honorable Members of the Board of Health Professions' Regulatory Research Committee,

Good morning and thank you for the opportunity to speak before the committee and provide my experience as it relates to HB 1235. My name is Charles Edwards. I am an orthopedic spine surgeon, and a business owner.

Prior to entering medical school, I did my undergraduate studies at Washington and Lee University, in Lexington Virginia, where I received graduation Honors in Engineering. It was my background in engineering, which has helped me to identify problems and develop solutions. That's what engineers do.

In my early years in clinical practice as an orthopedic spine surgeon, I recognized a striking problem. The problem was a healthcare financial crisis on one hand and the ridiculously high price of surgical implants on the other.

In 2006, I spoke to a colleague spine surgeon from Argentina who used the same spine implants from the same American manufacturer as me, but at 25% of the cost. I could not believe it. The problem was thus not the cost of manufacturing, but the cost of overhead and distribution.

So, the challenge to me became how to fix the problem. I first approached my hospital and asked them to bulk purchase implants from a generic manufacturer at tremendous cost savings. After several meetings, the Hospital declined my suggestion under the rationale that their expertise was in patient care and not implant selection and service.

With an engineer's perspective, I knew that there must be a solution to the problem. Since the major manufacturers would not lower their prices and my hospital did not want to enter the implant distribution marketplace, it made sense for me to do so.

With full disclosure to all parties and great care to respect all state and Federal regulations, I established a distribution company for spine implants 5-years ago. The company purchases FDA approved spinal implants from a

respected domestic manufacturer. The distribution company manages inventory and has a trained representative. The implants are sold to the hospital at 40% of the discount price of implants sold by the major manufacturers. Our distribution company is the lowest cost provider of spinal implants to our hospital, providing an annual cost savings of over 2 million dollars per. With that cost savings, my hospital can hire more nurses, provide more charitable care or invest in research.

100 years ago, Presidents Theodore Roosevelt and Taft recognized that trusts and oligopolies were harmful to the consumer and our economic system. Bucking the lobby of powerful landed interests, they broke up the anti-competitive trusts of oil, banking, steel and the railroads. Increased competition, lower prices and improved service were the result.

Here we are in 2014 witnessing the efforts of Big Medical interests to turn back the clock. If the proposed legislation were to have been succesful, it would limit competition and strengthen the power of a few large surgical implant companies or trusts. The legislation would have hurt small-business, reduced competition from the marketplace, and resulted in higher prices. The healthcare crisis will be magnified and all will be hurt, except for a few. The only ones that would benefit from HB 1235 are a handful of large public companies.

I hope that my testimony and my personal example has shown you how physicians are a very important part of the solution to our healthcare crisis. Removing them from participation in the marketplace is not only unwise, but runs counter to the proven effectiveness of small business as the creative engine to solutions and progress in America.

I would be pleased to answer any questions or provide any additional information that you would deem helpful.
Thank you.

AMERICAN ASSOCIATION OF SURGEON DISTRIBUTORS
Setting standards, protecting patients.

ETHICAL PHYSICIAN OWNED DISTRIBUTORSHIP

Standards and Criteria for Membership:

1. Distributorship maintains a business structure consistent with Federal Self-Referral and Anti-Kickback statutes, and reports in compliance with the Physician Payment Sunshine Act.
2. Distributorship demonstrates merit by proving to be the lowest average cost vendor of like implants during a comparable contract period.
3. Distributorship annual price increases to customers do not exceed 3% above the consumer price index (CPI).
4. Distributorship is a legitimate, free-standing stocking Distribution Company with employees, contracts, an address, a business license, and insurance.
5. Distributorship demonstrates adherence to the AASD Product Evaluation Policy.*
6. Distributorship demonstrates adherence to the AASD Employee Training Policy.*
7. Distributorship demonstrates adherence to the AASD Disclosure Policy.*
8. Distributorship demonstrates adherence to the AASD Investment and Distribution Policy.*
9. Distributorship submits utilization data annually and demonstrates adherence to the AASD Appropriate Use Monitoring Policy.*
10. Distributorship has written contracts with hospitals, with pricing that is consistent among hospitals, and contract periods of at least one year.
11. Distributorship does not leverage referrals to any hospital or surgery center.
12. Distributorship does not require, pressure, or otherwise leverage physician owners' use of the Distributorship devices.

* Expanded definitions below

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Product Evaluation Policy

The product evaluation policy ensures that surgeon owned distributors have a formal program in place to review and qualify Vendors, and to review and analyze the quality and value of implants prior to supplying those implants to customers.

Vendor Qualification

The distributorship shall review and qualify each Vendor prior to purchasing any products from that Vendor. Vendor qualification shall specifically include, but not be limited to, the following:

1. Evidence of valid, current product liability and completed operations insurance with minimum limits of $1,000,000 per occurrence, $2,000,000 aggregate
2. Evidence of valid FDA entity registration and FDA compliant quality systems
3. Review of FDA database information including product recalls, notices, warning letters, or any other relevant product or company information

Product Selection and Assessment

All products shall be subject to the following procedures prior to being approved for purchase and sale. Product acceptance shall require:

1. Product design features that are established by the surgeons
2. Evidence of FDA approval or 510k clearance by means of official documents
3. Comparison summary of comparable implants to include design attributes, functionality, performance, and mechanical testing if published
4. References of other surgeons currently using the products, if appropriate

Employee Training Policy

It is crucial to the operations of a well-run surgeon owned distributorship that the product representative is well trained and has an educated understanding of surgical procedure, including sterile technique and corporate compliance. The product representative is an important asset to a compliant distributorship and proper training is vital. The distributorship must provide written evidence of the Representative's:

1. Training in sterile technique
2. Training in the sterilization procedures required for each set
3. Product competency from each product vendor
4. Company compliance training
5. HIPPA compliance training
6. AdvaMed Code of Ethics and Compliance training
7. Acknowledgement and acceptance of Distributorship policies and procedures

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Disclosure Policy

The AASD disclosure policy applies to Distributor physician owners and serves to maintain integrity and full transparency with patients and colleagues. Distributorship must ensure:

1. In-office patients receive a written disclosure
2. Ownership disclosure is displayed in a visible area within the office
3. All contracted hospitals are informed that the Distributorship has surgeon ownership
4. Colleagues are informed that the Distributorship has surgeon ownership

Investment and Distribution Policy

Distributorship corporate and operating documents must evidence the following:

1. Ownership is determined by each surgeon's investment interest
2. Ownership after start-up is set and does not vary with volume of potential referrals
3. Any profits are distributed proportionate to ownership interests
4. Distributorship does not require mandatory termination of a physician owner's interest for a physician's failure or inability to use Distributorship devices.

Appropriate Use Monitoring Policy

To ensure that the operation of an AASD certified distributorship does not result any inappropriate increases in the utilization of implanted medical devices, the American Association of Surgeon Distributors has established the Appropriate Use Monitoring Policy and Program.

Appropriate Use Monitoring Program

The decision for surgery is governed sufficiently by published guidelines, peer review, utilization review, and community medical standards. Thus, the physician's recommendation for surgery and implant choice is guided by these factors, not by any perceived inducement. AASD and its ePOD certified distributorships are committed to the premise that instrumentation should only be used by qualified surgeons when medically indicated. This program is designed to monitor the medical appropriateness of implant cases when a physician member's utilization practice profile for instrumentation increases disproportionately compared to other clinical practice indicators. It is critical to note that the data measured is generated by the physician's clinical practice and includes all procedures without regard to whether that procedure included an implant from AASD applicant distributorship or another implant company.

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As part of the initial certification and annual renewal, each applicant distributorship shall submit practice profile data elements for each Physician Member. Required practice profile data elements are based on commonly accepted procedure codes (CPT) that will be aggregated into a baseline practice profile for that surgeon. Annually, the previous year's data elements shall be aggregated and compared with the baseline profile and prior year. A net change greater than 15% from the prior year that is not proportionate to non-implant related practice predictors (e.g. total patient visits) shall initiate a series of audits that will either, 1) validate the profile change and reset the surgeon's baseline, 2) initiate a medical chart audit by an independent auditor or 3) result in denial of the distributorship's initial application or the revocation of the distributorship's AASD certification.

Practice Profile Date Elements

- Years in Practice and Specialty
- Years at current primary office practice location
- Total patient visits in previous 12 months
- Total surgical procedure by type in previous 12 months

Independent Auditor

An independent auditor shall be required to perform all probationary and suspension reviews. An auditor must meet the following qualifications:

- For spine implant review: Board certified by the American Board of Neurosurgery, the American Board of Orthopedics with Spine Fellowship training, or the American Osteopathic Board of Orthopedic Surgery with Spine Fellowship training
- For non-spine implant review: Board certified by the American Board of Orthopedics or the American Osteopathic Board of Orthopedic Surgery
- Minimum of 7 years in surgical practice within the appropriate specialty
- In active practice and in good standing with appropriate medical licensing boards
- Must not perform surgical cases at any of the hospitals of the surgeon that is the subject of review

All audit cases shall be de-identified (patient and surgeon) prior to review.

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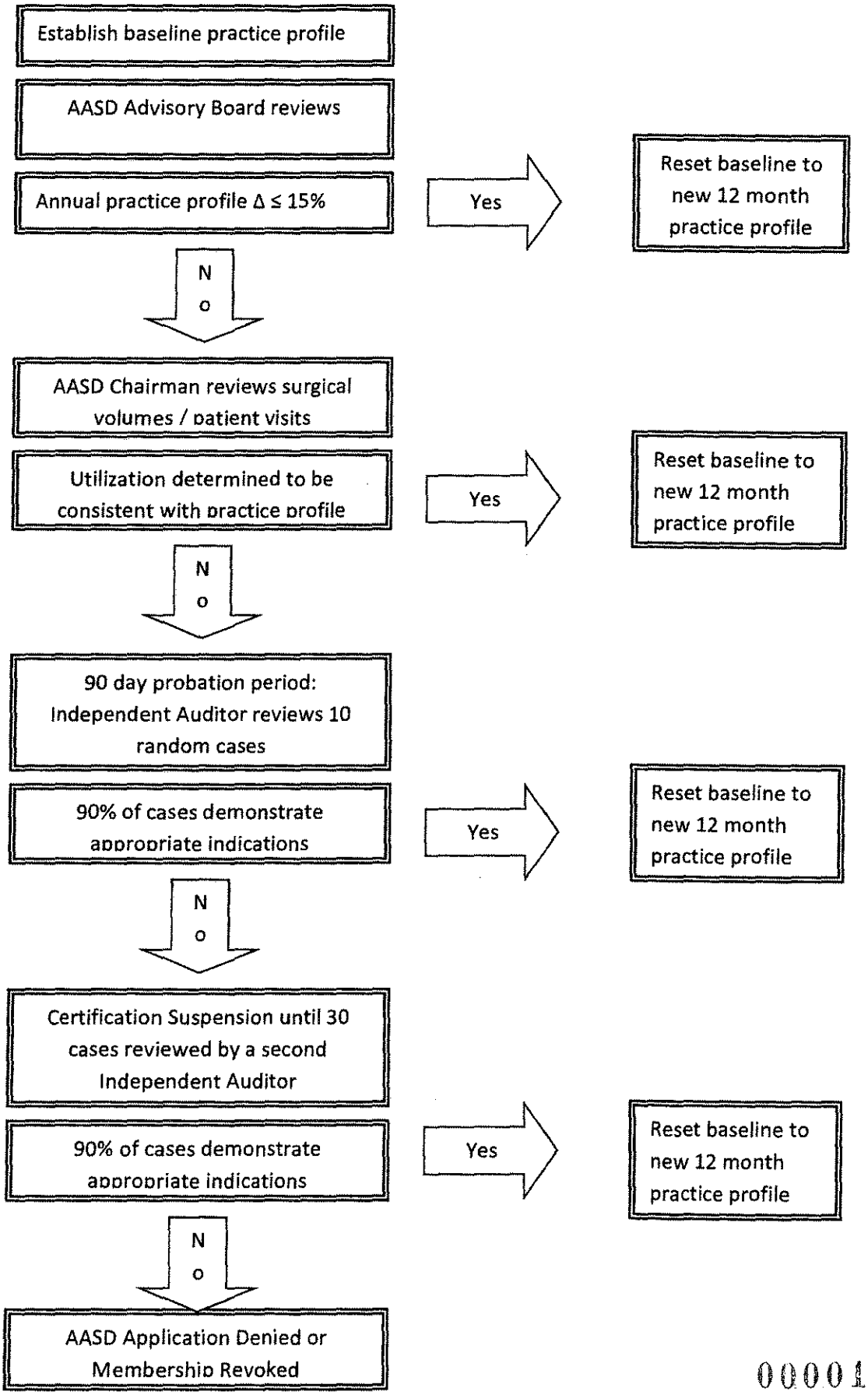
Algorithm for Monitoring Utilization Patterns of Physician Member



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Renovis E-MAX™ Highly Crosslinked Polyethylene

Technology Overview

Abstract: *Renovis E-MAX Highly Crosslinked Polyethylene was developed to build on lessons learned from the first-generation of highly crosslinked polyethylenes (XLPE). The reduction in mechanical properties caused by melt-annealing is well-known. Renovis E-MAX is annealed using an alternative mechanical compression process. This mechanical annealing eliminates free radicals while maintaining the mechanical properties of the polyethylene. Furthermore, recent retrieval studies of melt-annealed liners have revealed unexpected signs of in vivo oxidation. Renovis E-MAX contains 0.1%-weight vitamin E, which acts to scavenge free radicals, thus hindering the polyethylene oxidation cascade in vivo.*

Laboratory tests have verified the superior oxidative stability, increased tensile strength and improved toughness and fatigue properties of this vitamin E-blended, mechanically-annealed XLPE. Furthermore, wear testing has demonstrated very low wear rates—comparable to the most highly crosslinked first-generation XLPEs. Thus, Renovis E-MAX represents a step forward in the evolution of polyethylene, providing wear resistance, oxidative stability, and maintenance of mechanical properties.

Background: Successes and Setbacks with XLPE

Since its introduction in the 1960's, ultra-high molecular weight polyethylene (PE) has undergone a series of incremental improvements. Lessons learned from the successes and setbacks at each evolutionary step have been incorporated, ultimately improving implant survivorship and clinical outcomes. More recently, thermally-treated, highly crosslinked polyethylene (XLPE) has been adopted as the widely-accepted gold standard, accounting for 75% of hip liners implanted by 2007.[1]

XLPE materials were developed to address the two major factors known to affect PE longevity *in vivo*: [2]

- Wear, which leads to particle-induced osteolysis
- Oxidation, which leads to embrittlement and increased wear

While the XLPE process varies among manufacturers, generally it includes: radiation crosslinking for wear resistance and thermal annealing to address oxidation. Annealing below melt temperature results in partial elimination of free radicals, while melt-annealing results in a free radical concentration below or near the detection limits of measurement equipment.[3]

Laboratory and clinical studies have verified that XLPE results in improved wear when compared to conventional* PE. For instance, mid-term radiographic and retrieval studies of hip liners have demonstrated wear rate reduction in the range of 50% to 90%.[4-12] Knee simulator studies have also demonstrated significant reduction in wear and surface damage using XLPE.[13] Furthermore, in a retrospective comparison of 100 XLPE versus 100 conventional knees, Hoderick, et al. found evidence of fewer radiolucencies and revisions for the XLPE group.[26]

However, this increased wear resistance comes at the detriment to mechanical properties. The crosslinking process decreases plasticity, which has been shown to reduce fatigue and fracture resistance.[14] In addition, melt annealing decreases crystallinity, which further reduces the fatigue strength and also decreases yield and ultimate tensile strength. Annealing above the melt temperature reduces fatigue strength by about 20%.[15] These trade-offs are summarized in Table 1.

Process Step	Benefit	Drawback
Crosslinking (↓Plasticity)	↑ Wear resistance	↓Fatigue and fracture resistance
Melt Anneal (↓Crystallinity)	↑ Oxidation resistance	↓Fatigue and tensile strength

Table 1: First-Generation XLPE Trade-Offs[14,15]

Over the past several years, reports of surface damage and catastrophic failure in XLPE hip liners have been published. Adverse biomechanical loading scenarios (e.g. vertically malpositioned cups) have been noted in several of the published cases of early rim fracture, which have included melt-annealed liners from various manufacturers.[16-19] Other retrieval studies of melt-annealed liners have found:

- Pitting, which is typically associated with fatigue damage[20]

**The term "conventional" refers to the control in published studies: gamma-sterilized-in-air and, more recently, oxygenless-packaged PE.*

- Initiated—but usually non-catastrophic—cracks at rim notches[21,22]
- Surface wear characteristics similar to conventional PE.[22]

Recent retrieval studies of melt-annealed liners have also revealed unexpected findings regarding oxidation. As mentioned previously, these materials had no detectable free radicals and no measureable oxidation in artificial aging studies.[23] However, studies of melt-annealed retrievals have found:

- Measurable oxidation potential[24]
- Increasing oxidation with longer implantation time[25]
- Evidence that free radicals are introduced *in vivo*[3]

While the mechanisms of this *in vivo* oxidation are not fully understood, some researchers propose that the free radicals are introduced when lipids are absorbed into the polyethylene, triggering the oxidation cascade.[3]

Renovis E-MAX Design Rationale

Renovis E-MAX was developed with the goal of fulfilling three primary design requirements: wear resistance, oxidative stability, and maintenance of mechanical properties. Based on the lessons learned from first-generation XLPEs, specific objectives in each of the design requirement areas are as follows.

- **Wear Resistance: Achieve wear rates comparable to the most highly crosslinked polyethylenes.** The optimal radiation dose for improving wear resistance is about 10 Mrad, above which no further beneficial effects are observed.[2] A lower degree of crosslinking is preferred when designing for the knee for the reasons described under Mechanical Properties below.[14]
- **Oxidative Stability: Address *in vivo* oxidation.** Oxidation has been observed even in melt-annealed XLPEs, implying that reducing free radicals to below or near measurable levels does not completely eliminate *in vivo* oxidation.[3,24,25]
- **Mechanical Properties: Ensure suitable mechanical properties for the given application.** Radiation crosslinking affects mechanical properties, and melt-annealing further degrades strength and fatigue properties by about 20%.[15] Thus, an alternative to melt-annealing is preferred. Also, compared to the highly congruent hip articulation, the knee has more cyclic loading and higher contact stresses, making fatigue strength especially important for this application.[14,26]

Renovis E-MAX Process

Renovis E-MAX is vitamin E-blended (E), mechanically-annealed (MA), crosslinked (X) polyethylene. The Renovis E-MAX technology was developed by polymer scientists at Massachusetts General Hospital (MGH) and Cambridge Polymer Group (CPG). Renovis engineers fine-tuned the process to meet the retirements of Renovis hip and knee inserts. (Table 2 on following page)

Benefits of Renovis E-MAX

Wear Resistance

The radiation doses for Renovis E-MAX hip and knee liners were fine-tuned to achieve crosslinking densities comparable to first-generation XLPE's, which have demonstrated reduced wear rates both in simulators and in clinical use. Simulator studies comparing Renovis E-MAX to conventional polyethylene found:

- 89% reduction in hip wear[36]
- 74% reduction in knee wear[37]

Oxidative Stability

To address the unexpected *in vivo* oxidation observed in melt-annealed XLPE, Renovis E-MAX contains 0.1%-wt vitamin E. Vitamin E is a natural antioxidant that has a stabilizing effect against the oxidation of PE.[29] It acts by scavenging free radicals and hindering the oxidation cascade that leads to PE degradation *in vivo*.[30] Adding vitamin E via the diffusion method (as with Biomet E1™†) typically results in a non-homogeneous, gradient distribution.[31] However, in Renovis E-MAX, the vitamin E powder is blended with 1020 UHMWPE resin powder, so the vitamin E is distributed evenly throughout the material.[32,38]

Also, rather than thermally annealing after radiation crosslinking, Renovis E-MAX is mechanically annealed, which eliminates free radicals to levels near the detection threshold of measurement equipment.[33] The combined benefits of mechanical annealing and vitamin E were demonstrated in an aggressive artificial aging study by Wannomae, et al.[28] After squalene doping and aging, melt-annealed XLPE showed high oxidation, despite initially having no detectable free radicals. In contrast, the mechanically-annealed, vitamin E-containing material was protected from oxidation, even under such adverse aging conditions.

Mechanical Properties

With Renovis E-MAX, an undetectable level of free radicals is achieved without the trade-off in mechanical properties associated with melt-annealed XLPEs. Mechanical annealing preserves crystallinity, while thermal annealing, especially above melt, decreases crystallinity.[34] As mentioned previously, this reduced crystallinity leads to reduced mechanical and fatigue properties. Bhattacharyya, et al. found that mechanically-annealed XLPE had mechanical properties comparable to conventional PE and fatigue and toughness properties better than melt-annealed XLPE.[33] Similarly, Wannomae, et al. found that mechanically-annealed, vitamin E-containing XLPE had a higher yield and ultimate tensile strength compared to melt-annealed XLPE.[28]

†E1 is a trademark of Biomet, Inc., Warsaw, Indiana.

1 Raw material	1020 UHMWPE resin is blended with 0.1% (by weight) vitamin E powder.
2 Form bars	Raw material is compression-molded into sheets and machined into bars.
3 Radiation crosslinking	Gamma radiation is applied, creating crosslinks and some residual free radicals. The vitamin E scavenges some of the free radicals that would otherwise form crosslinks, consequently reducing the crosslinking efficiency of any particular radiation dose.[27] Thus, engineers optimized the radiation dose for Renovis E-MAX, ensuring that the crosslink density for hip liners is comparable to 10 Mrad XLPE. For tibial liners, where more fatigue strength is required, the radiation dose was optimized to achieve a crosslinking density comparable to 7 Mrad XLPE.
4 Mechanically anneal	The bars are warmed and then compressed, allowing the residual free radicals to become mobile and combine into additional crosslinks—removing free radicals.[33]
5 Machine, package, and sterilize	Components are machined, packaged and EtO-sterilized, thus avoiding a change in material properties or the reintroduction of free radicals associated with gamma sterilization.

Table 2: Renovis E-MAX Highly Crosslinked Polyethylene Process

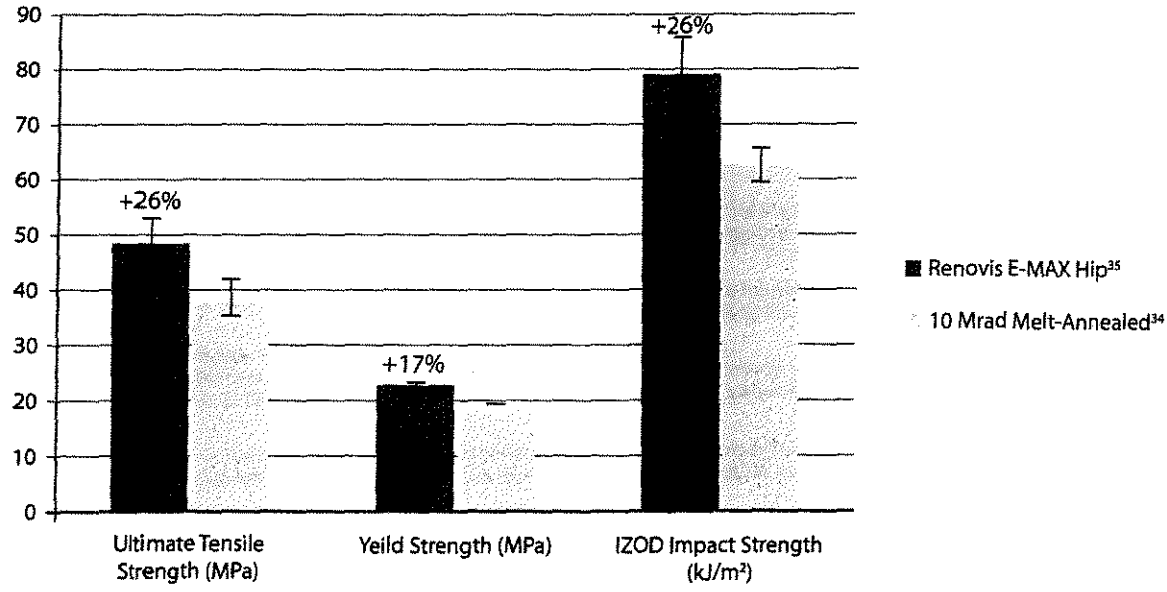
These results have been replicated in material characterization testing of Renovis E-MAX. (Figure 1) Tensile test results for Renovis E-MAX showed significant improvement in comparison to melt-annealed XLPE.[35] Impact testing also demonstrated a significant increase in toughness.35 Fatigue crack propagation analysis comparing Renovis E-MAX to 10 Mrad melt-annealed XLPE demonstrated:

- Renovis E-MAX had a significantly higher stress intensity factor for crack initiation, meaning that it is more resistant to crack initiation that the melt-annealed XLPE.[38]
- Renovis E-MAX had an overall decreased crack propagation rate compared to melt-annealed XLPE.[38]

Conclusion

To address in vivo oxidation, Renovis E-MAX contains vitamin E, which is an excellent free radical scavenger that acts by hindering the PE oxidation cascade. To address diminished mechanical properties, Renovis E-MAX is mechanically annealed; this process removes free radicals without the sacrifice of mechanical properties associated with melt-annealing. Laboratory tests have verified the superior oxidative stability, increased strength, and improved toughness properties. Thus, Renovis E-MAX Highly Crosslinked Polyethylene represents a step forward in the evolution of polyethylene, providing wear resistance, oxidative stability, and improved mechanical properties.

Figure 1: Tensile and IZOD Impact Test Results for Renovis E-MAX Hip Compared to 10 Mrad Melt-Annealed XLPE [Percent Improvement over Melt-Annealed]



References

1. Mendenhall S. Hospital resources and implant cost management—a 2008 update. Orthop Network News. 2009;20:15.
2. Muratoglu OK. Chapter 13 Highly Crosslinked and Melted UHMWPE. In UHMWPE Biomaterials Handbook Second Edition (ed. Kurtz SM). Elsevier: Amsterdam, 2009.
3. Muratoglu, O. K., Wannomae, K. K., Rowell, S. L., Micheli, B. R., Malchau, H. Ex Vivo Stability Loss of Irradiated and Melted Ultra-High Molecular Weight Polyethylene. JBJS 2010;92:2809-2816.
4. Kurtz S, Medel FJ, MacDonald D, Rimnac CM. In vivo oxidation, oxidation potential, and clinical performance of highly crosslinked UHMWPEs implanted for up to 8 years. 4th International Meeting UHMWPE for arthroplasty: From Powder to Debris 2009; Torino, Italy.
5. Digas G, Karrholm J, Thanner J, Herberts P. 5-year experience of highly cross-linked polyethylene in cemented and uncemented sockets: Two randomized studies using radiostereometric analysis. Acta Orthop 2007; 78(6): 746-54.
6. D'Antonio JA, Manley MT, Capello WN, et al. Five-year experience with Crossfire highly cross-linked polyethylene. Clin Orthop Relat Res 2005; 441: 143-50.
7. Engh CA, Stepniewski AS, Ginn SD, et al. A randomized prospective evaluation of outcomes after total hip Arthroplasty using cross-linked marathon and non-cross-linked Enduron polyethylene liners. J Arthroplasty 2006; 21(6): 17-25.
8. Olyslaegers C, Defoort K, Simon JP, Vandenberghe L. Wear in conventional and highly cross-linked polyethylene cups: a 5-year follow-up study. J Arthroplasty 2008; 23(4): 489-94.
9. Garcia-Rey E, Garcia-Cimbrelo E, Cruz-Pardos A, Ortega-Chamarro J. New polyethylenes in total hip replacement: a prospective, comparative clinical study of two types of liner. JBJS Br 2008; 90(2): 149-53.
10. Geerdink CH, Grimm B, Vencken W, Heyligers IC, Tonino AJ. Cross-linked compared with historical polyethylene in THA: An 8-year clinical study. Clin Orthop Relat Res 2009; 467(4): 979-84.
11. Glyn-Jones S, Isaac S, Hauptfleisch J, McLardy-Smith P, Murray DW, Gill HS. Does highly cross-linked polyethylene wear less than conventional polyethylene in total hip arthroplasty? A doubleblind, randomized, and controlled trial using roentgen stereophotogrammetric analysis. J Arthroplasty 2008; 23(3): 337-43.
12. Kurtz SM, Medel FJ, MacDonald DW, Parvizi J, Kraay MJ, Rimnac CM. Reasons for revision of first-generation highly cross-linked polyethylenes. J Arthroplasty. 2010 Sep;25(6 Suppl):67-74.
13. Kurtz SM. Chapter 8 The clinical performance of UHMWPE in knee replacements. In UHMWPE Biomaterials Handbook Second Edition (ed. Kurtz SM). Elsevier: Amsterdam, 2009.
14. Baker DA, Bellare A, Pruitt L. The effects of degree of crosslinking on the fatigue crack initiation and propagation resistance of orthopedic-grade polyethylene. Journal of Biomedical Materials Research 2003; 66A(1): 146-154.
15. Oral E, Malhi AS, Muratoglu OK. Mechanisms of decrease in fatigue crack propagation resistance in irradiated and melted UHMWPE. Biomaterials. 2006; 27(6):917-25.
16. Tower SS, Currier JH, Currier BH, Lyford KA, Van Citters DW, Mayor MB. Rim cracking of the cross-linked Longevity polyethylene acetabular liner after total hip arthroplasty. JBJS 2007; 89(10): 2212-2217.
17. Halley D, Glassman A, Crowninshield RD. Recurrent dislocation after revision total hip replacement with a large prosthetic femoral head. A case report. JBJS 2004; 86(4):827-830.
18. Moore KD, Beck PR, Petersen DW, Cuckler JM, Lemons JE, Eberhardt AW. Early failure of a cross-linked polyethylene acetabular liner. A case report. JBJS 2008; 90(11):2499.
19. Duffy GP, Wannomae KK, Rowell SL, Muratoglu OK. Fracture of a cross-linked polyethylene liner due to impingement. J Arthroplasty 2009; 24(1): 158.e15-158.e19.
20. Bradford L, Baker DA, Graham J, Chawan A, Ries MD, Pruitt LA. Wear and surface cracking in early retrieved highly cross-linked polyethylene . JBJS. 2004;86-A(6):1271-82.
21. Furmanski J, Kraay MJ, Rimnac CM. Crack Initiation in Retrieved Cross-Linked Highly Cross-Linked Ultrahigh-Molecular-Weight Polyethylene Acetabular Liners: An Investigation of 9 Cases. J Arthroplasty. 2010 Sep 20. [Epub ahead of print]
22. Schroder DT, Kelly NH, Wright TM, Parks ML. Retrieved highly cross-linked UHMWPE acetabular liners have similar wear damage as conventional UHMWPE. Clin Orthop Relat Res 2010; 469(2):387-94.
23. Muratoglu O, Bragdon, CR, O'Connor DO, Jasty M, Marris WH. A novel method of cross-linking ultra-high-molecular-weight polyethylene to improve wear, reduce oxidation, and retain mechanical properties. Recipient of the 1999 HAP Paul Award. J Arthroplasty 2001; 16:149-60.
24. Kurtz SM, MacDonald D, Brenner E, Medel FJ, Hozack W, Parvizi J, Goldberg V, Kraay M, Stulberg B, Rimnac CM. In vivo oxidation, oxidation potential, and clinical performance of first and second-generation highly crosslinked acetabular bearings for THA. Poster No. 1790 54th Annual Meeting of the ORS, 2008.
25. Currier BH, Van Citters D., Currier JH, Collier JP. In Vivo Oxidation in Remelted Highly Cross-Linked Retrievals. JBJS 2010; 92(14):2409-18.
26. Hodrick JT, Severson EP, McAlister DS, Dahl B, Hofmann AA. Highly crosslinked polyethylene is safe for use in total knee arthroplasty. Clin Orthop Relat Res 2008; 466:2806-12.
27. Kurtz S, Bracco P, Costa L. Chapter 16 Vitamin-E-blended UHMWPE biomaterials. In UHMWPE Biomaterials Handbook Second Edition (ed. Kurtz SM). Elsevier: Amsterdam, 2009.
28. Wannomae KK, Micheli BR, Lozynsky AJ, Muratoglu OK. A New Method of Stabilizing Irradiated UHMWPE Using Vitamin E and Mechanical Annealing. 11th Congress EFFORT. Madrid, Spain. June 2010.
29. Costa L, Bracco P. Chapter 21 Mechanisms of crosslinking, oxidative degradation, and stabilization of UHMWPE. In UHMWPE Biomaterials Handbook Second Edition (ed. Kurtz SM). Elsevier: Amsterdam, 2009.
30. Oral E, Godleski Beckos C, Malhi AS, Muratoglu OK. The effects of high dose irradiation on the cross-linking of vitamin E-blended ultrahigh molecular weight polyethylene. Biomaterials. 2008 ; 29(26):3557-60.
31. Gomez-Barrena E, Medel F, Puertolas JA. Polyethylene oxidation in total hip arthroplasty: evolution and new advances. The Open Orthopedics Journal 2009; 3:115-120.
32. Ticona GmbH. Introducing GUR UHMW-PE Vitamin E Filled Premium Grades for Orthopedic Implants [Brochure]. Kelsterback, Germany, 2009.
33. Bhattacharyya S, Matrisciano L, Spiegelberg S, Harris W, Muratoglu O. Mechanical elimination of residual free radicals in an irradiated UHMWPE rod: advantages over melting. 50th annual meeting of the orthopaedic research society. 2004:1474.
34. Bhattacharyya S, Spiegelberg SH, Harris WH, Muratoglu OK. Mechanical elimination of free radicals in UHMWPE after irradiation. 50th Annual Meeting of the ORS. San Francisco 2004.
35. Materials Characterization testing. Test report TP0322. On file with Renovis Surgical.
36. University of Nebraska Medical Center. Characterization of CIMA and E-CIMA UHMWPE as a bearing against CoCr femoral hip components: A hip simulation study. Test report dated July 15, 2011. On file with Renovis Surgical.
37. University of Nebraska Medical Center. An in-vitro wear durability study of the Renovis A200 CR Knee System: two sizes and two bearing materials. Test report dated November 11, 2011. On file with Renovis Surgical.
38. Cambridge Polymer Group. Analysis of CIMA and E-CIMA Material. Test report dated July 15, 2011. On file with Renovis Surgical.

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A Novel Orthopedic Implant Material

Contents

Guiding Principles

Designing for successful bone in-growth is a multifactorial problem that includes variables such as pore morphology and structural properties. Researchers have not reached consensus on the precise values required for some variables. However, clinical experience and animal studies have shown that bony fixation can be achieved reliably within certain ranges of values. Following are some guiding principles for bone in-growth, as established in the literature.

1. Surface Characteristics

These factors relate specifically to bone growth onto the porous structure's surface.

- **Composition (Material):** Titanium alloy has been used clinically for more than 35 years and remains the gold standard for bone on-growth. The titanium oxide layer that forms on the surface is well-recognized to have excellent biocompatibility.[1] Importantly, this oxide layer is stable but is not bioinert; studies have demonstrated that the biologic response elicited adjacent to the surface facilitates osteoblast attachment and proliferation along the surface.[1,2]
- **Roughness:** Surface roughness has been shown to positively affect the physiologic processes of bone growth (e.g. proliferation, matrix synthesis, and local factor production).[2,3] A roughened surface also provides physical anchorage for osteoblasts and increased surface area for cell adhesion.[4,5] In particular, osteoblasts have proven most responsive to titanium surfaces with roughness in the range produced by grit blasting (0.45 to 7 μm).[6,7]

2. Pore Morphology

Once a surface that promotes on-growth is established, the following factors promote growth of bone into the structure.

- **Interconnectivity:** To allow migration and proliferation of cells, as well as vascularization which is key to sustaining live bone within the porous structure, the pores must be connected to one another.[4,5]
- **Diameter:** The range of pore sizes observed to result in bone ingrowth includes 100-500 μm, with pore sizes at the upper range recommended to allow vascularization.[8,9,10,11]
- **Percent-Volume**: Generally, higher porosity results in more bone ingrowth.[12,13] Research has suggested a minimum porosity of 55-60%.[5]
- **Shape**: Increased bone ingrowth with angular (as opposed to rounded and smooth) pores; that is, a rugged, irregular pore cross-section is preferred.[5]

3. Structural Properties*

Note that these properties are dependent on other factors. For instance, the modulus of elasticity results from the material and porosity selection (i.e. higher porosity→lower modulus). Also, the coefficient of friction is a function of the macro-roughness of the surface, which is in turn related to pore size (i.e. in most cases larger pore size→large surface prominences).

- **Modulus of Elasticity**: To avoid stress shielding (or the loss of bone density/strength), the porous structure should have a modulus within the range of that of cancellous bone, which is about 0.76-4.0 GPa.[5,14]
- **Coefficient of Friction:** A high frictional coefficient enhances initial stability and promotes ingrowth by limiting micro-motion at the bone-to-implant interface.[15,16] The newest generation of porous structures have been designed improve coefficient of friction when compared to widely-used porous plasma spray, which is in the range of 0.5-0.66.[17]

Tesera meets or exceeds all of the published guiding principles for a porous structure which will promote and support bone ingrowth.

Published Guideline		Tesera	Meets/Exceeds Requirement
Material	Ti- alloy "gold standard"[1,2]	Ti-alloy	√
Micro-Roughness (μm)	Approximate grit-blasted (0.45-7.0)[6,7]	Yes[18]	√
Interconnected Pores	Yes	Yes	√
Average Pore Diameter (μm)	100-500; in upper range for vascularization[8,9,10,11]	504[23]	√
Pore Volume (%)	55-60; higher is better[5,12,13]	64±6.2[19]	√
Pore shape	Rugged, irregular	Rugged, irregular	√
Coefficient of Friction (Cancellous)	>0.66[17]; maximize[13,14]	0.98±0.01[20]	√
Modulus of Elasticity (GPa)	0.76 – 4.0; lower is better[14]	1.7[21]	√

Competitors versus the Guiding Principles for Bone Ingrowth

The following table shows how various porous technologies measure up to the quantifiable published guidelines for successful bone ingrowth. Note that Tesera, Trabecular Metal, and Trabecular Titanium are the only porous structures that meet all the published guidelines. Tesera outperforms Trabecular Metal in the parameters coefficient of friction and modulus of elasticity. Micrographs of each coating/structure are provided at the end of this document.

		Material	Micro-Roughness (µm)	Average Pore Diameter (µm)	Pore Volume (%)	Coefficient of Friction (Cancellous)	Modulus of Elasticity (GPa)
Published Guidelines		Ti- alloy "gold standard"[12]	Approximate grit-blasted (0.45-7.0)[6,7]	100-500; In upper range for vascularization[8,9,10,11]	55-60; higher is better[5,12,13]	>0.66[17]; maximize[13,14]	0.76 – 4.0; lower is better[14]
Technology	**Manufacturer**						
Tesera	**Renovis**	Ti-alloy	Yes[22]	504[23]	64±6.2[23]	0.98±0.01[24]	1.7[25]
Trabecular Metal	**Zimmer**	Tantalum	Yes	430[26]	75[26]	0.88±0.09[27]	3[28]
Trabecular Titanium	**Lima**	Ti-alloy and cp Ti	Yes[29]	640[29]	65[29]	0.78[29]	1.2[29]
Stiktite	**Smith & Nephew**	Ti-alloy	NA	200[30]	60[30]	0.89[30]	106-115[30]†
Gription	**DePuy**	Ti-Alloy	NA	120-650[31]	50-90[31]	0.99[31]	106-115[30]†
Biofoam	**Wright**	cp-Ti	NA	530[30]	60-70[30]	0.58[30]	2.9[30]
Regenerex	**Biomet**	Ti-alloy	NA	300[28]	67[28]	NA	1.9[32]
Tritanium	**Stryker**	cp-Ti	NA	546[30]	60[28]	1.01[30]	106-115[30]†

Other Benefits of Tesera

In addition to meeting the requirements for a bone ingrowth structure, the Tesera process offers the following benefits:

- Tesera is not a coating.
  - The solid and porous portions of the device are produced in one step (no delamination).
  - No sintering process which weakens the implant substrate.
  - EBM produces solid Ti-alloy (i.e. the non-porous body of the device) with properties equivalent to wrought Ti-alloy.[33]
- EBM makes possible the design of a gradient pore structure, which addresses the trade-off between modulus and strength.[34] That is, Tesera has a higher porosity, and thus a lower modulus, at the crucial bone-to-implant interface and a lower porosity at the solid surface of the implant.

Qualitative Comparison (Best in Class for Porous Structures)

This qualitative chart includes the guiding principles for bone ingrowth, plus the other benefits above.

† Because the coating is bound to its substrate, it assumes the modulus of solid Ti-alloy.

		Tesera (Renovis)	TM (Zimmer)	TT (Lima)	Stiktite (S+N)	Gription (Depuy)	Biofoam (Wright)	Regenerex (Biomet)	Tritanium (Stryker)
Process	Not a coating	√	√	√			35‡	√	
Gradient Porosity	Porosity increases at bone interface[34]	√				√			
Material	Biocompatible; Ti- alloy "gold standard"[1,2]	√	√§	√	√	√	√	√	√
Micro-Roughness (µm)	Approximate grit-blasted (0.45-7.0)[6,7]	√[22]	√	√[29]	NA	NA	NA	NA	NA
Interconnected Pores	Yes	√	√	√	√	√	√	√	√
Average Pore Diameter (µm)	100-500; *in upper range for vascularization*[8,9,10,11]	√[23]	√[26]	√[29]	30**	√[30]	√[30]	28**	√[30]
Pore Volume (%)	55-60; higher is better[5,12,13]	√[23]	√[26]	√[29]	√[30]	√[30]	√[30]	√[28]	√[28]
Pore shape	Rugged, irregular, not rounded	√[22]	√	√	√	√		√	√
Coefficient of Friction (Cancellous)	>0.66[17]; maximize[13,14]	√[24]	√[27]	√[29]	√[30]	√[30]	30	NA	√[30]
Modulus of Elasticity (GPa)	0.76 – 4.0; lower is better[14]	√[25]	√[28]	√[29]	30	31	√[30]	√[32]	30

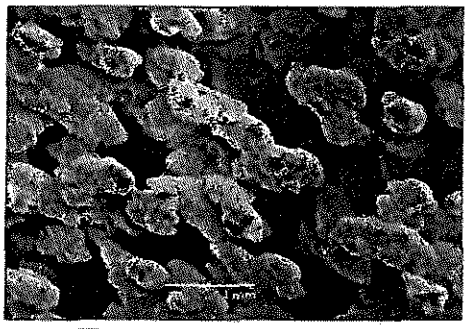
Microscopic Views of Porous Structures

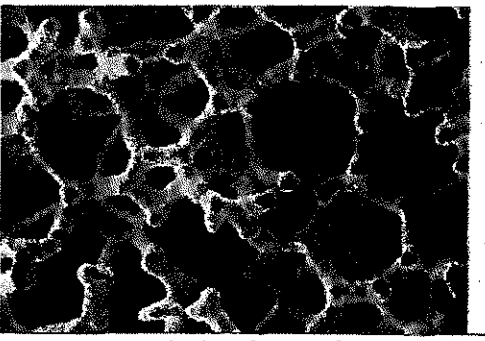
Tesera (Renovis)	Trabecular Metal (Zimmer)

‡ While Biofoam can be produced in bulk, the porous structure is manufactured separately from the shell and then pressed on in a high temperature/pressure environment.

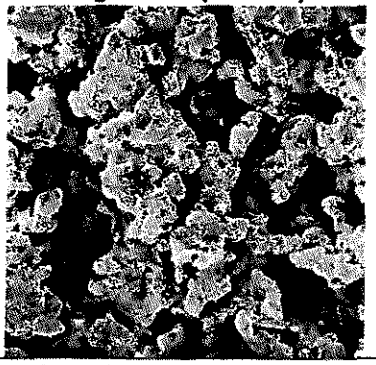
§ Trabecular metal is tantalum, a metal with proven biocompatibility. All others are cp or alloyed titanium.

** The average pore size of 200 for Stiktite and 300 for Regenerex is below the average of 500 µm recommended for vascularization.

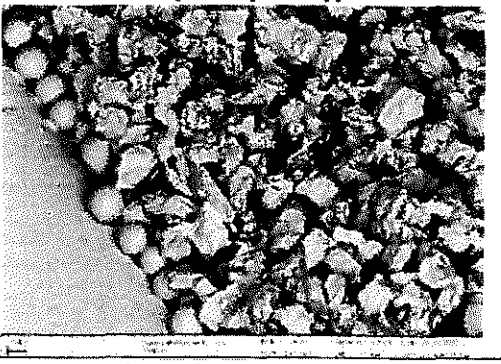




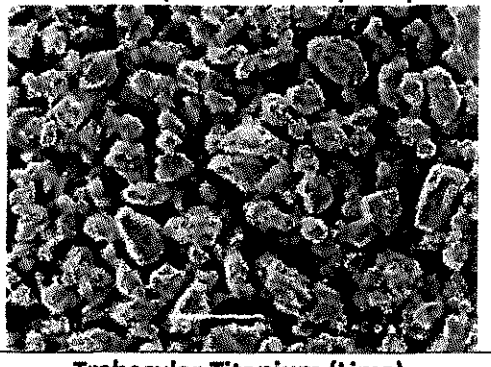
Regenerex (Biomet)



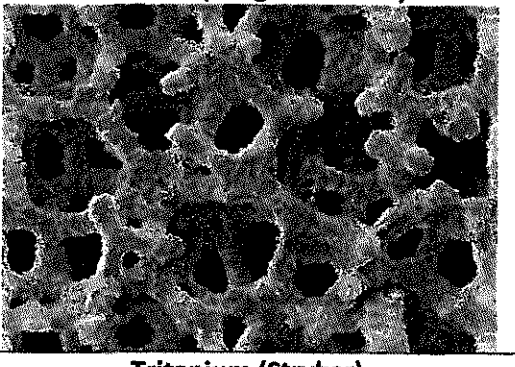
Gription (DePuy)



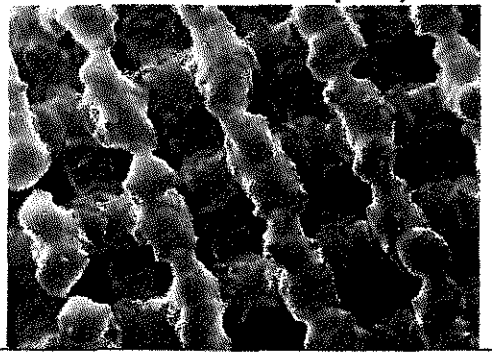
Stiktite (Smith and Nephew)



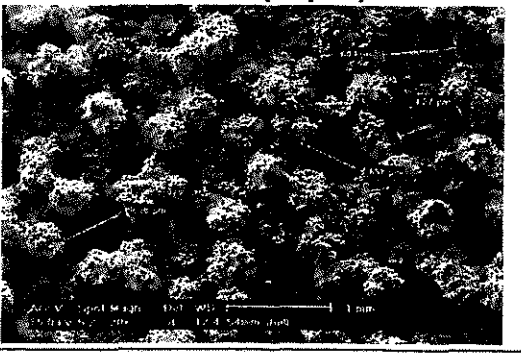
Biofoam (Wright Medical)



Trabecular Titanium (Lima)



Tritanium (Stryker)



References

[1] Oshida Y. Bioscience and bioengineering of titanium materials. Elsvier. Oxford. 2012

[2] Kieswetter K, et al. The role of implant surface characteristics in the healing of bone. Crit Rev Oral Biol Med, 7(4):329-345.

[3] Arcelli D, Palmieri A, Pezzetti F, Brunelli G, Zollino I, Carinci F (2007) Genetic effects of titanium surface on osteoblasts: A meta-analysis. J Oral Sci 49: 299-309.

[4] Mour. Advances in Porous Biomaterials for Dental and Orthopaedic Applications Materials 2010, 3, 2947-2974.

[5] Alireza Nouri, Peter D. Hodgson and Cui'e Wen (2010). Biomimetic Porous Titanium Scaffolds for Orthopedic and Dental Applications, Biomimetics Learning from Nature, Amitava Mukherjee (Ed.), ISBN: 978-953-307-025-4

[6] Hacking SA, Bobyn JD, Tanzer M, Krygier JJ. The osseous response to corundum blasted implant surfaces in a canine hip model. Clin Orthop Relat Res. 1999 Jul;(364):240-53.

[7] Feighan JE, Goldberg VM, Davy D, Stevenson S. The influence of surface-blasting on the incorporation of titanium-alloy implants in a rabbit intramedullary model. JBJS Am 1995; 77:1380-1395.

[8] Simske, S.J.; Ayers R.A.; Bateman T.A. Porous materials for bone engineering. *Mater. Sci.Forum* 1997, *250*, 151–182.

[9] Bobyn JD, Pilliar RM, Cameron HU, Weatherly GC. The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. Clin Orthop Relat Res. 1980 Jul-Aug;(150):263-70

[10] Miao X, Sun D. Graded/Gradient Porous Biomaterials. Materials 2010; 3: 1-22.

[11] Bansiddhi, A.; Sargeant, T.D.; Stupp, S.I.; Dunand, D.C. Porous NiTi for bone implants: A review. *Acta Biomater.* 2008, *4*, 773–782.

[12] C. R. Bragdon, M. Jasty, M. Greene, H. E. Rubash, and W. H. Harris, "Biologic Fixation of Total Hip Implants," Journal of Bone & Joint Surgery, vol. 86, pp. 105-117, 2004.

[13] Karageorgiou V, Kaplan D. Porosity of 3D biomaterial scaffolds and osteogenesis. Biomaterials. 2005 Sep;26(27):5474-91.

[14] M. Jasty, C. Bragdon, D. Burke, D. O'Connor, J. Lowenstein, and W. Harris, "In vivo skeletal responses to porous-surfaced implants subjected to small induced motions.," Journal of bone and joint surgery, vol. 79, pp. 707-714, 1997.

[15] Dammak M, Shirazi-Adl A, Schwartz M Jr, Gustavson L (1997) Friction properties at the bone–metal interface: comparison of four diVerent porous metal surfaces. J Biomed Mater Res 35:329–336

[16] Biemond JE, Aquarius R, Verdonschot N, Buma P. Frictional and bone ingrowth properties of engineered surface topographies produced by electron beam technology. Arch Orthop Trauma Surg. 2011 May;131(5):711-8.

[17] Shirazi-Adl A, Dammak M, Paiement G. Experimental determination of friction characteristics at the trabecular bone/porous–coated metal interface in cementless implants. J Biomed Mater Res 1993;27(2):167–75.

[18] Data on file. SEM Evaluation. K13047307-1.

[19] Data on file. Coating Evaluation per ASTM F1854-09. K12076592-4

[20] Data on file. Coefficient of Friction. K13047307-4.

[21] Data on file. Tensile/Compression Tests. K13047307-5.

[22] Data on file. SEM Evaluation. K13047307-1.

[23] Data on file. Coating Evaluation per ASTM F1854-09. K12076592-4

[24] Data on file. Coefficient of Friction. K13047307-4.

[25] Data on file. Tensile/Compression Tests. K13047307-5.

[26] Piehler HR. Metallic biomaterials. In An Introduction to Biomaterials (eds. Guelcher SA, Hollinger JO) 2006 CRC Press Boca Raton Page 289

[27] Zhang Y, Ahn PB, Fitzpatrick DC, Heiner AD, Poggie RA, Brown TD. Interfacial frictional behavior: cancellous bone, cortical bone, and a novel porous tantalum biomaterial. Journal of Musculoskeletal Research. 1999;3(4):245-251.

[28] Levine B, Della Valle CJ, Jacobs JJ. Applications of porous tantalum in total hip arthroplasty. J Am Acad Orthop Surg 2006 Nov;14(12):646-55.

[29] Trabecular Titanium Naturae imitation. Lima brochure. Not dated.

[30] Fabi DW, Levine BR. Porous Coatings on Metallic Implant Materials. In ASM Handbook, Volume 23, Materials for Medical Devices (ed. Narayan R) 2012 ASM International.

[31] DePuy Brochure: Gription Porous Coating, 2009.

[32] Biomet brochure: Regenerex Porous Titanium Construct, 2008.

[33] Hiemenz J. EBM offers a new alternative for producing titanium parts and prototypes. Time-Compression Technologies 2006; May/June: 16-20.

[34] Wang, H., Johnston, S. R. and Rosen, D. W. (2006) "Design of a graded cellular structure for an acetabular hip replacement component." in Proceedings of the The Seventeenth Solid Freeform Fabrication Symposium Austin, TX, August 14-16, 2006.

[35] Biofoam Cancellous Titanium Matrix. Fixation with Bite. Wright Medical brochure, MH506-1009, 2009.

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Surgeon Ownership in Medical Device Distribution

An analysis of cost savings

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Abstract

Background

Surgeon ownership in medical device distribution is a new model that proposes to effectively reduce the costs associated with surgical implants. This model introduces effective market forces into the purchase of implants by establishing a legal framework whereby the surgeon (decision maker) also becomes the purchaser through ownership and management of a stocking distributorship.

Methods

Five existing surgeon-owned distributorships were retrospectively reviewed, and the pricing from these distributorships was compared to 2010 pricing from the best contract or capitated rate for non-surgeon owned distributorships for like implants at the same hospital.

Results

The average first year cost savings associated with the surgeon owned distributorships was 36%, with a total savings for 2010 of $2,456,521 and an average savings per distributorship of $490,304. For those distributorships in business for two or more years, the average annual price increase from the surgeon owned entities was -1.76%, which represents a marked improvement given the reported annual price increases in non-surgeon owned distributorships of 7-13% from 1995 (Healy 2006).

Conclusions

This study demonstrates that surgeon owned distribution companies are capable of providing considerable healthcare savings through lower implant costs and reduced annual price escalations as compared to traditional implant distributorships. (The American Association of Surgeon Distributors has established Standards ensuring the ethical and legal application of this model.)

Clinical Relevance

It is expected that these savings will result in improved access, improved hospital clinical support, and an overall reduction in healthcare costs to society.

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Introduction

Healthcare costs in the United States continue to place an overwhelming burden on individuals, businesses, local and federal governments. Although some of the rise in health care costs can be attributed to technological advances and an aging population, significant costs are also attributable to fundamental flaws in the economics of healthcare delivery in the United States. One prominent flaw results from separation between the decision maker (usually a healthcare provider) and the purchaser (usually a hospital, government, or insurance company). This creates a 'market failure' whereby typical market forces are not available to control costs. Market failure due to separation of the decision maker and purchaser is intrinsic to many facets of our current healthcare system.

A visible example of this market failure is the orthopedic and spinal implant marketplace. With these types of implants, the surgeon typically selects the specific product to be used based on his/her determination of which implant is best for the patient (usually on a case by case basis). Occasionally, a patient will have such a unique condition that only one or two products will meet their need. For a large majority of patient conditions, however, several competitive products are available. When multiple appropriate product options are available, the surgeon will make a selection based on a combination of factors including: personal experience, preference for product features, sales relationships, marketing, and company loyalty. Once the surgeon selects a specific implant, it is purchased by a hospital or surgery center. The costs of the implants are then borne by the hospital or reimbursed by third-party insurers including Medicare in certain circumstances.

Under the current healthcare paradigm, the purchaser (hospital) is given an order from the surgeon for a specific implant. The purchasing hospital is left with very little leverage in creating competition or in negotiating the price for a specific implant.

Although it is not appropriate for a hospital or government program to specify the brand of surgical implant to be used by a surgeon for a specific patient, one solution is to place the surgeon in a purchasing position. Restoring the roles of decision maker and purchaser to a single entity would thus re-establish normal market forces to, in theory, reduce surgical implant costs. The paradigm shift would align surgeon's decision making algorithm with the priorities of the patient and society – to provide the optimal implant for each patient while eliminating unnecessary expense.

The need for effective market forces in orthopedics is underscored by the growing cost burden of orthopedic procedures and the disproportionate impact of implant costs. By 2030, the demand is projected to increase by 173% for total hip arthroplasties and by 673% for total knee arthroplasties, representing over 4 million primary hip and knee replacements (Kurtz and others 2007). Implant costs account for the largest single expense in total hip and knee replacement operations (Scott and others 2009). Measurable implant cost savings thus has the potential to result in the most significant reduction in the cost for these procedures.

Surgeon ownership of medical device distribution is a novel model that places the surgeon in the position of value-driven implant purchasing, which re-establishes market forces, creates competition, and has the potential to result in substantial healthcare savings. The purpose of this study is to determine if there is evidence of significant cost savings resulting from surgeon ownership of medical device distribution. A secondary goal is to determine whether any cost savings achieved with a surgeon owned distributorship model would be sustained over time. Our null hypothesis is that surgical implant costs to the hospital are the same regardless of whether the implants are provided by a surgeon owned distributor or the conventional paradigm. Given the historical trend for annual inflation of surgical implant costs, we also hypothesized that the cost of implants sold by surgeon owned distributorships (SD) would increase each year.

Materials and Methods

In order to test this hypothesis, a study sample and control were selected from the American Association of Surgeon Distributors (AASD) member database. The AASD is a nonprofit public benefit company that has established recognized compliance standards for certifying distributorships with physician ownership. Surgeon owned distributors may become members of the Association by satisfying all requirements of membership which include the submission of a 12-month log of consecutive surgical cases. The submitted case data is de-identified for any patient specific information prior to submission. Permission was received from each SD for their data to be used in the analysis. Institutional Review Board approval for this study was waived because no individual patient-specific information was utilized in this study.

Criteria for inclusion were availability of a 12-month interval of data ending in July 2011, and hospital willingness to provide independent verification of implant pricing. Based on these criteria a sample population of five surgeon distributorships (SD) was selected.

The hospital pricing for implants supplied by the SD was compared to the best current contract pricing for implants of like quality and function supplied by non-surgeon owned distributorships (NSD) to the same hospital. Current hospital pricing for the NSD was provided by hospital purchasing departments and published hospital capitated rates.

For those distributorships that have been operational for 2 or more years, annual and cumulative data was reported. Comparison of the year to year pricing for each SD would provide data on surgical implant price inflation under the SD model.

One hundred percent of surgical cases from the SD inception through the study date were included in the data set analyzed.

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Results

Five distributorships fulfilled the eligibility for inclusion. The distributorships represented 18 surgeons in four states and are profiled in **Table 1**. Twelve of the surgeons specialize in general orthopedics and total joint arthroplasty and six of the surgeons are principally specialized in the treatment of spinal disorders. The distributorships have been in continuous operation for an average of 2.3 years (range: 1.0 to 4.4 years).

Table 1

	Start of Operation	# Surgeons –Spine	# Surgeons -TJA/Gen Ortho	Total Surgeons
SD1	February 2006	3	2	5
SD2	March 2007	2	2	4
SD3	November 2009	0	1	1
SD4	June 2010	1	0	1
SD5	July 2010	0	7	7

The study sample represents 1,366 surgical procedures (total knee replacement: 487, total hip replacement: 231, anterior cervical fusion: 154, posterior lumbar fusion: 247). The volume of cases varied according to the number of surgeons served by the distributorship and the practice complexions represented. The volume of cases for each distributorship in the sample was meaningful for each of the procedure types surveyed (minimum: 20 anterior cervical fusions by SD4; maximum: 189 total knee replacements by SD5), **Table 2**.

Table 2. Hospital Implant Prices: Surgeon vs Non-Surgeon Distributorships

Total Knee Replacement	Procedures	SD Price	NSD Price	Average Annual Savings
SD1	90	$3,588	$5,385	$161,730
SD2	116	$3,889	$6,573	$311,344
SD3	92	$3,285	$5,568	$210,036
SD5	189	$3,817	$4,288	$92,799
Total Hip Replacement		SD Cost	NSD Cost	Average Annual Savings
SD 1	35	$5,128	$7,295	$75,845
SD2	78	$4,630	$7,117	$193,986
SD3	52	$4,250	$6,900	$137,800
SD5	66	$4,288	$4,694	$29,370
Anterior Cervical Fusion		SD Cost	NSD Cost	Average Annual Savings
SD1	91	$2,092	$2,651	$50,869
SD2	43	$2,140	$2,230	$3,870
SD4	20	$1,345	$3,861	$50,320
Posterior Lumbar Fusion		SD Cost	NSD Cost	Average Annual Savings
SD1	118	$6,410	$11,007	$542,446
SD2	83	$13,564	$14,628	$88,312
SD4	46	$4,892	$15,931	$507,795

*SD = Surgeon Distributorship

**NSD = Non-Surgeon Distributorship

The implants sold by each of the five SDs varied, as did their pricing structure. The pricing structure of each SD, however, remained the same for each of the hospitals and surgery centers that it served. For the NSD control group, implant cost was determined as an average of the costs for same type implants provided by the NSD's at the hospitals/surgery centers served by the corresponding SD, **Table 2**. For each distributor, across all implant classes; the SD price was less than the NSD cost. For total knee replacement, the mean implant cost was $1,814 (33%) less for the SD ($3,640 vs. $5,453). Hip replacement implant costs were $1,937 (30%) less on average for the SD compared to the NSD ($4,564 vs. $6,501). For anterior cervical fusion cases, the SD implant cost was $1,055 less for the SD (36%; $1,859 vs. $2,914). The lumbar fusion implant costs were $5,567 (40%) less on average for the SD ($8,289 vs. $13,855). Across each of the implant lines studies, the SD implant cost was on average $2,589 (32%) less than the NSD cost. Considering the 1,366 cases included in the sample population, the one-year cost savings to hospitals/surgery centers and society was $2,456,521 (Table 2).

There was a variation of aggregate cost savings among the five distributorships, Table 3. The cost savings provided by the SD's ranged from 11% to 69%, with a mean aggregate annual savings of $490,304 per distributorship. Following the trend for the distributorships, there was also marked variation in the cost savings per surgeon. The greatest cost savings occurred for a single surgeon spine implant distributorship (SD4: $558,109). The least cost savings came from a total joint arthroplasty

distributorship serving seven general orthopedists ($17,453 per surgeon over 12-months). While not specifically studied, the variation may be explained at least in part by differences in practice emphasis (general orthopedics vs. spine), geographic market price differences (four states represented), and distributorship scale. (Table 3).

Table 3. Aggregate Annual Savings for All Procedures and Percentage Cost Reduction

Distributorship	Surgeons	% Cost Savings	Total Aggregate Annual Savings	Annual Savings per Surgeon
SD1	5	36%	$830,890	$166,178
SD2	4	23%	$597,512	$149,378
SD3	1	40%	$347,836	$347,836
SD4	1	69%	$558,109	$558,109
SD5	7	11%	$122,169	$17,453
		Average: 36%	Average: $490,304	Average $247,792

*SD = Surgeon Distributorship

For those distributorships with greater than one year of data, annual changes in implant pricing are reported in Table 4. Three distributorships have been in existence for two or more years and thus have multi-year pricing data available (5 years, 4-years and 3-years respectively). The three distributorships (SD1, SD2 and SD3) have carried a combined total of ten product lines since inception. Over this twelve year combined experience, only one product line for one distributorship has seen a price increase (1% increase in total knee replacement implant prices for SD3 over a 3-year time course). Each of the other nine product lines has not had a price increase. Seven product lines for two distributorships received a price decrease and two were unchanged. The combined aggregate price change of the three distributorships in was -1.41%.

Table 4. Average Annual Change in Implant Pricing

Distributorship	Total Knee Replacement	Total Hip Replacement	Anterior Cervical Fusion	Posterior Lumbar Fusion
SD1 (5 yr average)	-0.6%	-2.4%	-1.6%	-1.0%
SD2 (4 yr average)	1%	-2%	-4%	-3%
SD3 (3 yr average)	0%	0%	n/a	n/a
Avg Price Change	0.24%	-1.40%	-2.70%	-1.76%

*SD = Surgeon Distributorship

From July 2007 to July 2011, the average cost of goods in the United States (CPI) rose by +8.34% (www.bls.gov/cpi/tables.html). Based on this index, the actual price of the implants sold by the SD decreased by 9.75% over the four years in constant dollars (8.34% - -1.41%).

Discussion

The market failure associated with the current model of medical device distribution is evidenced by the increase in implant prices despite increases in volume and increases in the number of companies producing equivalent products (commoditization).. Any product cleared by the FDA under a 510(k) process is, by definition, substantially equivalent to a device currently marketed in the United States.

In industries where market forces act, such commoditization should result in dramatically reduced costs to society. The medical device industry has been shielded from this because of the unique circumstance whereby there exists separation between the individual making the implant choice and the party having to pay for that choice. Surgeon ownership in medical device distribution proposes to remove such separation and to establish more effective competition.

In 2009, there was an initial report from a single distributorship finding a 34% reduction in implant costs across three hospital systems (Steinmann and others 2009). No other studies have validated the cost savings associated with this model. This paper represents the first study of multiple SD in multiple states, utilizing many different manufacturers, and presents the effect of this model on the costs of medical devices to all contracted hospitals.

It is notable that cost savings were achieved in all products across all studied distributorships. In addition, these savings were significant, ranging from 11% to 69% and totaling $2,456,521, with an average cost savings of 36% across all five SD. These savings are of importance for the years ahead when considering the anticipated increased demand and the annual increases that have been the norm for this industry.

The 2010-2011 Orthopaedic Industry Annual Report (OrthoWorld 2011) cited total United States orthopedic product sales of $23.7 billion, with total joint reconstruction sales at $7.3 billion. The escalation in total joint implant price over the 14-year period from 1994 through 2006 was reported to be 171% (average 13%) (Healy 2006). Surgeon owned distributorships have shown the ability to save 37% the first year and to keep annual escalations at or below 1.0%.

The substantial first-year reductions in implant prices and sustained downward pressure on annual price changes that result from surgeon ownership in medical device distribution will have a profound effect on healthcare costs associated with orthopedic implants. The magnitude of cost savings in total joint reconstruction is projected in Figure 1. Here it is assumed that the 13% annual escalations (reported by Healy 2006) associated with NSD would decrease for the next 20 years to 7.5%. It is further assumed that the SD model, with a first-year reduction in cost of 36%, would demonstrate a 1.5% annual escalation in price as opposed to the -1.76% change currently demonstrated. Figure 2 uses the same assumptions but includes all orthopedic implants, to demonstrate the broader potential cost savings associated with the SD model.

This calculation reveals that over the next 20 years, the SD model has the potential to save $229 billion in total joint reconstruction costs alone (Fig. 1). This figure does not take into account the expected substantial increase in demand that was discussed previously, thus probably significantly understating the potential long-term savings associated with this model. When looking at this from the perspective of the entire orthopedic medical device industry, the potential savings exceed $734 billion over 20 years (Fig. 2).

Figure 1. The Potential Economic Benefit of Surgeon Owned Distribution on Total Joint Reconstruction Devices

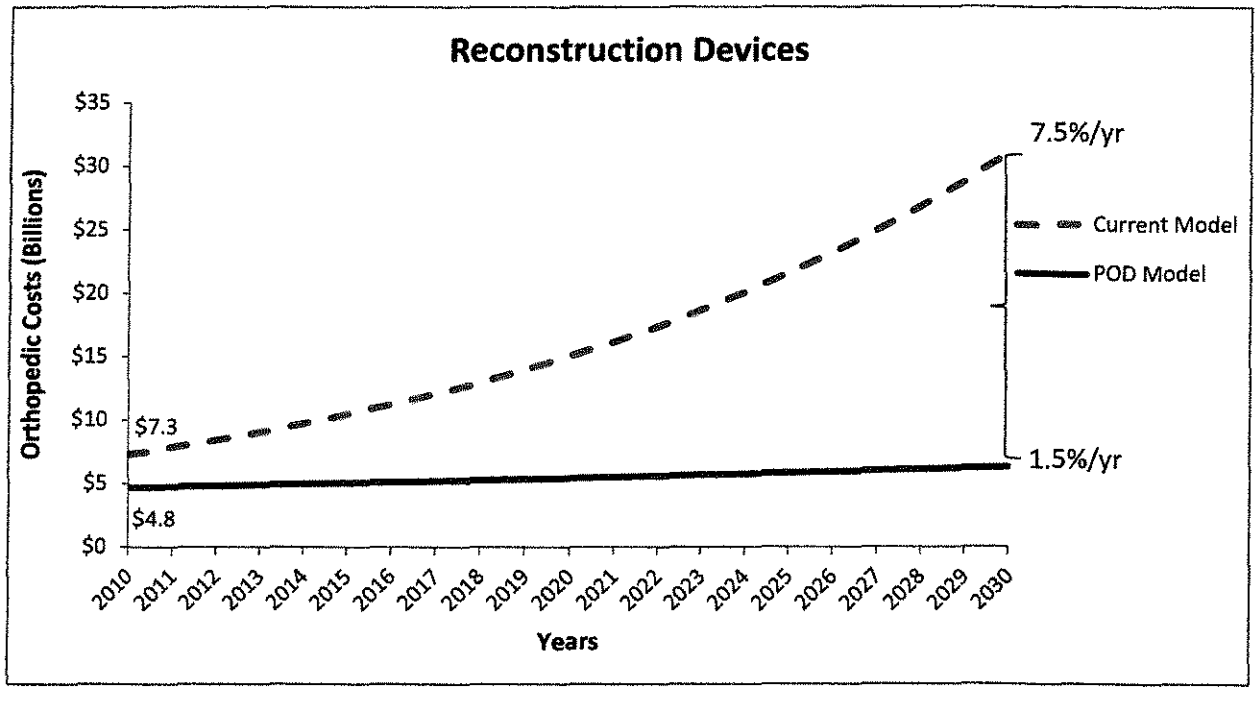
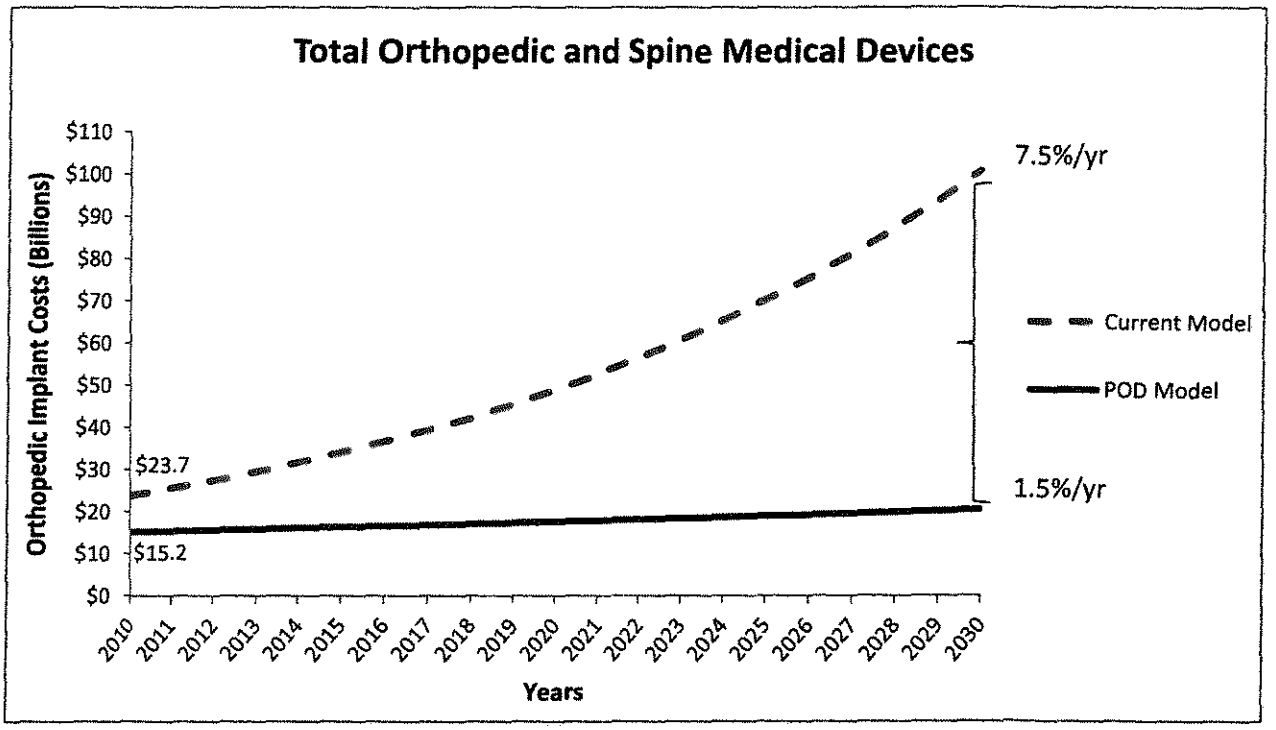


Figure 2. The Potential Economic Benefit of Surgeon Owned Distribution on Total Medical Devices



The demand will increase by 673% for total knee replacements and by 174% for total hip replacements over the next 20 years (Kurtz and others 2007). Payments made to hospitals for total joint arthroplasties are not enough to keep up with inflation (Scott and others 2009), causing concern for the financial feasibility of total joint procedures. With fewer surgeons to provide total joint procedures (Fehring 2010) and the economic disincentive for hospitals to provide total joint reconstruction services, continued access to these valuable surgical procedures may be threatened, particularly for seniors who represent the majority of total joint reconstruction patients. This threat to access further intensifies the need for significant change in the methods in which these products are acquired.

Legitimate concerns exist regarding this model. Those concerns question if the model will incentivize overutilization or the use of substandard products. Other concerns include the degree of transparency/disclosure and whether surgeons will continue to create such cost savings. In a separate ongoing study by the authors of this paper, the utilization of orthopedic implants by seven different surgeon distributors are compared to each distributors utilization for a 12-month period prior to the initiation of the distributorship, to analyze if there is evidence to support that utilization is influenced by this model. Preliminary results indicate no change in practice pattern following investment in the surgeon owned distributions under study.

A promising response to the concerns regarding the surgeon owned distribution model has been the development of Standards established by the American Association of Surgeon Distributors (AASD 2011) (Table 5).

Table 5. Standards and Criteria for Membership: American Association of Surgeon Distributors

1. Distributorship must maintain a business structure consistent with all Federal Stark and Anti-Kickback statutes.
2. Distributorship must demonstrate merit by proving to be the lowest average cost vendor of like implants during a comparable contract period.
3. Annual price increases must not exceed 3% above the consumer price index (CPI).
4. Distributorship must demonstrate adherence to the AASD Product Evaluation Policy.
5. Distributorship must demonstrate adherence to the AASD Employee Training Requirements.
6. Distributorship must demonstrate adherence to the AASD Disclosure Policy.
7. Distributorship must demonstrate investment risk and compliance with the AASD Investment and Distribution Policy.
8. Distributorship must submit utilization data annually consistent with the AASD Utilization Review Policy.
9. Distributorship must not leverage referrals to any hospital or surgery center.
10. Distributorship must be a legitimate free standing stocking Distribution Company with employees, contracts, address, business license and insurance.
11. Distributorship must have written contracts with hospitals and vendors for at least one year.
12. Distributorship pricing must not vary between hospitals.

These standards ensure an accredited SD is demonstrating legal compliance, cost savings, transparency, product quality evaluations, appropriate employee training, and utilization reporting.

As surgeons, we have an obligation to the highest level of care to the patient with whom we have a relationship. Given the reality of limited resources, surgeons need to be mindful of ways to continue to provide the highest quality of care to their patients at prices that our society can afford. Failure to do so will result in a threat to sustained access to important medical technologies that have the ability to improve the quality of life.

The SD model is a tested and viable model with great promise to re-establish market forces and reduce healthcare costs and preserve access to valuable healthcare services. Safeguards, such as those established by the AASD, will serve to protect the best interest of patients and society on an ongoing basis.

Bibliography

1. Kurtz S, Ong K, Lau E, Mowat F, Halpern M. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am. 2007 Apr;89(4):780-5.

2. Scott WN, Booth RE Jr, Dalury DF, Healy WL, Lonner JH. Efficiency and economics in joint arthroplasty. J Bone Joint Surg Am. 2009;91:33-6.

3. 2010 Hip and Knee Implant Price Comparison. Orthopedic Network News. 2010;21(3):9-12.

4. Steinmann J, Hopkins G, Burton P, Skubic J. Surgeon Ownership in Medical Device Distribution: Economic Analysis of an Existing Model. Las Vegas (NV): American Academy of Orthopedic Surgeons Annual Meeting; 2009 Feb, Scientific Exhibit SE48.

5. The 2010-2011 Orthopaedic Industry Annual Report. Chagrin Falls (OH): OrthoWorld; 2011 July.

6. Healy WL. Gainsharing: A primer for orthopaedic surgeons. J Bone Joint Surg Am. 2006 Aug; 88(8):1880-7.

7. Fehring TK, Odum SM, Troyer JL, Iorio R, Kurtz SM, Lau EC. Joint replacement access in 2016: a supply side crisis. J Arthroplasty. 2010 Dec;25(8):1175-81.

8. American Association of Surgeon Distributors (AASD). Standards and Policies: Distributor Members. [Internet]. Available from: http://www.aasdonline.org/StandardsandPolicies/DistributorMembers.aspx. Accessed 2011 July 11.

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Surgeon Ownership in Medical Device Distribution

Does this model influence utilization?

John C. Steinmann, D.O.; Charles Edwards II, M.D.; Thomas Eickmann, M.D.; Angela Carlson, MHA

Introduction

Surgeon ownership in medical device distribution, otherwise commonly referred to as physician owned distribution (POD) is a novel model that has gained considerable popularity in recent years. Best described, this model represents a stocking distributorship model whereby the surgeons invest in and take title to a large inventory of implants and often instruments and contract with hospitals to sell products from that inventory. The model makes effective use of volume purchasing, effective negotiation and competition among manufacturers of like quality products.

Proponents suggest that this model introduces market forces that are largely absent in the traditional commissioned model, leading to substantial reduction in healthcare costs. One published report (Steinmann, Burton, Hopkins, & Skubic, 2009) found that surgeon ownership in medical device distribution led to 36% first year savings for like implants including both spine and total joint devices. This reduction in healthcare costs should help to protect the financial viability of local hospitals resulting in sustained access for patients to many valuable surgical services. Proponents of the model will also argue that surgeons offer far greater value as the distributor than a non-surgeon distributor due to their ability to value new technology and negotiate pricing more effectively.

Those segments of the industry that oppose the proliferation of this model suggest that the model will incentivize overutilization and the use of substandard products. While the issue of product selection will be separately studied, the issue of utilization is a very important concern to society. The performance of surgery on patients who may not meet appropriate indications will lead to patient harm and increased expense to the healthcare system.

There exist strong arguments for and against the potential influence that surgeon ownership in medical device distribution might have on utilization but, to date, no study has investigated this concern. The purpose of this study is to investigate the influence that establishment of a surgeon owned distribution model has on surgical treatment decisions.

Materials/Methods

Four surgeon owned orthopedic and spine implant distributorship companies that met inclusion criteria were studied. Inclusion criteria included: surgeon equity ownership in a

stocking medical device distributorship, minimum of one year of distributorship operations by December 31, 2010, and sufficient and accurate surgical performance data preceding the onset of the distributorship for a minimum of one year. CPT (current procedural terminology) codes were reported by the surgeon's clinical practice billing department, and accuracy of the data was confirmed by the surgeon. Of the possible ten distributorships considered, only four met the ownership and operations criteria. Six distributorship were excluded due to distributorship start dates after May 2010, and therefore had insufficient data to be included under the parameters of this study.

Practice volume was measured by the number of new, established, and consultative patient visits (PV) captured for Current Procedural Technology (CPT) codes: 99201 -99205, 99211-99215, 99241-99245. This same data was then gathered prospectively.

Surgical volume (SV) was measured by the volume of primary total knee and hip replacements, and instrumented posterior lumbar surgical cases performed. Surgical volume includes one hundred percent of the procedures for the CPT code reported, regardless of the source of implants used (from the surgeon owned distribution company or not). Capturing representative spine data is problematic as most spine CPT codes do not distinguish between the primary surgical code and additional levels. Data for SV was, therefore, limited to only those CPT codes that clearly represent a "decision for surgery". Surgical case volume CPT codes included:

Total Joint Replacement

- 27447(Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (TKA);
- 27130 (Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft)

Instrumented Posterior Lumbar

- 22840 (Posterior non-segmental instrumentation (e.g., Harrington rod technique, pedicle fixation across one interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation);
- 22842 (Posterior segmental instrumentation; 3 to 6 vertebral segments)
- 22843 (7 to 12 vertebral segments)
- 22844 (13 or more vertebral segments)

Bilateral total joint arthroplasty performed under the same anesthetic is considered two procedures. Spine fusion (regardless of number of levels) is considered a single procedure.

CPT billing codes were collected for the 12 calendar month interval preceding the initiation of the distributorship and for each 12 calendar month interval thereafter. The twelve calendar

months prior to the establishment of the distributorship is defined as the baseline for comparison.

This data was collected as part of each distributorships application to the American Association of Surgeon Distributors (AASD).

Results:

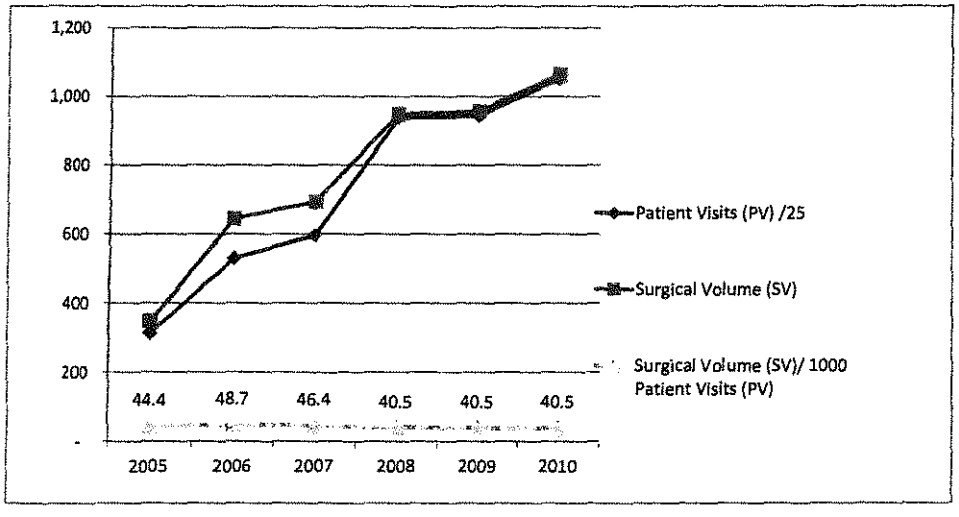
Four surgeon owned distribution companies meeting the inclusion criteria completed data on both patient visits and surgical volumes(Table 1). The number of surgeons in the distributorship by year was determined by the date which the surgeon began participating in the distributorship. Surgeons who had at least nine months of participation in a calendar year were included in that calendar year. Surgeons with less than 3 months participation were included in the following year for the purposes of Table 1.

Table 1. Aggregate Patient Visit and Surgical Volume

Year	Patient Visits (PV)	Patient Visits (PV) /25	Surgical Volume (SV)	Surgical Volume (SV)/ 1000 Patient Visits (PV)	# Surgeons in Distributorship
2005	7,820	313	347	44.4	0
2006	13,220	529	644	48.7	4
2007	14,924	597	693	46.4	7
2008	23,403	936	948	40.5	7
2009	23,589	944	956	40.5	9
2010	26,243	1,050	1,063	40.5	10

Figure 1 graphically compares the number of patient visits to surgical procedures.

Figure 1. Surgical Volume vs. Patient Volume



The SV/PV ratio could be viewed as a "decision for surgery" index. Figure 1 identifies that between 2005 and 2010 there was remarkable consistency among surgeons regardless of practice type (group or solo) and a trend identifying a decrease in the likelihood to recommend surgery (44.4/1000 to 40.5/1000). This data suggests that the decision for surgery is independent and not influenced by these surgeons participation in a medical device distributorship.

Discussion

Inherent in the doctor patient relationship is the ethical covenant that the physician's decision making is guided solely by what is in the patient's best interest. Surgeon ownership in medical device distribution introduces the potential conflict of interest that the surgeon might be incentivized to recommend surgery inappropriately due to their potential to financially benefit from the sale of implants through their ownership interest in the distribution company. Even the perception of conflict in interest is potentially damaging to the doctor patient relationship. This study is very important as no published study to date has investigated the influence of surgeon ownership of medical device distribution on actual physician practice patterns and specifically, the surgeon's decision to treat surgically.

Figure 1 identifies that surgical volume remained consistent across all distributorships and varied only with changes in patient volume. Surgical volume and patient volume increased as more surgeons are added to the study group yet the ratio of surgical procedures to patient volume remained stable.

Although general comparison can be made to previously published data, substantive comparison is limited by differences in data source and sample size. Previous reports are based on hospital claims data (Deyo, Mirza, Martin, Kreuter, Goodman, & Jarvik, 2010; 303(13)) (Weinstein, Lurie, Olson, Bronner, & Fisher, 2006) and most are limited to Medicare enrollee information.

This study utilized professional procedure codes rather than hospital claims. Furthermore, the patient data included all payor types. Studies restricted to Medicare will not be representative of the overall spinal fusion rates in the United States since spinal fusions are more likely to be performed on younger patients (Merrill & Elixhauser, July 2007).

To our knowledge this is the first study to report total joint replacement or spinal fusion rates relative to practice profile metric such as patient volume. This comparison may provide valuable data on a surgeon's decision for surgery within a given population.

Only forty percent of the original groups were included in this study, due to insufficient data. Given the consistency of the decision for surgery metric, we would not anticipate alternate findings in a broader sample set, however, a broader data set would be desirable in future studies.

Conflicts of interest already exist in many areas of the surgeon/patient relationship. When a surgeon recommends a surgical procedure, the surgeon is financially remunerated for their performance of the procedure. While surgeon ownership in implant distribution adds to this financial conflict of interest, it is important to note that remuneration from distributions from the implant distribution company are a fraction of the remuneration provided by the surgeons professional fee and as such, the surgeons ownership in implant distribution should not be considered to present a new or substantial influence.

Potential conflicts of interest, when identified, should be managed with full transparency to patients, hospitals and surgical colleagues. Furthermore, it is advisable for all distributorships to track surgical volume and to adopt a method for dealing with a surgeon who might show an increase in utilization that is not explained by a corresponding increase in reliable practice patterns. The American Association of Surgeon Distributors (AASD) has published standards governing the legal and ethical application of this model and have established mechanisms for such tracking and auditing of implant utilization.

Patients and society need to be satisfied that surgeon ownership interest in a distribution company does not compromise their dedication to serving the patient's best interest. The current study demonstrates that for a select sample of surgeons, their commitment to ethical and professional standards were not compromised by their ownership interest in implant distribution. This result is especially meaningful as the surgeons were unaware that this investigation would be carried out until after the data collection periods for the control and trial years were completed.

The authors of this study support the safeguards established by the AASD that serve to ensure that the POD model is ethically implemented and maintained. These include full transparency and disclosure to the patient, hospitals and to colleagues. In addition, such standards should ensure the surgeon distributorship remains the lowest average cost vendor to the hospital and can demonstrate and document a rigorous process to insure product quality assessments prior to purchase of products for the distributorship.

Conclusion

This study demonstrates that, in this group of surgeons, all who have demonstrated proper intent through transparency, cost savings and endorsement of the AASD standards, ownership

in the distribution of medical devices does not seem to influence surgical practice patterns and hence, does not corrupt the sacred doctor patient relationship. To encourage ongoing ethical and legal operation of a surgeon invested medical device distributorship, full transparency and independent ongoing assessments of practice patterns are recommended.

Works Cited

Deyo, R., Mirza, S., Martin, B., Kreuter, W., Goodman, D., & Jarvik, J. (2010; 303(13)). Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. *Journal of the American Medical Association*, 1259-1265.

Kurtz, S., On, K., Lau, E., Mowat, F., & Halpern, M. (2007 (89)). Projections of Primary and Revision Hip and Knee Arthroplast in the United States from 2005 to 2030. *Journal of Bone and Joint Surgery*, 780-785.

Merrill, C., & Elixhauser, A. (July 2007). *Statistical Brief # 34 -Hospital Stays Involving Muscoloskeletal Procedures: 1997 - 2005.* Rockville, Maryland: U. S.Agency for Healthcare Research and Quality: Healthcare Cost and Utilization Project.

Steinmann, J., Burton, P., Hopkins, G., & Skubic, J. (2009). Surgeon Ownership in Medical Device Distribution: Economic Analysis of An Existing Model. *American Academy of Orthopedic Surgeons*, (p. Scientific Exhibit).

Weinstein, J. N., Lurie, J. D., Olson, P., Bronner, K., & Fisher, E. (2006). United States' Trends and Regional Variations in Lumbar Spine Surgery: 1992 - 2003. *Spine*, 31(23).

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June 19, 2014

VIA FEDERAL EXPRESS

Ms. Elizabeth A. Carter, Ph.D
Executive Director
Virginia Board of Health Professions
9960 Mayland Drive, Suite 300
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Re: Follow-up to May 20 Testimony Regarding POD Regulation in Virginia

Dear Dr. Carter and Board Members:

Thank you for the opportunity to speak before the Board on the issue of physician-owned distributorships ("PODs"). Enclosed please find a whitepaper I authored in 2013 on legal and ethical concerns regarding PODs and the growing trend of hospitals to prohibit such arrangements under conflict of interest provisions.

This whitepaper also addresses the many concerns articulated by regulators, enforcers and public health interests with the medical conflict of interest generated when physicians undertake business arrangements that take advantage of the physician patient relationship. White coat marketing is a real abuse in the context of a physician's financial interest in the product recommended for use in patient procedures. Such a potent circumstance for potential abuse should not be left to so-called voluntary disclosures made by conflicted physicians to their sick or injured patients in the process of consenting to treatment decisions.

It is well recognized that these type of physician owned entities may also raise health care costs over time to both patients and payors, including Virginia Medicaid and Workers' Compensation Plans. This was the experience of the California workmen's compensation program, causing its legislators to ban such entities for that program. Overutilization is one of

the fundamental rationales of the federal anti-kickback statute and related state anti-kickback provisions.

The forecast of overutilization and medically unnecessary services associated with these business models is not farfetched but simple common sense. As far back as 1992, researchers have presented statistically significant data that physician ownership in ancillary services leads to medically inappropriate services and high outlier utilization rates. *See* Swedlow et al., *Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self-Referral by Physicians,* 327 New England J. of Med. 1502 (1992). Medically unnecessary procedures are harmful to patients and to the public fisc.

Senator Martin's initiative presents a compelling opportunity to protect the public from financial conflict of interest in medical decision making for these types of entities. For all of these reasons, favorable consideration to regulations addressing this issue is urged.

Very Truly Yours,

Kathleen McDermott

Encl.

DB1/ 79634067.1

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ANTI-FRAUD CONCERNS FOR PHYSICIAN-OWNED DISTRIBUTORS FOR MEDICAL DEVICE PRODUCTS: WHAT'S NEW IS OLD. WE WON'T BE FOOLED AGAIN.

Kathleen McDermott
Jacob J. Harper
Washington, DC
March 2013

Executive Summary

The shadowy momentum for physician-owned distributorships ("PODs") models to advance health reform goals of healthcare cost-savings does not disguise that its predominate purpose is to achieve an increase in physician income from the sale of medical products from the physician's own business for use in his pre-determined hospital surgeries. The business model is a vexing artifice that contradicts long standing and effective legal safeguards that protect patients and the public interest from physician conflict of interest in medical decision-making. Like all artifices, the POD model is shrouded in misleading debate by proponents of the model that purport to have the support of legal and medical experts. The expert bench, however, is thin in support of PODs and does not credibly match the extraordinary legal and ethical precedents that disfavor PODs.

Physician-owned or investor entities, moreover, have a sad legal trajectory that can be fairly predicted from over 40 years of anti-fraud legislating and prosecuting the evils of such arrangements. When physicians "take a piece of the action" from their patient referrals or related medical decision making activities, their professional effort is tainted, patients are potentially harmed and the public interest is undermined. And, yes, procedure utilization goes up...alot. Then, investigations eventually show that procedures tainted by physician conflict of interest were substantially medically unnecessary. Yes, we have been here before but we won't be fooled again.[1] PODs are not a legally credible business model to advance healthcare cost-savings or any other legitimate public health goal. PODs cannot be safely formed consistent with fraud and abuse laws such as the federal anti-kickback statute and the physician self-referral ban (known as Stark) or with government and industry compliance best practices.

Private sector watchdogs, government regulators and enforcers, and the U.S. Senate Finance Committee have all justifiably raised compelling legal and policy concerns regarding the POD business model. While the issue is under review and audit, POD models continue to grow. It will take more concentrated government action to protect patients and safeguard important public health prerogatives. Physician ownership of health care entities that prove too great a risk to the public interested have been legislatively banned or regulated to remove or diminish conflict of interest.

While government stakeholders consider the POD business model concerns, other stakeholders such as hospitals and health systems are actively assessing the tremendous legal risk of PODs. Several community and national hospital chains and health systems have adopted policies and procedures that either ban or place significant restrictions on doing business with physician owned entities and other vendors who have a financial relationship with the hospital's physicians. In light of the many hesitations and concerns from industry stakeholders, as well as the risks and costs associated with PODs identified through historical empirical evidence, it is now time for the government stakeholders, including the OIG, to provide clear guidance with

respect to these questionable business ventures and to demonstrably enforce existing fraud and abuse laws.

This review focuses on the federal fraud and abuse, conflict of interest and medical ethics concerns associated with physician-owned distributor entities (hereinafter PODs) in the medical device products industry and provides a compelling rationale for more explicit Office of Inspector General (OIG) fraud and abuse guidance and action on the anti-kickback implications of these proliferating arrangements.

I. Physician-Owned Distributor Entities in the Medical Device Industry: A Pandora's Box.

Physician owned or invested entities are controversial and have a long history of proven overutilization, quality of care and improper payment concerns. Objective empirical evidence of similar arrangement scenarios to PODs reveals a predictable pattern of higher utilization and medically unnecessary procedures.[2] History is a good teacher but does not promise that its lessons are fully embraced by proponents of new and lucrative business models. In 1992, an objective study published in the New England Journal of Medicine proved the connection between physician financial conflict of interest in imaging center ownership and dramatic increases in medically unnecessary procedures billed to the California workers' compensation system attributable to physician-owned imaging centers.[3] In 2012, the California legislature examined physician-owned companies in the medical device industry and, arguably recognizing the same public health dangers as physician-owned imaging centers 20 years ago, now prohibits physicians from billing the workmen's compensation program for medical device products distributed by companies in which the surgeon has an ownership interest.[4] This wisdom is not rationally limited to workmen's' compensation systems and applies broadly to items, services and goods reimbursed under federal health care programs and regulated by the federal anti-kickback statute.

Regulating physician financial conflict of interest and assuring strong enforcement and regulatory policies to avoid kickbacks or tainted self-referrals in the health industry is not advanced by allowing surgeons the opportunity to make extra income from the sale of products that they decide will be used in the performance of their own hospital procedures. Apart from the potential legal exposure for the surgeon, such a model also exposes hospitals to inordinate risk for compliance and risk management problems and exposes patients to the unacceptable risk of potentially unnecessary procedures. These concerns regarding the potential risk of abuse are not hypothetical but a realistic forecast based on over 40 years of federal health care fraud enforcement experience that has caused Congress to enact and expand anti-kickback and physician self-referral legislation and to fund a war on health care fraud since 1996. Physician-owned distributorships, like physician-owned imaging centers and other like arrangements, are déjà vu all over again for fraud, waste and abuse business practices negatively affecting publicly funded health care programs.

Medical ethics, sound compliance practices and current risk management standards compel the presumption that physician-owned distributorships violate the criminal, civil and administrative provisions of the anti-kickback statute because it is not objectively reasonable to presume such arrangements operate, in practice, without regard in some fashion to a surgeon's referral leverage with a hospital. The anti-kickback statute's broad reach and "one purpose" legal standard for assessing the legal rationale of arrangements is likely violated in virtually every arrangement. Indeed, proponents of PODs do not deny the fundamental justification of POD arrangements is to achieve remuneration for surgeons that is related to procedures performed as part of their medical judgment.[5]

Some advocates of physician-owned distributorships and entities purport to have legal opinions approving such arrangements but this position does not diminish the serious doubt and ambiguity over the legitimacy of the various POD models that are proliferating in the medical device industry. The publicly available legal opinions and white papers, moreover, all acknowledge the anti-kickback implications of such arrangements and couch any approval in caveats that presume the *full implementation* of numerous and highly complex compliance safeguards. These legal positions supporting the formation of PODs further presume that there is "no intent" to violate the law by the physicians who own the entity or the hospital that contracts with the entity under the one-purpose test of the anti-kickback statute, but it is challenging to offer any credible justification for this model apart from the fact that it gives physicians the opportunity to earn profits that are derived solely from self-referrals.

It should be of significant concern to health industry stakeholders, the OIG and related enforcers and regulators that the promotion of physician-owned entities under the parameters of compliance safeguards and "model" provisions are wholly unproved. Enforcement experience tells us that such models are often a compliance house of cards that may collapse by a simple request to show *full implementation* of such compliance safeguards by the physician-owned entity. The legal risks inherent in the various models of physician owned entities caused the physician organization, the Association for Medical Ethics, to conclude that "*participating in PODs is both unethical and illegal and likely to ensnare physicians and hospitals in future enforcement activities and lawsuits.*"[6]

II. Physician-Owned Distributorships Undermine the Physician Gatekeeper Legal Safeguards.

The debate on the legal and policy legitimacy of PODs focuses on arguments of cost, value, healthcare savings, supply chain models, competition, conflict of interest, and fraud and abuse compliance. What is obscured in the justifications offered in defense of PODs is the seminal policy rationale that has driven legislative and enforcement policy, and in recent years, critical voluntary compliance and risk management efforts by health industry stakeholders and enhanced codes of ethics by medical societies and industry associations: the health care professional's role as the gatekeeper to medical utilization.

As Congress, government enforcers and medical ethics has long recognized, it is necessary to regulate physician compensation, ownership and investment activities because of

the physician's unique and singular gatekeeper role in determining medical utilization that exists parallel to his or her financial interest in compensation and investment from their medical decisions and medical interventions for the patient.[7] Physician financial conflict of interest must be regulated because it is presumed harmful to the public interest. For this reason alone, the anti-kickback statute provides criminal and administrative sanctions even when a procedure tainted by a kickback is medically necessary and had a good patient outcome or when only one of many reasons for the arrangement is an illegal intent to seek or accept a kickback.[8] Good rationales do not legally co-exist with bad actions under the anti-kickback statute for well-defined policy reasons. The conflict cannot be legally justified by medical necessity or good patient outcomes and cannot be cured by promised but unproven healthcare savings outcomes. As the Senate Finance Committee aptly explained, *"even if the POD structure did lower healthcare costs, such an arrangement should not trump or justify violation of the anti-kickback statute or other Federal fraud and abuse laws."*[9]

Physician-owned entities pose the greatest risk for unlawful financial conflict of interest because of physicians' influence and leverage in both selecting products and using products in their own determined medical procedures. Physician involvement in hospital procurement negotiations and decisions over their own sponsored products is a scenario that presents grave risks to hospitals and physicians – risks that are not well managed by voluntary "model physician distributor guidance." The POD business model challenges a red line that has been established by government enforcement actions, government compliance guidance, industry compliance guidance and medical codes of ethics. The fraud and abuse concerns cannot be superficially deflected as competitor concerns by device companies that do not want to contract with PODs. The Senate Finance Committee June 2011 report soberly notes its substantial concern over PODs: "[a] number of legal and ethical concerns have been identified as a result of this initial inquiry into the POD models . . . We believe it is incumbent upon the Committee to work with OIG . . . to effectively address the patient and program risks presented by PODs."[10] The Report further notes that, *"[i]n effect, these entities act as a middleman entity that exists to give its physician investors the opportunity to profit from the sale and utilization of the medical devices they provide to hospitals."*[11]

The emergence of PODs as a business model undermines the rationale for the anti-kickback statute and associated government enforcement efforts. It also undermines a decade of compliance progress by hospitals, physicians, and device companies that has promoted public health and societal interests in curbing financial conflicts that are barriers to the public's access to affordable and high-quality healthcare. Transparency, disclosure, and the absence of self-interested physician influence on hospital procurement decisions are now hallmarks of good hospital business practices.

With a few notable exceptions, the hospital community has largely been absent in the POD debate, but may be the most important stakeholder with the most at legal risk. PODs undermine the hospital management's ability to control procurement objectively, manage tort liability, regulate its medical staff for compliance, and establish sound firewalls for financial conflict of interest. Doing business with PODs, moreover, is a *rebuttable* presumption of an illegal kickback to maintain or obtain physician procedures in the hospital that will always

require explanation, express oversight and objective justification by hospital management and Board of Director members. As set out in greater detail below, the OIG has noted that PODs "should be closely scrutinized under the fraud and abuse laws."[12] CMS has further noted that physician-owned entities raise concerns of "possible program or patient abuse" and *"serve little purpose other than providing physicians the opportunity to earn economic benefits in exchange for nothing more than ordering medical devices or other products that the physician-investors use on their own patients."*[13] Hospital CEOs and Boards have many challenges and internally reviewing POD arrangements and managing against the risk of anti-kickback and false claims exposure in light of demonstrable government concerns will prove exceptionally challenging.[14]

One challenge will be responding to government inquiries. As a result of the Senate Finance Committee's inquiry in June 2011, the OIG initiated a nationwide survey of hospitals that billed the Medicare program for spinal surgery procedures.[15] The OIG survey and audit of PODs has focused on hospital arrangements and operations. The survey questions seek information on a number of factors that may have influenced a hospital to purchase spinal implants from PODs, including: cost savings on devices, quality of devices, clinical effectiveness, and preference of surgeons.[16] The OIG sought to know what benefits hospitals may derive from the POD distribution model.[17] It also inquired whether a hospital had a policy in place that requires physicians to disclose any ownership in medical device companies and whether that information is provided to patients, and finally, what other services the hospital purchases from PODs.[18]

Also in response to the Senate Finance Committee's report, the OIG issued a letter in September 2011 which detailed the agency's plan to further evaluate and scrutinize "the recent proliferation of physician-owned distributorships."[19] Specifically, while declining to broadly address the Committee's question on the legality of this model, the Inspector General noted that:

> "the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute an illegal inducement under the Federal Anti-Kickback Statute. When evaluating the legality of such an investment, OIG would consider, among other factors, the terms under which a physician may invest in the entity . . . ; the actual return or projected return on the physician's investment; and the amount of revenues generated for the entity by its physician-investors."[20]

It is no surprise but hardly credible that POD proponents have asserted that the OIG letter effectively blesses certain PODs by not categorically declaring them illegal *per se.* This is a low bar for legally compliant arrangements and gives no comfort to physicians or hospitals assessing risk. Indeed, the OIG indicated that it will take enforcement action against physician-owned entities when appropriate, citing a July 2010 settlement involving the solicitation and receipt of remuneration from various hospitals by certain lithotripsy, urology, and prostate entities in exchange for the referral of Medicare beneficiaries controlled by the entities' physician-owners.[21] As a result, the OIG, while not yet providing further explicit guidance to industry, has well-positioned itself for future prosecution and litigation activities focused on the structure and operation of PODs for the contracting parties.

Given the OIG guidance, DOJ enforcement history and Congressional concern, hospitals and health systems, individually and collectively, have a strong incentive to assess PODs both for traditional fraud and abuse risk but also under enterprise risk management ("ERM") standards to assure that policies are in place that require transparency, disclosure and documented risk assessment and mitigation. In addition to fraud and abuse risks, there may be increased risks for class actions, negligence suits and competition challenges related to procurement arrangements with PODs.[22] Further, identification of physicians participating in PODs will be a simple task for government enforcers and plaintiffs' attorneys under the recently released Sunshine Act provisions.[23] Many PODs will likely be required to report physician ownership interests in these entities, and when such data becomes available to OIG or the public, interested parties will be better able to tie negative treatment outcomes to inappropriate physician financial incentives. In courts and administrative tribunals, this could be a compelling argument for imposing liability – not only against the individual physician whose judgment was impaired, but against the hospital or ASC that failed to avoid these types of arrangements and failed to adequately comply with federal guidance. As such, hospitals and similar entities that purchase from PODs or give privileges to physician-owners are at substantially greater risk, both civilly and criminally.

Some hospitals perceive this risk and have acted to implement clear policies for their medical staff. Providence Health & Services, a health system that operates in several jurisdictions, notably in 2012 approved a policy that prohibits generally the purchase of items and services from physician-owned vendors (POV) that are owned or controlled by physicians on their medical staff or their immediate family members, citing the OIG determination that such arrangements are highly suspect and subject to scrutiny.[24] Similarly, Hospital Corporation of America (HCA), the world's largest private operator of health care facilities in the world, recently enacted a policy that discourages any of its affiliates (both hospitals and free standing surgical centers) to conduct business with a POV.[25] Other hospitals have taken steps to prohibit or regulate PODs.

III. The Legal Question: PODs are Okay If Carefully Crafted...?

Advocates of physician-owned distributorships do not deny the anti-kickback implications of the various POD business models but argue that such business models may exist under the anti-kickback statute *if carefully crafted.*[26] Further, innovation and lower product costs are ostensibly promoted by PODs competing with the outdated industry distributor model that structures impenetrably high mark-ups of products sold by manufacturers.[27] Of course, the rise of POD formations by surgeons also coincides with a perceived unfairness in the decrease in Medicare reimbursement from federal health care programs in the last few years.[28] PODs may provide some surgeons with significant income tied directly to their medical determinations of surgical intervention and use of their own product in patient procedures.

In 2011, the American Association of Surgeon Distributors (AASD) was formed by physicians with POD ownership interests, "as a response to an expressed desire of surgeons, hospitals, and implant companies to have a means of qualifying ethical entities committed to positive patient outcomes and healthcare savings."[29] Its mission is to "promote healthcare

savings through the advancement of legally compliant surgeon owned distributorships."[30] The AASD lists standards and policies pertaining to transparency, disclosure and anti-kickback compliance.[31] Whether PODs demonstrably promote healthcare savings or not does not diminish the anti-kickback and other risks associated with the business model. In fact, it is not even the right question for entities committed to legally compliant arrangements.[32]

Advocates of the various physician-owned entity models argue, in addition to cost savings, that POD arrangements are no different than other arrangements such as physician-owned laboratories or ambulatory surgical centers (ASC). This argument is quite superficial. Physician-owned ASCs and laboratories are highly regulated for clinical and Medicare participation standards and part of the anti-kickback statute's safe harbor guidance. In contrast, POD arrangements have not been the subject of CMS or OIG programmatic review and are not regulated for Medicare participation. A Medicare beneficiary is unprotected as a patient in POD arrangements and likely is quite unaware of any voluntary professional standards or even disclosure of the POD arrangement. Business arrangements that are unethical and presumptively violative of the anti-kickback statute, moreover, are not likely to put patient notice and disclosure on the list of operational priorities. Of course, this point can be debated endlessly by lawyers but the OIG and Congress should ask: why should patients be at any risk from the foreseeable dangers of POD arrangements? Who speaks for the patients when their physician has a conflict of interest or kickback compliance issue associated with their care?

Advocates further argue that POD arrangements are no different than health care professional compensation from research, education, and product training activities funded by industry, which should be viewed as a similar impermissible conflicts of interest. Industry support for research and education activities are separately compensated *bona fide* activities wholly unrelated to the exercise of independent medical judgment. In contrast, POD arrangements are more akin to physicians getting a piece of the action from their own surgical self-referral by leveraging compensation for the product they choose to use in their own surgeries.

Physician ownership or investment interests in laboratory, durable medical equipment, home health, imaging equipment, hospitals, ambulatory surgical centers and pain clinics have a well documented history of successful enforcement actions for anti-kickback, regulatory and billing violations.[33] PODs similarly foster many of the same negative consequences associated with non-compliance with the anti-kickback statute: overutilization, unfair competition, conflict of interest, and billing irregularities. Such a relationship cannot be legally or ethically managed within the confines of the anti-kickback statute or codes of ethics that do not permit physicians to profit from their medical decisions related to patient care. The OIG has explained that, *"[g]iven 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," and that, "[w]e 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 [OIG] guidance."*[34]

The legal foundation for these concerns is not new. On its face, the federal anti-kickback statute prohibits the exchange of anything of value, cash or otherwise, for referrals, arrangements for furnish items or services, *or* for purchasing or recommending any good, facility, or service for which payment may be made under a Federal health care program.[35] Notably, the law punishes both sides of the transaction, both those offering or paying kickbacks and those soliciting or receiving them.[36] Fundamentally, for physicians, any remuneration for the exercise of medical judgment implicates the anti-kickback statute and that premise is a long standing judicial interpretation of its purpose.[37] Congress, of course, has authorized OIG over the years to issue a number of safe harbors which recognize specific business practices that will not be prosecuted under the anti-kickback statute if compliant with each and every requirement set forth in the safe harbor.[38] There is no safe harbor, however, for POD arrangements. All POD arrangements are legally unprotected under the anti-kickback statute.

Moreover, OIG has long been wary of so-called "sham transactions," arrangements that appear to be structured to meet the four corners of a relevant safe harbor, but are otherwise intended to transfer prohibited remuneration. Since 1994, OIG has noted that because of the ability to manipulate safe harbors in ways OIG has not contemplated, it seeks to prevent sham arrangements from receiving the protection of safe harbors.[39] The OIG has repeatedly emphasized that in reviewing an arrangement for compliance with safe harbor requirements:

> We will evaluate both the form and substance of arrangements. To be protected, the form must accurately reflect the substance. . . . If a sham contract is entered into, which on paper looks like it complies with these provisions, but where there is no intent to have the space or equipment used or the services provided, then clearly we will look behind the contract and find that in reality payments are based on referrals. Thus, these contracts would not be protected under these provisions. This same general principle would apply in determining compliance with other safe harbors.[40]

Accordingly, an arrangement predominately or solely designed to take advantage of surgeons referral leverage in exchange for ordering or arranging for the purchase of certain medical device products raises serious fraud and abuse concerns because at their core, their primary purpose is to enable physicians to earn additional profits for referrals. The parties' intent and the purpose of the statute rather than only the structure of the arrangements are the touchstones for the legal assessment.

While the anti-kickback statute requires a degree of intent (knowing and willful) to establish liability, recent laws including the Affordable Care Act, have effectively diminished that scienter requirement in the wake of conflicting case law on the statute's intent requirements.[41] In particular, the Affordable Care Act added a provision which states that specific intent or actual knowledge of an anti-kickback statute violation is no longer necessary for conviction; rather, a defendant need only intend to violate the law generally.[42]

Further, the purpose of the anti-kickback statute is to remove any financial element or incentive from a physician's medical advice or medical intervention for a patient as such advice

or intervention should be objective, independent and reliable. Of the anti-kickback statute, the former Inspector General of HHS, June Gibbs Brown, stated, *"[the law] is the guarantor of objective medical advice for federal [sic] health care program beneficiaries and helps ensure that providers refer patients based on the patients' best medical interests and not because the providers stand to profit from the referral."*[43] The OIG has also described why kickbacks are so harmful in the healthcare industry: "they can (1) distort medical decision-making, (2) cause overutilization, (3) increase costs to the federal health care programs, and (4) result in unfair competition by freezing out competitors unwilling to pay kickbacks."[44] While this Federal Register commentary analyzes contractual joint ventures ("CJVs") between physicians and other entities, the concerns of CJVs are heightened with PODs. For instance, the OIG explains that a physician entering into a CJV with a supplier would be "receiving in return the profits of the business as remuneration for its federal program referrals."[45] The only substantive difference is that in CJVs, physicians (or other referral sources) contract with an existing entity to provide inventory, while in PODs, physicians simply create an entirely new business to do the same thing.

Importantly, as discussed in the OIG's 1989 Special Fraud Alert, a "legitimate reason" to enter into a CJV is "raising necessary investment capital."[46] Consequently, ventures that do not seek to raise much investment capital are considered "questionable" or "suspect" because these ventures ". . . may be intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for these referrals."[47]. The OIG has affirmatively declared that "some of these joint ventures may violate . . . the anti-kickback statute."[48]

Notably, one of the aspects most troubling Congress and the OIG about PODs is that physician investment – and therefore risk – in these ventures is typically minimal, on the scale of hundreds to thousands of dollars. These physician-owned entities, then, fail to meet reasonable standards of legitimacy and raise nearly the same set of concerns as CJVs. In fact, in response to the initial proliferation of physician-owned entities in 2006, the OIG specifically referenced its 1989 guidance on joint ventures, explaining further that, *"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."*[49]

IV. OIG Advisory Opinions on Anti-Kickback Compliance Do Not Support POD Models.

Over the years, the OIG has released a number of advisory opinions concerning potential improper relationships and ventures between physicians and other health care entities which may violate the anti-kickback statute.[50] Recently, the OIG issued Advisory Opinion 12-01 (2012), which blessed a group purchasing organization ("GPO") purchasing supplies on behalf of participants who were owned by the same parent company as the GPO.[51] Citing the GPO safe harbor regulations, the OIG noted that, while concerned about the risk of abuse and waste associated with GPOs, this arrangement had put in place, "a number of protections to guard against these negative results."[52] Specifically, the OIG found that the GPO was not incentivized to increase costs for two reasons: first, any administrative revenues in excess of the GPO's costs

were passed back to the participants, who had to report in turn these amounts as rebates/discounts.[53] Further, the GPO was open to both affiliated participants (those owned by the same parent) and un-affiliated participants (those not associated with the GPO or parent company at all).[54] The OIG, therefore, found that the GPO was incentivized through competitive forces to seek the lowest prices possible for its members. PODs, on the other hand, are often restricted to specific physician groups with privileges at only one or two hospitals. Likewise, PODs are not typically set up to return revenues to purchasers as discounts, but rather return those amounts to the physician owners as profits. This incentive structure fails to put in place the protections that the OIG found necessary to reduce anti-kickback risk.

The concern with physician owned entities and investors was further emphasized in OIG Advisory Opinion 11-15 (2011), where the OIG declined to support physician investors in a pathology laboratory management company on the basis that the return on investment and compensation violated the anti-kickback statute, notwithstanding suggested compliance safeguards.[55] Similarly, in Advisory Opinion 04-17 (2004), the OIG analyzed a proposed arrangement whereby a physician group would own and operate a pathology laboratory.[56] The OIG concluded that this arrangement raised serious risks and could be prosecuted under the anti-kickback statute. Of particular importance to PODs, the OIG explained that:

> . . . even if each of the individual agreements making up the Proposed Arrangement could satisfy the applicable safe harbor conditions under the space and equipment rental safe harbors and the personal services and management contracts safe harbor, the safe harbors would only protect the remuneration paid by the Physician Groups to the Requestor for actual services rendered or space or equipment rented. In the Proposed Arrangement, a *Physician Group's retained profit from the pathology services would not be protected by any safe harbor*.[57]

Because of the unique ability of a physician to direct referrals (or purchase items) and the financial incentives involved, profits derived through an ownership interest in an upstream supplier or other ancillary service remain troubling for the OIG.

Several other Advisory Opinions issued by OIG throughout the years illustrate the legal problems with PODs and the significant risk of OIG sanctions associated with them. In Advisory Opinion 06-02 (2006), for instance, the OIG analyzed two proposed programs by which a durable medical equipment (DME) company would offer delivery management services to physicians.[58] Under the proposed arrangements, the physicians' financial incentives would directly align with those of the DME company, a fact the OIG found troubling: "[t]he proposed program offers physician practices the potentially lucrative opportunity to expand into the DME and orthotics business with little or no business risk and to retain a share of profits from DME and orthotics business generated by the physician practice."[59] Even with Federal health care programs carved out of the arrangement, the OIG still held that this program would generate unprotected, prohibited remuneration.[60] This analysis is directly comparable to PODs, which are offering physicians those same lucrative opportunities to expand into upstream markets, except under the POD model, physician distributors are not even bothering to carve out federal business.

Notably, the OIG further explained:

> [t]he only significant difference between the first proposed program and the problematic contractual joint ventures identified in the Special Advisory Bulletin is the absence of Federal health care program business. The "carve out" of Federal business is not dispositive, however, on the question of whether the proposed program potentially violates the anti-kickback statute. . . . Thus, we cannot conclude that there would be no nexus between the *potential profits physicians may generate* from the private pay DME and orthotics business and prescriptions of the Requestor's products for Federally insured patients.[61]

Clearly, then, even if POD proponents attempt to carve Federal health care program business out of their model, the OIG would still recognize the inherent threat of physicians motivated by profit considerations, medically unnecessary services, and overutilization.

Even more recently, in Advisory Opinion 11-08 (2011), the OIG identified significant program risk stemming from physician financial interest in ancillary service industries: "[a]rrangements that closely tie DME suppliers to IDTF staff members, physicians with financial interests in the IDTFs who are in a position to prescribe, and patients . . . are particularly susceptible to problematic marketing schemes."[62]

Given the significant sway physicians have not only on patients, but also on hospitals, certain arrangements can cause those physicians to refer or recommend items and services contrary to their independent medical judgment.[63] This is often known as "white coat" marketing, which the OIG describes as a practice in which "a physician or other health care professional is involved in the marketing activity . . . White coat marketing is closely scrutinized under the anti-kickback statute because physicians . . . are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services . . .".[64] The risks of fraud and abuse when physicians are misincentivized are significantly compounded.[65]

Other OIG Advisory Opinions further address the parameters of physician ownership or investment incentives and the ability to refer, all suggesting that arrangement elements of various POD models are legally problematic. For example, in Advisory Opinion 08-20 (2008), an arrangement in which a DME company was given access to hospital staff and patients avoided the anti-kickback statute prohibitions because no remuneration flowed back to the hospital and physicians capable of making referrals.[66] However, if physicians are also owners of the medical products, as the POD model would allow, the anti-kickback statute will be implicated, since referrals or recommendations will flow from the physicians to the suppliers and remuneration, vice versa, will flow from the suppliers back to those potential referral sources, in the form of profits and return on investment.[67] Such a practice appears contrary to the OIG's guidance.

Furthermore, the OIG has noted in Advisory Opinion 03-12 (2003) that one important way to reduce or mitigate the risk of fraud and abuse in joint ventures is to ensure that physician investors are not referral sources, thus limiting the potential for abusive, financially-motivated

referrals.[68] Unfortunately for its proponents, however, the POD model crumbles without physician investors being the primary, and in many cases the only, source of referrals (defined broadly under the anti-kickback statute) to the POD entity. In addition, OIG regularly requires that any return on investment be directly proportional to the percentage of capital investment, and therefore risk, actually contributed by the physician investor.[69] Many PODs make the promise of a low-risk, high-reward system and require little legitimate capital contribution.

Suppliers can also mitigate the risk of fraud and abuse through providing freedom of choice to patients when selecting an ancillary item or service provider.[70] In Advisory Opinion 02-04 (2002), the OIG blessed an arrangement whereby a supplier would provide a list of local competitors to potential referral sources and encourage distribution of the list to patients deciding on a supplier.[71] The OIG, in addition, also required that the DME provider not rent a "consignment closet" nor make any payment whatsoever to its potential referral sources.[72] Under many POD models, moreover, patients are not informed when undergoing certain treatment that a POD is the supplier of the applicable items or services. Instead, hospitals are generally making these decisions, and may be subject to significant leverage from surgeons also operating PODs.

The OIG has consistently warned against physicians benefiting financially from referrals to ancillary service providers. In Advisory Opinion 99-13 (1999), the OIG stated that, "[n]or are we able to exclude the possibility that the physicians may be soliciting improper discounts on business for which they have the opportunity earn money in exchange for referrals of business for which they have no opportunity, but for which the laboratories can receive additional revenue."[73] In this scenario, physicians were backing into the revenue of laboratories because they couldn't bill directly for laboratory services themselves.[74] Similarly, in the POD model, physicians don't have the opportunity to earn money from arranging for certain surgical hardware and other supplies unless they have an ownership interest in the relevant supplier. Of course, when physicians obtain such ownership interest, the data shows that procedures, and the associated costs of those procedures, increases substantially.

V. Physician Self-Referral Prohibitions Apply to PODs? Yes, They Do.

Separate from the anti-kickback statute, the Federal prohibition against physician self-referrals (commonly called the "Stark Law") may also create a significant compliance risk for hospitals participating in POD relationships.[75] The Stark Law was originally developed to combat the inherent conflict of interest that develops when a physician, as the gatekeeper to medical utilization, maintains a financial relationship with the entities to which he or she refers a patient. In 1989, as a prelude to and support for the passage of the Stark Law, the OIG conducted a statistical study of the effects of self-referrals by physicians and found that physician financial interest played a major role in which services patients received, how much of those services were received, and who provided the services.[76] In its report to Congress, the OIG concluded that "patients of referring physicians who own or invest in independent clinical laboratories received 45 percent more clinical laboratory services," resulting in over $28 million in bills to Medicare in 1987.[77] Unsurprisingly, these numbers led Congress to quickly enact the bill.

After the passage of the Stark Law, CMS began promulgating proposed regulations for comment. As CMS (known as the Health Care Financing Administration at the time) specifically noted:

> We believe that [the Stark Law] was enacted out of concern over the findings of various studies that physicians who have a financial relationship with a laboratory entity order more clinical laboratory tests for their Medicare patients than physicians who do not have a financial relationship. There have been at least 10 studies conducted over the past few years that concluded that patients of physicians who have financial relationships with health care suppliers receive a greater number of health care services from those suppliers than do patients generally.[78]

The Stark Law "*reflects the Congress' unmistakable intent to recognize and accommodate the traditional role played by physicians in the delivery of ancillary services to their patients, while constraining the abuse of the public fisc that results when physician referrals are driven by financial incentives.*"[79] It is these illegitimate financial incentives that make PODs a significant compliance risk. CMS has further noted that the Stark Law was specifically enacted to "*address over-utilization, anti-competitive behavior, and other abuses of health care services that occur when physicians have financial relationships with certain ancillary services entities to which they refer Medicare or Medicaid patients. . . . Overutilization increases program costs because Medicare (or Medicaid) pays for more items or services than are medically necessary.*"[80] Even taking POD proponents' word at face value that this model reduces the price of each device purchased, it ignores the larger problem that these items might not be necessary in the first place.

Legally, the Stark Law prohibits a physician from making a referral to an entity for "designated health services" (DHS) if that physician (or his immediate family) has a financial relationship with the entity, unless an exception applies.[81] The term "referral" is defined broadly to include any request or order by a physician for DHS or a physician certifying the need for DHS.[82] The term also includes the establishment of a plan of care by a physician which includes the provision of DHS.[83] As well, financial relationship is also broad, including not just ownership, equity, or debt situations, but also direct and indirect compensation arrangements, whereby a DHS entity provides certain supplies, services, or other valuable consideration as payment for a referral.[84]

While there is debate on the scope of Stark physician referral compliance as it relates to physician-owned entities in medical products, it should be assumed that POD physicians are making referrals for certain designated health services (inpatient and outpatient hospital services) to an entity in which they have a financial relationship (contracted hospital). Proponents of PODs argue that the indirect compensation exception may apply to shield the referrals from the scope of Stark.[85] Here, again, there is substantial doubt and high risk in assuming any Stark exception applies. The indirect compensation exception does not apply if there is any anti-kickback compliance violation and arguably is not applicable at all. The financial penalties for violating the Stark law are substantial. Accordingly, hospital management and hospital Boards will take a very large risk to simply presume no Stark and consequent False Claims Act potential liability

exists with POD arrangements. Assuming the Stark law has no application to hospitals doing business with PODs is legally reckless.

VI. A Survey of Hospital Policies Show A Steady and Growing Concern Over PODs.

While the federal government has repeatedly noted its growing concern over the questionable incentives inherent in PODs, not all hospitals have unequivocally stated their opposition to doing business with these entities.[86] In fact, some facilities, cognizant of the risks associated with PODs, have nevertheless entered into purchase agreements with physician-vendors.[87] Still, a large and steadily increasing number of hospitals are revising their policies and procedures to make it clear that their organization will not conduct business with physician-owned entities.

Noting concerns from the Senate Finance Committee and the OIG of PODs and related entities, which the government suggests may be illegal under the anti-kickback statute, major hospital chain HCA has implemented a broad and restrictive policy against purchasing any items or services for use in patient care from physician-owned entities.[88] The HCA policy applies to approximately 160 hospitals and 110 ambulatory surgical centers (ASCs) across the United States, as well as HCA's home health agencies, physician practices and other service centers. HCA's policy references the specific concerns of the OIG and the factors identified by the OIG which may result in a problematic relationship. It also acknowledges the "One Purpose Test" of the anti-kickback statute, whereby if any one purpose of an arrangement is to generate improper referrals or remuneration, the conduct is in violation of the statute, regardless of any number of positive off-setting purposes of the arrangement.

In addition, given its size, HCA appears to have structured its procedures so that it can protect itself from unwittingly doing business with a POD. The organizations' procedures require that purchases be made at fair market value for any and all vendors, and should a vendor be found to be a physician-owned entity during the purchasing process, the purchase must be specifically reviewed and approved by HCA's counsel.

Likewise, other facilities have adopted similar policies, including Providence Health & Services, Tomball Regional Hospital, and Martin Memorial Hospital.[89] In the past two years, each of these facilities has identified the risks associated with PODs and affirmatively decided to avoid doing business with them. Scott Samples, spokesman for Martin Memorial, explained his facility's rationale: "[w]e were looking at the potential legality of [PODs] and trying to determine what we thought was in the best interests of Martin Memorial and decided to be very proactive and not participate in PODs."[90]

Martin Memorial's policy bans entering into purchasing agreements with physician-owned intermediaries where physician ownership is in excess of 5% or the physician investor is affiliated with the hospital.[91] Tomball, which was recently acquired by Community Health Systems (see below), maintains a near-verbatim policy as HCA, noting the risk identified by OIG and discouraging the purchasing of any items or services from PODs.[92] Providence explains that due to the national scrutiny of the relationship between hospitals and physician-owned entities,

no Providence-affiliated entity may purchase items or services from a POV where the POV owners or operators are physicians associated with Providence.[93] Memorial Hospital in Colorado states that it will not purchase any medical devices requested by a physician if that physician is receiving payment from the manufacturer of the device, unless such payment is reasonable compensation associated with a clinical trial.[94]

Each of these health systems has taken specific affirmative steps to distance themselves and their purchasing practices from the specter of PODs. As the spokesman for Martin Memorial expressed, hospitals are not eschewing PODs for the fact that they do not represent a potential economic benefit for hospitals, but rather that any derived benefit is far outweighed by the substantial and apparent legal and compliance risks associated with physician-owned entity relationships.

Other hospitals have strong conflict of interest policies that while not directed at PODs would appear to prohibit such arrangements. Community Health Systems, for example, one of the largest hospital chains in the country with 120 locations in 28 states, explains in its Code of Conduct that:

> [e]mployees should not have any personal interests or outside activities that are incompatible, or appear to be incompatible, with the loyalty and responsibility owed to the organization. Employees must avoid any outside financial interest that might influence decisions or actions in the performance of their duties for the organization . . . Potential conflicts of interest might include: A personal or family interest in an enterprise that has a business relationship with the organization or a facility.[95]

Other hospitals have restricted and regulated associations with PODs, or have implemented broad conflict of interest policies ostensibly limiting such associations without stating so outright. For instance, University of Colorado Hospital requires that all vendor representatives disclose any financial relationships physicians or staffs of the hospital have with the representative's company.[96] Methodist Le Bonheur Healthcare, a regional system in Tennessee, places a duty on its employees to avoid conflicts of interest where their business decisions could be or appear to be influenced.[97] Importantly, many policies like Methodist's contemplate and outlaw even the appearance of impropriety.

Cognizant of the importance of a reputation for objectiveness in medical decision making and compliance with legal standards that many patients expect, hospitals have enacted policies intended to bolster such a reputation. For instance, Hardin Memorial Hospital in Kentucky and Hilo Medical Center in Hawaii have put policies into place concerning conflicts of interest with vendors, as well as policies calling for all purchasing to be completed in a commercial reasonable manner without exceeding what is necessary to accomplish legitimate business purposes.[98] However, while these policies are seemingly broad and sufficiently prohibitive, they may allow PODs when examined critically.

While few hospital systems have outright announced their association with a POD, it is believed that over two hundred hospital entities may be currently doing business with physician-owned companies. Palomar Pomerado Health in California narrated its internal review and approval process of a purchase agreement with a POD through meeting minutes and quarterly reports.[99] Cognizant of the substantial risk involved, even to the point of requiring any agreement to contain a cease and desist clause should PODs officially become illegal, the Board Finance Committee of Pomerado approved of entering into a purchase agreement and was actively "supportive of the business reasons behind PODs."[100] Of course, it is not usual for parties to have the right to cancel an illegal agreement when it is "officially" determined to be illegal. Whether the POD arrangement with Palomar meets recommended compliance safeguards is unknown.

VII. PODs by the Numbers: What Does the Data Really Show Us?

Much of the POD advocacy eschews lofty ideals of medical ethics and anti-kickback compliance, preferring to argue the numbers and costing savings of PODs. Notably, despite the arguments and limited unverifiable summary data from certain self-interested physicians groups and the American Association of Surgeon Distributors (AASD), there is no objective data to support a cost-saving rationale for physician owned entities that exist solely to provide unearned financial returns to physicians from product sales related to procedures performed predominantly in the hospital setting. Even if cost-savings could justify the financial conflict of interest, the public cannot realistically expect such cost-saving data to ever materialize if over 40 years of health care fraud enforcement experience is any guide.

The available data has clear bias. AASD, for example, conducted a cost study through the entity owned by the AASD board members, who are all orthopedic surgeons in California, and three area hospitals.[101] This study, which was conducted from May 2006 to May 2008, examined the potential cost savings a hospital could realize through a purchasing relationship with a POD for certain orthopedic implants, including screw and plate systems, knee replacements and hip replacements. The study ultimately concluded that hospitals, when purchasing these items, could save up to 34% of the cost of purchasing through traditional channels. Specifically, AASD examined its sales over the two year period, totaling $2,058,217, and compared that to the projected cost of purchasing "equivalent" implants at the three hospitals' average rate, which was $3,099,192. AASD thereby concluded that the POD structure saved $1,040,974 over the time period.[102]

Conversely, a study examining spinal fusion treatments concluded that increases in invasive and potentially medically unnecessary surgeries coincide with, and likely result from, the rise in physician-owned entities. This data is consistent with studies performed in other areas such as imaging centers owned by physicians.

In this study, cited by the Senate Finance Committee, researchers found that utilization rates of a certain medical procedure and associated medical device jumped 360% in one year

after surgeons formed a POD.[103] Analysts reviewed spinal fusion and refusion data from a certain hospital from 2002 to 2006; in 2005, spinal surgeons at the hospital decided to form a POD to sell the screws and rods used in these procedures. Prior to 2005, spinal refusions (where the first fusion fails) were steady at approximately 15-17 per year. In 2005 and 2006, surgeons associated with the POD performed 78 and 69 spinal refusions respectively. This was not associated with a similar rise in the number of initial spinal fusions, and, in fact, the rate of failure for initial spinal fusions (requiring refusion) increased from 2% to 11% in 2005.

Researchers pointed to two possible reasons for this sudden increase: first, that the refusions increased as a result of inferior quality screws and rods used during the first surgery that were sold by the POD, instead of the implants previously used which were ostensibly more effective; second, that the surgeons were performing medically unnecessary procedures in order to increase the use of their device and subsequent return. In spinal fusions, it is often the case that additional fusions will have to be done in the future. When this happens, the study supposes, instead of simply affixing the new rod and screws to the existing implant, the surgeons take out the original implant from competing manufacturers altogether and implant an entirely new device from their own company.

The other studies, while addressing costs associated with PODs, are not independent, particularly the AASD study finding decreased costs as a result of physician ownership of the vendor. There, the researcher and the subject were the same entity, creating an obvious conflict and likely damaging the validity of the data obtained. While the POD did decrease costs relative to the hospital's average costs for similar items, the entity was acutely aware of its role as a test subject. Moreover, the study did not address whether any of the $2,058,217 in fees was for items that were not medically necessary, which raises an important point: the concern with PODs is not only that the individual price of each item will rise, but rather that the sheer number of items and related procedures to implant those items will increase, thus affecting both healthcare costs and the harm and suffering of patients undergoing unnecessary medical treatment. The AASD study, moreover, does not demonstrate compliance with AASD voluntary compliance standards or identify whether any other legally recommended compliance standards were implemented.

VIII. Conclusion

Physician-owned entities in the medical products arena present the same long-standing medical conflict of interest and anti-kickback concerns that always exist when physicians want to achieve additional financial gain in connection with medical procedures they have determined must be performed for their patient. Structuring economic advantage for product sales from the exercise of medical judgment is "any remuneration" under the anti-kickback statute. PODs do not exist to remedy the implant marketplace or to assure health cost savings for federal health care programs anymore than physician owners and investors in imaging centers, laboratories or lipthoscopy clinics do. But, even if those ambitions could be achieved, they will not be justified by profits to physicians from medical conflicts of interests or improper financial arrangements with hospitals and device companies. Government policy makers and enforcers should recognize that the POD controversy is not about dueling data on implant costs. The public interest at risk is inherently far greater than the implant cost debate and cannot be deflected.

Hospitals should consider that POD arrangements substantially undermine compliance and risk management functions. Device companies that enter into POD arrangements are similarly challenged to maintain the extraordinary compliance enhancements that have occurred industry wide in the last several years in managing ethics, conflicts of interest and anti-kickback compliance. What hospital or device company CEO or member of a Board of Directors is willing to bet that any particular POD arrangement is fully compliant with the anti-kickback statute, or engage in oversight efforts to guarantee such compliance? What insurer wants to insure the risk hospitals face from POD arrangements in negligence and product liability situations?

Finally, while Congress may act, the enforcers need to speak with greater particularity to the fraud and abuse concerns that correspond specifically to the various types of POD arrangements with the recognition that the Achilles'' heel of these arrangements is physician ownership of the medical products entity. The OIG is entrusted with the role of prevention and education under the seminal 1996 HIPAA fraud and abuse program and has achieved in this role an exceptionally credible voice in promoting health industry fraud and abuse compliance. Its efforts to address POD anti-kickback compliance concerns, including its limited hospital survey, are critically important and appreciated. Yet, more is needed, particularly as hospitals, physicians and the health industry grapple with new business models under the Affordable Care Act.

Referring to prior guidance, now decades old, and articulating careful lawyerly pronouncements of "it depends" in response to hard questions on the legitimacy of PODs is not sufficient guidance for this particular type of arrangement. The welfare of patients and the potential negative impact on Federal health care programs are reasons enough not to simply wait to see what happens next.

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[1] The Who (1971).

[2] In the physician administered drug arena, marketing the spread has been prosecuted as illustrated by the TAP Pharmaceutical Investigation that resulted in criminal prosecution of the company and several physicians in 2002; in the laboratory and pathology arena, physician compensation, investment and ownership has been disapproved in several OIG Advisory Opinions and prosecuted by the U.S. Department of Justice in numerous investigations in Florida and other jurisdictions since the 1990s; in the health care imaging sector, physician over-utilization patterns have been documented and such arrangements even banned in some jurisdictions.

[3] *See* Swedlow *et al.*, *Increased Costs and Rates of Use in the California Workers' Compensation System as a Result of Self-Referral by Physicians*, 327 New England J. of Med. 1502 (1992 (finding that 38% of MRI testing ordered by a "self-referring physicians" group was medically inappropriate and noting trends in Florida and California of high outlier rates of utilization of imaging services in centers owned by physicians).
[4] S 863, 2011-2012 Leg., Reg. Sess., §6(c) (Ca 2012).
[5] *See* Steinmann *et al.*, Surgeon Ownership in Medical Device Distribution: Economic Analysis of an Existing Model (2009), *available at* http://www.hoganlovells.com/files/upload/Feb2009_SurgeonOwnershipDevices.pdf (hereinafter "Steinmann Study") (noting that PODs provide "a more fair compensation to surgeon" and that traditional supply methods "exert a negative influence on surgeon reimbursement.").
[6] Association for Medical Ethics, *Bias – Physician Owned Distributorship (POD)*, http://www.ethicaldoctor.org/physician-owned-distributorship (last visited Jan. 15, 2013).
[7] *See* Social Security Amendments of 1972, Pub. L. 92-603, 86 Stat. 1329 (1972).
[8] *See, e.g.*, *U.S. v. Greber*, 760 F.2d 68, 69 (3rd Cir. 1985), cert. denied, 474 U.S. 988 (1985) (setting forth the "one purpose test").
[9] Attachment A, Minority Staff of S. Fin. Comm., 112th Cong., Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight 4 (Comm. Print 2011).
[10] *Id.* at 8.
[11] *Id.* at 2.
[12] Letter from Vicki Robinson, Chief, Industry Guidance Branch, Office of Counsel to the Inspector General, Office of Inspector General (Oct. 6, 2006), *available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/GuidanceMedicalDevice%20(2).pdf (hereinafter 2006 OIG POD Letter).
[13] Medicare Program; Proposed Collection of Information Regarding Financial Relationships Between Hospitals and Physicians, 73 Fed. Reg. 23528, 23694 (Apr. 30, 2008).
[14] While hospital management and executives may see short term benefits through association with PODs, boards of directors must actively monitor and assess risk and compliance for the institution. *See In re* Caremark Int'l, Inc. Derivative Litig., 698 A.2d 959 (Del. Ch. 1996); *see also* United States *ex rel.* Piacentile v. Merck & Co, Inc., No. 00-cv-00737 (E.D. Pa. final settlement announced Oct. 23, 2006). Moreover, recent Corporate Integrity Agreements entered into by the OIG have imposed substantial affirmative duties on board members to ensure oversight of compliance operations in health care entities.
[15] *See* Nina Youngstrom, *OIG Noses Around Hospital Purchases of Spinal Implants from MD-Owned Entities*, AISHealth (Oct. 29, 2012), http://aishealth.com/archive/rmc102912-02 (highlighting aspects of the OIG letter initiating the POD survey).
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] Letter from Daniel Levinson, Inspector General, Office of Inspector General (Sept. 13, 2011), *available at* http://www.finance.senate.gov/newsroom/ranking/download/?id=eceb4bb0-c3da-4449-b8b3-d5715c63ef4e
[20] *Id.* at 2.
[21] *Id.*
[22] This risk is substantially increased by the requirements that PODs publically report physician ownership interests and profits and payments under the "Sunshine" law and regulation. 42 U.S.C. §1320a-7h(a)(1)(A) *et seq.*; 42 C.F.R. §403.904 *et seq.*
[23] *Id.*
[24] *See* Attachment B, Hospital PODs Policy; *see also* Providence Health & Services, *Purchases from Physician-Owned Intermediaries/Distributors* (Feb. 9, 2012), *available at* http://www2.providence.org/phs/integrity/Documents/PROV-ICP-723%20-%20Purchases%20from%20Physician-Owned%20Distributors.pdf.
[25] *See* HCA, *Physician-Owned Vendor Relations* (Nov. 1, 2012), *available at* ec.hcahealthcare.com/CPM/LL027.doc.

[26] *See* Hooper Lundy & Bookman, *HLB Health Law E-Alert* (Sept. 22, 2011), *available at* http://health-law.com/wp-content/uploads/2011/11/POD_E-Alert_9-11.pdf (arguing that a "properly structured and operated" POD would not violate federal laws).
[27] *See* Steinmann Study, *supra* note 5 (explaining that current distribution methods are inefficient, far too costly, and lead to escalations in orthopedic implant prices).
[28] *Id.* ("[t]he costs of orthopedic implants continue to rise, over 13% annually, in a market in which hospital profit and physician reimbursement continue to decline.").
[29] American Association of Surgeon Distributors, http://aasdonline.org/ (last visited Dec. 28, 2012).
[30] *Id.*
[31] AASD Standards and Criteria for Surgeon Owned Distributor Membership:
a.) Distributorship must maintain a business structure consistent with all Federal Stark and Anti-Kickback statutes; b.) Distributorship must demonstrate merit by proving to be the lowest average cost vendor of like implants during a comparable contract period; c.) Annual price increases must not exceed 3% above the consumer price index (CPI); d). Distributorship must demonstrate adherence to the AASD Product Evaluation Policy; e.) Distributorship must demonstrate adherence to the AASD Employee Training Requirements; f.) Distributorship must demonstrate adherence to the AASD Disclosure Policy; g.) Distributorship must demonstrate investment risk and compliance with the AASD Investment and Distribution Policy; h.) Distributorship must submit utilization data annually and is subject to audit; i.) Distributorship must not leverage referrals to any hospital or surgery center; j.) Distributorship must be a legitimate free standing stocking Distribution Company with employees, contracts, address, business license and insurance.; k.) Distributorship must have written contracts with hospitals and vendors for at least one year; l.) Distributorship pricing must not vary between hospitals.
[32] *See* Truhe, *Should Surgeons Be Encouraged to Take An Active Role In the Implantable Medical Device Supply Chain Through Physician Owned Entities?*, Food and Drug Policy Forum, Vol. 2, Issue 10 (May 2012). Mr. Truhe is the Senior Vice President and General Counsel for PDP Holdings, a physician-owned entity that seeks financial arrangements with industry for the use of device products in the physician investor surgeries. He argues a compliant physician-owned entity, in compliance with OIG anti-kickback guidance, would have the following minimal structure in place: No joint venture with a manufacturer or distributor; substantial capitalization, including the purchase of inventory and cost of case managers; investment return strictly proportional to investment; case support by personnel uninvolved in product sales; universal inventory of implants available for surgeon use with financial considerations excluded; surgeons use other company products when their product is not available; hospital product negotiations are conduct by entity management, not entity surgeons; hospital compliance program involved to assure transparency; utilization reviews; demonstrated cost savings; and, robust compliance training for surgeons. It is doubtful any physician owned entity meets this complex structure. Other advocates suggest that such arrangements must also be for fair market value, written agreement and prices that are equal or better than non physician owned vendors. *See* Oppenheimer, Presentation, *Physician-Owned Distributors: To Be or Not to Be?* American Health Lawyers Association (Sept. 18, 2012).
[33] Over 25 states, including California, Massachusetts, Maryland, Texas, and Florida, presently ban physicians from self-referring patients to diagnostic imaging centers in which they have an ownership interest, even if those patients are not covered by a Federal health care program. *See* Mark Friedman, *Doctor-Owned Imaging Center Raises Eyebrows,* Arkansas Business (08/25/08) *available at* http://www.arkansasbusiness.com/article/41927/doctor-owned-imaging-center-raises-eyebrows?page=all.
[34] 2006 OIG POD Letter, *supra* note 12.
[35] *See* Criminal penalties for acts involving Federal health care programs, 42 U.S.C. § 1320a-7b(b) (2012).
[36] *Id.*
[37] *See U.S. v. Hancock,* 604 F.2d 999, 1001 (7th Cir. 1979) (physician decision to refer lab work for handling fees is basic element of corruption: "the potential for increased costs to the Medicare-Medicaid system and misapplication of federal funds is plain, where the payments for the exercise of such judgments are added to the legitimate cost of the transaction"). *See also Hanlester Network v. Shalala,* 51 F.3d 1390 (9th Cir. 1995) (Congress introduced the broad term "remuneration" in the 1977 amendment of the statute to clarify the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid. H.R.Rep. No. 95-393, Pt. II, 95th Cong., 1st Sess. 53 *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056. The phrase "any remuneration" was intended to broaden the reach of the law which previously referred only to kickbacks, bribes, and rebates. The phrase "to induce" in § 1128B(b)(2) of

the Act connotes "an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.").
[38] *Id.*
[39] 59 Fed. Reg. 37202 (July 21, 1994).
[40] 64 Fed. Reg. 63518, 63530 (Nov. 19, 1999) (citing 56 Fed. Reg. 35972).
[41] *Compare* Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(2), 124 Stat 119 (2010) *with Hanlester Network*, 51 F.3d 1390, 1400 (9th Cir. 1995) *and Ratzlaf v. United States*, 510 U.S. 135 (1994).
[42] Affordable Care Act § 6402(f)(2).
[43] Press Release, Inspector General Announces Eight New Anti-kickback Statute Safe Harbors, Office of Inspector General, Nov. 18, 1999 *available at* https://oig.hhs.gov/fraud/docs/safeharborregulations/safenr.htm.
[44] 68 Fed. Reg. 23148, 23148 (Apr. 30, 2003).
[45] *Id.*
[46] 59 Fed. Reg. 65372, 65373-74 (Dec. 19, 1994).
[47] *Id.*; *see also* 56 Fed. Reg. 35969 (July 29, 1991) (noting that physician ownership increases the likelihood that a joint venture's primary purpose is to control a stream of referrals).
[48] 59 Fed. Reg. 65373-74.
[49] 2006 OIG POD Letter, *supra* note 12.
[50] *See* Attachment C, OIG Advisory Opinions Relevant to PODs (describing the conclusions and holdings of various advisory opinions issued by the OIG over the past decade which restrict or entirely condemn the use of certain joint venture models).
[51] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 12-01 (2012).
[52] *Id.* at 9.
[53] *Id.* at 9-10.
[54] *Id.* at 10.
[55] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 11-15 (2011).
[56] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 04-17 (2004).
[57] *Id.* at 7.
[58] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 06-02 (2006).
[59] *Id.* at 6.
[60] *Id.* at 1-2, 7.
[61] *Id.* at 7.
[62] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 11-08 at 6 (2011).
[63] *Id.*
[64] *Id.*
[65] *Id.*
[66] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 08-20 (2008).
[67] *See id.* at 5 (noting that despite "serious concerns," remuneration and referrals flow the same way).
[68] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 03-12 at 6 (2003).
[69] *Id.* at 7.
[70] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 02-04 at 2, 3 (2002).
[71] *Id.*
[72] *Id.*
[73] Office of Inspector General, Dep't of Health and Human Services, Advisory Opinion No. 99-13 at 5 (1999).
[74] *Id.* at 2, 5.
[75] *See* 42 U.S.C. § 1395nn.
[76] Office of the Inspector General, U.S. Dep't of Health and Human Services, Financial Arrangements Between Physicians and Health Care Businesses, OAI 12-88-01410 (May 1989).
[77] *Id.* at iii.
[78] Physician Financial Relationship with, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements, 60 Fed. Reg. 41,914, 41,923 (Aug. 14, 1995) (codified at 42 C.F.R. pt. 411).
[79] 66 Fed. Reg. 856, 862 (Jan. 4, 2001).

[80] 69 Fed. Reg. 16054, 16124 (Mar. 26, 2004).
[81] 42 U.S.C. § 1395nn(a).
[82] *Id.* at § 1395nn(h)(5)(A).
[83] *Id.* at § 1395nn(h)(5)(B).
[84] *Id.* at § 1395nn(a)(2).
[85] 42 C.F.R. §411.357(p). *See also United States ex. rel Drakeford v. Tuomey Healthcare System Inc.*, No.10-1819 (4th Cir. 2012) (considering the scope of the Stark law and the application of the indirect compensation exception).
[86] *See generally* Attachment B, Hospital PODs Policy.
[87] *Id.*
[88] *See* HCA, *Physician-Owned Vendor Relations* (Nov. 1, 2012), *available at* ec.hcahealthcare.com/CPM/LL027.doc.
[89] Attachment B, Hospital PODs Policy.
[90] Rep. on Medicare Compliance Vol. 20 No. 22 at 2 (June 20, 2011).
[91] Martin Memorial Health Systems, Inc., *Physician-Owned Intermediaries* (May 6, 2011), *available at* http://www.hoganlovells.com/files/Uploads/Documents/Hospital%20Policy%20on%20Physician%20Owned%20Intermediaries.pdf.
[92] Tomball Regional Hospital, *Physician-Owned Vendors* (July 2010), *available at* http://www.tomballregionalmedicalcenter.com/PhysicianPortal/Documents/phy-OwnedVendors.pdf.
[93] Providence Health & Services, *Purchases from Physician-Owned Intermediaries/Distributors* (Feb. 9, 2012), *available at* http://www2.providence.org/phs/integrity/Documents/PROV-ICP-723%20-%20Purchases%20from%20Physician-Owned%20Distributors.pdf.
[94] Memorial Health System, *Business Transactions Policies*, *available at* http://www.memorialhealthsystem.com/wps/wcm/connect/bcb5f20040f5853da456ff74e1e6f338/MHS_BusinessTransactionPolicyHandbook.pdf?MOD=AJPERES&CACHEID=bcb5f20040f5853da456ff74e1e6f338 (last visited Dec. 28, 2012).
[95] Community Health Systems, *Code of Conduct* 7, *available at* http://www.chs.net/company_overview/Code%20of%20Conduct%202012.pdf (last visited Dec. 28, 2012).
[96] University of Colorado, *Vender Representative (VR) Policy* (Nov. 2008), *available at* http://www.uch.edu/docs/pdf/Vendor_Policy.pdf.
[97] Methodist Le Bonheur Healthcare, *Standards of Conduct: A Guide to Compliance* (Jan. 2007), *available at* http://www.methodisthealth.org/static/files/1170349225494/SOC_Vendor.pdf.
[98] *See* Hardin Memorial Hospital, *Code of Ethical Business and Professional Behavior* 2 (Nov. 1995, rev. Aug. 2009), *available at* http://www.hmh.net/ContentMgmt/uploads/Documents/Code%20of%20Ethical%20Business%20and%20Professional%20Behavior.pdf; *see also* Hilo Medical Center, *Non-Physician Arrangements* (Aug, 2007), *available at* http://www.hhsc.org/easthi/hmc/procurement_documents/ResourceLibrary/PDFs/850-101-31%20Non-Physician%20Arrangements.pdf.
[99] Palomar Pomerado Health, *Board Finance Committee Meeting Minutes* 4 (Aug, 29, 2011) *available at* http://www.palomarhealth.org/media/BoardMeetings/min_20110829_1140.pdf.
[100] *Id.*
[101] *See generally* Steinmann Study, *supra* note 5.
[102] *Id.*
[103] Quality Implant Coalition, *Physician-Owned Implant Companies: Evidence of Product Quality Deficiency and/or Overutilization at One Hospital* 1 (Nov. 2009), *available at* http://www.hoganlovells.com/files/upload/PODWhitePaper_Nov2009.pdf.

Physician-Owned Distributorships: History & OIG Concern

May 20, 2014

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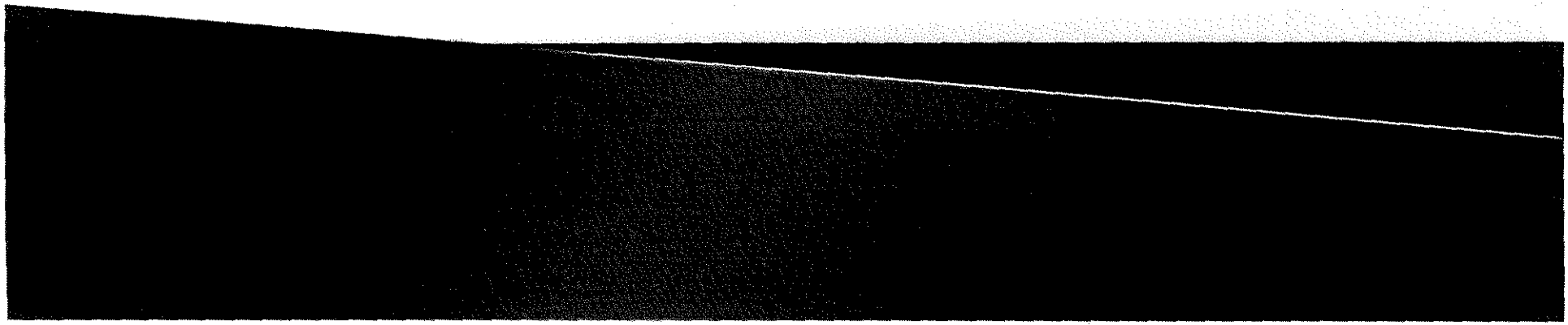

POD Controversy - Vulnerabilities

- Proponents claim that PODs lower device supply costs through decreased need for sales representatives, increased competition in the market, and procurement of inventory from smaller manufacturers.

- Opponents assert that PODs create a medical conflict of interest, affect physician decision-making, encourage unnecessary and inappropriate surgeries, and do not comply with the law. When physicians get a piece of the action, over-utilization occurs. No evidence PODs lower costs. Ample experience of over-utilization and undermining of patient relationship from conflict of interest. Who protects the patient from the conflict of interest?

- Hospitals, including HCA, Beth Israel Deaconess, Bon Secuors, Methodist Le Bonheur, Providence, and Martin Memorial Hospital, beginning to act to regulate or ban PODs. This includes Virginia hospitals such as Chippenham Hospital, Johnston-Willis Hospital, and Parham Doctors' Hospital.

WHY DID OIG INVESTIGATE PODS?

- The number of PODs throughout the U.S. has grown exponentially over the past decade, particularly from 2009 onward, raising significant patient safety and medical ethics concerns.

- In 2011, the U.S. Senate Finance Committee issued a report identifying several key legal and ethical concerns about PODs. The Committee found that the "very nature of PODs seem[s] to create financial incentives [such that] patient treatment decisions may be based on personal financial gain." The Committee requested that OIG further investigate this issue.

- Based on this Congressional mandate, as well as a Special Fraud Alert about PODs issued by OIG in May 2013, OIG conducted a statistical review of POD utilization and cost data for FY 2011 and 2012.

OIG Figures on PODs

- OIG further established that when hospitals began purchasing from PODs, their rate of spinal surgery grew three times faster than the overall growth rate of spinal surgery in the sample.

- In 2012, hospitals that purchased from PODs performed over a quarter more spinal surgeries than hospitals that did not purchase from PODs.

- OIG found that while physicians typically were required by hospital policy to report POD investments to hospitals, they were not required to report those investments to patients.

PODs and Ethical Concerns

- The OIG study focused exclusively on assessing the utilization and cost claims of PODs. Thus, it did not consider the ethical problems and patient harm related to unnecessary or excessive surgical procedures that PODs could potentially generate.

- Moreover, OIG's study did not address how these entities comply with existing federal law, though the OIG's Special Fraud Alert noted that "PODs are inherently suspect under the anti-kickback statute." The Alert also explained that simple patient disclosure did not provide "sufficient assurance" against legal and ethical concerns.

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AdvaMed
Advanced Medical Technology Association

Statement of Thomas Tremble, Vice President, State Government Affairs
Advanced Medical Technology Association
before the
Virginia Board of Health Professions
Public Hearing Concerning House Bill 1235
May 20, 2014

Chairman Farquhar and members of the Board, my name is Thomas Tremble. I am Vice President of State Government Relations at the Advanced Medical Technology Association or AdvaMed. AdvaMed is the national trade association of medical technology manufacturers. We provided comments to the General Assembly when they considered the issue and are pleased to share our comments with you today.

AdvaMed is comprised of approximately 400 member companies, ranging from the largest to the smallest medical technology innovators, which manufacture the wide range of medical technology, from syringes and needles to surgical tools, implantable devices and sophisticated diagnostic equipment. Included in our membership are the primary manufacturers of implantable orthopedic devices that allow patients to regain mobility.

I want to leave you with four points today about PODs:

1. PODs are "inherently suspect" as the HHS Office of Inspector General cited.
2. PODs have an inherent conflict of interest because their success is based on referrals by their investors.
3. HHS studies have shown that PODs can threaten patient safety by performing a higher rate of surgeries and increase health care costs.
4. As the OIG has advised, it is not possible to create a good POD where the purpose of the investment is inducing or rewarding referrals.

<u>Device Development Process</u>

First, I think it would be helpful if I gave a brief overview of the medical device development process. One of the unique characteristics of our industry is that, to a large extent, innovation occurs in the field of professional practice from companies working with physicians to incorporate their recommendations for improvements to existing devices. Such collaborations have resulted in the development of numerous technologies that have significantly advanced patient care.

In some cases, physicians will create a company to develop their idea for a device innovation. Often, if a physician has been instrumental in the development of a new medical device, the manufacturer will pay the physician a royalty for his or her contribution.

revenue generators for the companies. These entities include physician-owned distributors, group purchasing organizations, and manufacturers. These arrangements are designed to leverage device purchasing into income-generating opportunities for investing physicians. A primary characteristic of these PODs is that they sell devices to hospitals at which the physician-owners treat patients.

Government Reactions

As PODs proliferated, evidence of inappropriate surgeries, with the potential to harm patients and increase health care costs, led Congress and federal regulators to take a closer look at the practice.

In March of 2013, the Office of Inspector General, at the Department of Health and Human Services, issued a rare Special Fraud Alert (SFA), calling the POD model "inherently suspect". The introduction to the SFA pointed out that in prior guidance (10/06), the OIG cited:

> "the strong potential for improper inducements between and among the physician-investors, the entities, device vendors, and device purchasers."

The 3/13 SFA described eight characteristics of PODs that it believes produce substantial fraud and abuse risk and pose dangers to patient safety. Key findings of the SFA:

Questionable features of PODs may include, but not be limited to:

- Selecting investors because they are able to generate substantial business for the entity;
- The size of investment offered to physicians varies with the expected or actual volume of POD devices used by the physician;
- Physician-owners conditioning their referrals to hospitals on their purchase of the POD's devices through coercion or promises;
- Requiring investors who stop practicing in the service area to divest ownership interest; and
- Distributing extraordinary returns on investment compared to the level of risks involved.

- Surgeries involving POD devices used fewer devices, but did not have lower costs than non-POD surgeries. Generally, POD devices cost the same or more than non-POD devices.
- The growth rate of spinal surgery at hospitals purchasing from PODs was three times that of all hospitals.
- The cost of the POD devices and the increased volume at POD hospitals may increase the cost of spinal surgery to the Medicare program and beneficiaries over time.

Conclusion

In no way do we mean to question the integrity of the many Virginia physicians acting in the best interests of their patients. The perception, and reality in some cases, that health care decisions are being made for economic reasons as opposed to what is in the best interest of the patient.

Therefore, I urge the Board to carefully consider the findings of the HHS Office of Inspector General's Special Fraud Alert and its strong admonition that "PODs are inherently suspect under the anti-kickback statute" and that they are concerned about their proliferation.

We suspect that after reviewing the SFA, the Board will concur with its findings as well. We urge the Board to play a role in helping to make health care practitioners in Virginia aware of the dangers of PODs.

Jackson, Laura (DHP)

From: Carter, Elizabeth A. (DHP)
Sent: Friday, June 20, 2014 3:41 PM
To: Amy Hewett
Cc: DelBOrrock@house.virginia.gov; Chris Peace; district11@senate.virginia.gov; Matt Mansell; JOHNSON, SCOTT; Sterling Ransone; Jackson, Laura (DHP)
Subject: RE: MSV comments on HB 1235-PODs

Dear Ms. Hewett:

Thank you for providing Dr. Ransone's letter. It will be shared with the Board of Health Professions' Regulatory Research Committee and incorporated into their review regarding HB1235.

Very best regards,

Elizabeth A. Carter, Ph.D.
Director, DHP Healthcare Workforce Data Center
Executive Director for the Virginia Board of Health Professions
Perimeter Center
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Alternate E-mail: Laura.Jackson@dhp.virginia.gov

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From: Amy Hewett [mailto:ahewett@msv.org]
Sent: Friday, June 20, 2014 2:25 PM
To: Carter, Elizabeth A. (DHP)
Cc: DelBOrrock@house.virginia.gov; Chris Peace; district11@senate.virginia.gov; Matt Mansell; JOHNSON, SCOTT; Sterling Ransone
Subject: RE: MSV comments on HB 1235-PODs

My apologies for the second email, I forgot the attachment.

Amy Hewett
Medical Society of Virginia
T 804-377-1036

From: Amy Hewett
Sent: Friday, June 20, 2014 2:23 PM
To: 'Elizabeth.Carter@dhp.virginia.gov'
Cc: 'DelBOrrock@house.virginia'; 'Chris Peace'; district11@senate.virginia.gov; Matt Mansell; JOHNSON, SCOTT <sjohnson@hdjn.com>
Subject: MSV comments on HB 1235-PODs

Dear Dr. Carter,

Please see the attached comments from Dr. Sterling Ransone on behalf of the Medical Society of Virginia (MSV) on HB 1235. We appreciate the opportunity to comment on the Regulatory Research Committee's evaluation of implantable medical devices distributed by physician-owned distributorships (PODs).

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Thank you,
Amy

Amy Hewett
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Elizabeth A. Carter, Ph.D.
Executive Director
Board of Health Professions
9960 Mayland Drive
Henrico, VA 23233

June | 20 | 2014

Re: HB 1235-DHP; use of implantable medical devices distributed by physician-owned distributorships

Dear Dr. Carter:

Thank you for the opportunity to comment on the Board of Health Professions' Regulatory Research Committee's evaluation of implantable medical devices distributed by physician-owned distributorships (PODs). The Medical Society of Virginia represents over 11,000 physicians, resident and medical student members of all medical specialties from across the Commonwealth. MSV closely tracked HB 1235 and the Senate version of the bill, SB 536, during the General Assembly session.

MSV believes that the effort to ban PODs in Virginia is an unwarranted step that may stifle medical innovation and research that could positively advance patient care. Moreover, strict restrictions on PODs discount any potential for the best device for a patient to be one developed and provided via a POD.

Virginia code already includes safeguards related to medical devices. Virginia Code §54.1-2914 (B) specifies that a physician "shall not sell such articles to his own patients either for his own convenience or for the purpose of supplementing his income." According to Virginia's statute against self-referral, Virginia Code §54.1-2964, physicians must already disclose any material financial interest they may have in a facility when referring a patient there for health related services, including devices. MSV suggests that rather than banning PODs, it may be more appropriate for Virginia to consider expanding this code section to include PODs in the types of arrangements that physicians must disclose to their patients.

MSV supports transparency in the health care delivery system as well as initiatives that promote patient safety and satisfaction. While complying with state and federal requirements and ethical guidelines, physicians should be free to pursue research and business arrangements that allow them to provide the best possible care to their patients and at the same time make the existence of any such relationships to their patients clear.

Please consider MSV as a resource to you as you continue to evaluate PODs in Virginia; we would be pleased to provide you with any additional information.

Sincerely,

Sterling N. Ransone Jr., M.D., FAAFP
President

cc: The Honorable Robert D. Orrock, Sr.
The Honorable Christopher K. Peace
The Honorable Stephen H. Martin
Matt Mansell, MSV Director of Government Affairs
Scott Johnson, MSV General Counsel

Jackson, Laura (DHP)

From: Carter, Elizabeth A. (DHP)
Sent: Friday, June 20, 2014 12:06 PM
To: Cal Whitehead
Cc: Mark J. Romness, MD; Andrew Mann; Ralston King; Jackson, Laura (DHP)
Subject: RE: Romness to DHP re HB 1235 PODs review

Thank you for providing the memorandum from Dr. Mark Romness of the Virginia Orthopaedic Society. It will be shared with the Regulatory Research Committee as part of their HB1235 review.

Cordially,

Elizabeth A. Carter, Ph.D.
Director, DHP Healthcare Workforce Data Center Executive Director for the Virginia Board of Health Professions Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233
804-367-4403, 804-527-4434(fax)
E-mail: Elizabeth.Carter@dhp.virginia.gov Alternate E-mail: Laura.Jackson@dhp.virginia.gov

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-----Original Message-----
From: Cal Whitehead [mailto:cwhitehead@whiteheadconsulting.net]
Sent: Friday, June 20, 2014 12:00 PM
To: Carter, Elizabeth A. (DHP)
Cc: Mark J. Romness, MD; Andrew Mann; Ralston King
Subject: Romness to DHP re HB 1235 PODs review

Hello Dr. Carter, please see the attached memo from Dr. Romness re HB 1235 public comment. Please confirm receipt and let us know if you have questions.

Have a nice weekend.
Cal
Virginia Orthopaedic Society

****

Cal Whitehead
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Virginia Orthopaedic Society

Founded 1933

June 20, 2014

To: Elizabeth A. Carter, Ph.D.
Executive Director, Board of Health Professions

From: Mark J. Romness, MD, President

Re: Comments on Physician Owned Distributorships (HB 1235)

The Virginia Orthopaedic Society (VOS) exists to enhance its members' ability to provide the highest quality musculoskeletal care possible through education and professional development while championing the interests of physicians and patients through its advocacy efforts. We are grateful for the opportunity to comment on the Board of Health Professions' Regulatory Research Committee's review of implantable medical devices distributed by physician-owned distributorships (PODs).

Since fall of 2013, VOS has engaged in discussions with interested parties about PODs, which are described as physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices. These may include such entities that purpose to design or manufacture their own medical devices or instrumentation. These entities are under scrutiny by the U.S. Department of Health and Human Services Office of Inspector General (OIG).

VOS expects its members to adhere to all professional ethical guidelines as well as state and federal regulations and statutes. Orthopaedic surgeons, when complying with ethical and legal requirements, should be free to manage their medical/surgical practices and business arrangements with other parties. VOS would oppose financial arrangements where a physician's medical judgment would be compromised or financial incentives exist that would promote utilization inconsistent with standard of care. At this time, we have little evidence that PODs exist or are prevalent in Virginia and no concrete information has emerged that orthopaedists medical judgment is being influenced or that patient safety and quality care are at risk because of PODs.

We vehemently reject the notion that physician ownership and provision of services or products ancillary to care delivery is inherently bad. To the contrary, physician ownership and provision of such services can promote integrated and coordinated care, increase patient convenience and satisfaction, expedite care delivery, and spur innovation. To protect patients and public health system dollars, federal and state laws currently regulate practitioner "self-referral". We support these laws and the specific exceptions that recognize that ancillary services are a vital component of the diagnostic and treatment regimens.

VOS continues to work with physician organizations, hospitals, academic medical centers, and industry to learn about PODs as a business model, determine their existence and prevalence in Virginia, and measure the impact they may have on patient care and public healthcare dollars. At this time, we would be willing to strengthen or otherwise clarify existing self-referral laws to promote transparency and disclosure of physician financial interest in health care business arrangements, but we see no reason to ban or otherwise restrict legal arrangements that can contribute to innovation, market competition, and quality products and services for patients.

Please let me know how the Virginia Orthopaedic Society can continue to assist DHP as you conduct this review.

Cc: American Academy of Orthopaedic Surgeons
The Honorable Christopher K. Peace, Delegate 97th District
The Honorable Stephen H. Martin, Senator 11th District
Sterling N. Ransone Jr., M.D., FAAFP, President, Medical Society of Virginia
Matt Mansell, Director of Government Affairs, MSV
Cal Whitehead, Advocacy Director, VOS

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BOARD OF HEALTH PROFESSIONS

REGULATORY RESEARCH COMMITTEE

DATE: MAY 20, 2014

TIME: 10:00 A.M.

PLACE: DEPARTMENT OF HEALTH PROFESSIONS
PERIMETER CENTER
9960 MAYLAND DRIVE
SECOND FLOOR
HENRICO, VIRGINIA

APPEARANCES: DR. IRENE V. FARQUHAR
Board of Medicine

ELIZABETH A. CARTER, Ph.D.
Executive Director, BHP

YVONNE HAYNES
Board of Social Work

DAVID E. BROWN, D.C., Director
Department of Health Professions

CHARLOTTE MARKVA
Board of Counseling

LAURA JACKSON
Operations Manager, BHP

DR. IRENE FARQUHAR: Good morning. Today's hearing for the Board of Regulatory Research Hearing HB1235 implantable medical devices is now called to order. It's May 20, 2014, 10:00 a.m.

Good morning. I am Dr. Irene Farquhar. I am Chair of the Regulatory Research Committee. This is a public hearing to receive public comments on the Board's study of HB1235 implantable medical devices.

Dr. Carter will instruct us on the emergency exit procedures. Then we will continue.

DR. ELIZABETH CARTER: In the event of an emergency, which I hope will not happen, but we will exit out of that door, or this one, and make an immediate right. We will walk across the parking lot. You can see the fence over there, and we will just wait for the instructions. It happens every once in a while a fire alarm will go off, or something like that. I just want to let you know ahead of time. If you have any other questions, just let the staff know. Thank you.

DR. IRENE FARQUHAR: The Code of Virginia authorizes the Board of Health Professions to advise the Governor and the General Assembly and the Department Director of Regulations of Health

Care Occupation and Professions. Accordingly, the Board is conducting this study and will provide recommendations on whether there is a need for regulation.

At this time, I will call on persons who have signed up to comment. As I call your name, please come forward and tell us your name and where you are from. Thank you.

I have the list. I will go through the list of signees and what HB1235 is about. I do apologize in advance if I mispronounce a name.

John Steinmann, please state your name and where you are from. Once again, I apologize if I mispronounced your name.

MR. JOHN STEINMANN: No, apology. Can everyone hear me okay?

DR. IRENE FARQUHAR: Yes.

MR. JOHN STEINMANN: My name is John Steinmann. I am from Berlin, California. Honorable Members of the Board, my name is John Steinmann. Honorable Members of the Board of Health Professions' Regulatory Research Committee. Good morning. Thank you for the opportunity for allowing me to speak before this Committee, and to provide to you my experience as it relates to HB1235.

I am an orthopedic surgeon, in practice for 23 years, and stand before you today representing surgeons and companies that desire to protect their right to bring much-needed innovation, competition, and cost savings to the U.S. healthcare system.

We have a problem facing American citizens and American businesses, for which we all share responsibilities. Individuals and businesses are forced to pay twice as much for healthcare in this country being the next most expensive country.

Every year, this leads to thousands of medical bankruptcies, loss of jobs, and businesses that leave our country. Those businesses that stay here find it increasingly difficult to compete globally under this burden -- economic burden imposed by our healthcare system.

So, we must address this problem, and yet we must also realize that we cannot depend upon the existing large business interests responsible for these costs to drive necessary cost savings innovations.

A good example of this is the primary force behind the very issue we are addressing today, which is an incumbent device company intent on

suppressing any innovation or competition that might serve to reduce healthcare costs.

Companies only reduce pricing when there is a decrease in demand, or an increase in competition. Since there is no anticipated decrease in demand we must look for and support competitive forces that create cost savings in healthcare states.

The issue under consideration by this Committee relates to physician ownership in medical device manufacturing and medical device distribution. It's my desire, in the next few minutes, to share insight as to why we must retain the ability for physicians to develop and implement innovative methods to improve the value of the medical devices we utilize in this country.

Did you know that a total hip replacement manufactured by any of the large U.S. device companies sells for more than $6,000 in the United States. That same exact device sells for $3,000 in Europe. We don't find ourselves paying twice as much for blue jeans or a Chevrolet in this country, so why should we accept paying double for medical devices, which is an inherent problem in our system.

In the area of medical devices, I, as a surgeon, is here to tell you that there is a vast commoditization of products whereby many spinal fixation devices and joint replacement products share the very same features with no clear benefit of one over the other.

The American public then therefore needs purchasing decisions to be based on value, and the surgeon is in the best possible position to do this.

I am personally involved with three entities that have fostered a spirit of innovation in establishing models that bring sensible, competitive forces to bear on the medical device industry.

These entities are directly responsible for tens of millions of dollars in annual healthcare savings for the communities they serve. And, there exists the potential for tens of billions in savings if these types of models are endorsed nationally.

Surgeons are the most qualified individuals to assess technologies and features, and to help bring effective competition to the device industry.

In the properly constructed physician-owned distribution company, the surgeon group carefully evaluates a number of competitive products that meet their design criteria and negotiate bulk purchases for the implants they have historically required in the treatment of their patients.

Alliance Surgical Distributors has developed a model that allows surgeons to pool their collective purchasing power, derive a collective consensus on the most valuable product choice, and negotiate with the medical device companies for the purchase of large quantities of the medical devices they will use collectively through the year.

The features of competitive bidding and bulk purchasing combined to result in savings of 35 percent. I believe you have been provided before you the two studies that demonstrate this.

This model requires surgeons to invest considerable amounts capital of their own money in inventory and to hire and manage service representatives. Can a physician make a profit with this model? Yes, potentially they can, as should be the case for taking risks providing expertise and oversight and investments that result in a better

solution to the market for everyone.

The incumbent device company responsible for the amendment before you will try and argue that physicians cannot be trusted to manage the conflict of interest that results from participation in the purchasing and selling of products they choose to use in surgery. Well, they will profile a few clearly "bad apples" that have a long history of unethical behavior, and will then ask you to conclude that this participation in a medical device distributorship is what made these individuals act improperly. That is simply not the case.

As physicians, we deal with conflict of interest everyday. While we fully understand that there is an abuse potential and that strict standards (such as those developed by the American Association of Surgical Distributors) are necessary to prevent abuse. We have shown that this conflict is easily managed through transparency that ensures proper conduct and ensures cost savings.

Surgeon ownership in ambulatory surgery centers is a well-established model that has brought the American public considerable improvements in patient satisfaction, and outcomes

at a 40 percent savings over hospital-based outpatient surgery centers. This model is supported by a sensible set of standards that ensures conduct always remains in the patient's and society's best interest.

Physician ownership in medical device distribution or manufacturing offers the same remarkable benefits for patients and society as surgeon-ownership in ambulatory surgery centers; yet must be conducted under a set of standards that promotes transparency and costs savings.

The American Association of Surgeon Distributors has published a set of 12 standards governing proper conduct when surgeons are in a position of ownership in medical distribution companies.

You have been provided background information on this Association, as well as the Standards and Policies that define membership.

I would ask that instead of supporting anti-competitive tactics of the incumbent device industry that you instead support the strict standards developed by the American Association of Distributors, and the much-needed competition and cost savings resulting from surgeon ownership in

medical device distribution.

Lastly, Renovis Surgical Technologies represents the story of an up-and-coming medical device company that is developing industry-leading technologies, while simultaneously developing delivery models that allow the American public to obtain the benefits of these products and technologies at a considerably lower price.

Renovis has both surgeon and non-surgeon ownership and is therefore targeted by the anti-competitive nature of the issue I am here speaking to you about here today.

You have been provided two white papers that identify two very important technologies developed by this company. The first represents the innovative use of additive manufacturing to produce a surface coating (Tesera) that are used in spinal cord applications in patients that appear to be ideal in every measurable respect. This technology an evolutionary has been taken a step forward.

The second paper you have been provided profiles the development of possibly the industry's best bearing surface for total joint replacement. This product was developed in conjunction with the renowned polymer scientists at

Harvard's Massachusetts General Hospital and provides a combination of strength and wear resistence not previously made possible. Both of these technologies are threatened by the legislation before you.

Surgeons have a long history of developing most of the important advances we have seen in medical devices. It cannot be in society or a patient's best interest to restrict their innovative potential.

In conclusion, I have taken two days out of my practice and traveled across the country to stand before you because I am concerned by the anti-competitive behavior behind the original Senate Bill 536.

You can see that there has been a great deal of honorable work performed by many outstanding individuals representing outstanding companies that have demonstrated a dedication to bringing change that is vital to our national healthcare system. We cannot allow the interests of those profiting from this overly expensive system to suppress the innovation and competition that our system so badly needs.

I hope to offer you a resource today

and in the future as you address the issues surrounding physician ownership in medical device manufacturing and distribution.

Thank you for your consideration and for weighing the case for innovation, cost savings and value. Thank you very much.

DR. IRENE FARQUHAR: Thank you very much for your very informative presentation as a an expression of considerations.

Would anyone have any questions?

MS. ELIZABETH CARTER: I just have one. Thank you. The American Association of Surgeon Distributors, if that's the title of the group. Do you know how many of the proportions of surgeons in Virginia that are members of that organization? That would be very helpful for us to know.

MR. JOHN STEINMANN: I am an adviser to that organization. I do not believe that there are surgeon memberships from the State of Virginia.

MS. ELIZABETH CARTER: Thank you.

DR. IRENE FARQUHAR: Any other questions, please? Thank you very much.

Dr. Edwards.

DR. CHARLES EDWARDS: Good morning.

DR. IRENE FARQUHAR: Good morning.

DR. CHARLES EDWARDS: Honorable Members of the Board, I thank you for giving me the opportunity to speak to you this morning.

I drove down from Baltimore this morning because I wanted to give you a personal story of an individual, a physician, that's involved not only in the care of patients but in the marketplace of spinal implants. I hope that my story, my experience, might be helpful to you as you consider this piece of legislation.

Prior to entering medical school, I did my undergraduate studies in Lexington, Virginia at Washington and Lee University where I received graduation Honors in Engineering. It was my background in engineering, which has helped me to identify problems and develop solutions. That's what engineers do.

In my early years in clinical practice as an orthopedic spine surgeon in Baltimore, I recognized a striking problem. The problem was the healthcare prices on one hand and the ridiculously high price of surgical implants on the other.

So, in 2006, to try to reconcile this

problem, I spoke to a colleague of mine who is a spinal surgeon in Argentina. He used the same surgical implants that I used made by the same American manufacturer. When I asked him how much the hospital charged, the amount was 25 percent of what my hospital was charged for the same exact implants.

What that taught me was that the problem was not the cost of manufacturing implants, because the same implants were in South America, but was rather the cost of the corporate overhead and the cost of the distribution system.

So, a challenge for an engineering mind was, well, how do you fix or solve this problem. So, I first approached my hospital and asked them if they would bulk purchase the surgical implants, because if you buy them in bulk you should be able to get a better price.

After several meetings, my hospital declined my suggestion, even though we had an offer to them to buy these implants in bulk from a general manufacturer, but they said their focus was really directly on patient care and not in product selection and managing inventory. They said that's what distribution companies do. As a hospital, we

really need to stay focused on direct patient care.

So, with an engineer's perspective, I knew that there must be a solution to the problem. Since the major manufacturers would not lower their prices to Argentina's level, and my hospital didn't want to enter the implant distribution marketplace, it made sense for me to consider doing so.

So, with a full disclosure to all the parties, my hospital, my patients, and in respect to all State and Federal regulations, I established a distribution company for spinal implants five years ago.

The company purchases FDA approved spinal implants made in the United States from a respected domestic manufacturer. The distribution company manages the inventory and we have trained representatives. The implants are sold to the hospital at 40 percent of the implant price sold by the major manufacturer. That's a tremendous savings.

Our implant distribution company is the lowest cost provider of spinal implants to my hospital, and each year provides a cost savings of over 2 million dollars for the three surgeons who use the distribution company. With that 2 million

dollar cost savings, my hospital can hire more nurses, provide more charitable care, and invest in research.

One hundred years ago, Presidents Theodore Roosevelt and Taft recognized that trusts and oligopolies were harmful to the consumer and our economic system. Bucking the lobby of powerful landed interests, they broke up the anti-competitive trusts of oil, banking, steel, and the railroads. As you know, increased competition, lower prices, and improved service were the result.

So, here we are in 2014 witnessing the efforts of Big Medical to turn back the clock. If the proposed legislation were to have been successful, it would limit competition and strengthen the power of the few large surgical implant companies.

The legislation would have hurt small business, reduced competition from the marketplace, and result in higher prices. The healthcare crisis will be magnified and all will be hurt, except for a few large companies.

Critics of Physician-owned distributors distribution companies often cite the October 24, 2013 OIG study on the prevalence and

uses of spinal devices. This study is often mischaracterized. I am grateful that it has been included today in your materials for your review.

Some would have you conclude from this study that the physician-owned distributorship incentives to increase their surgical volume. Fortunately, a close review of the study before you will reveal that such is not the case.

When you read the study, let me ask you to take note of two very important findings, implant density, number one, and reoperation rate.

Any spinal fusion procedure, a surgeon determines the number of implants to place within the body, and also the location to place them. There is no scientific consensus on the operable implant density for a given patient, whether you put in four screws or six screws. There is no scientific consensus on that. It's up to the surgeon.

Now, there might be a financial interest for a physician-owned distributorship owner to put in more screws, because the more you put in the more money you might make. So, you might think that the OIG study would show that physician-owned distributorship surgeons would put in more implants,

but the opposite was the case.

When you read the study before you, you will see that the surgeons that were part of distributorships put in 13 percent less implants than their colleagues who were not owners of distribution companies.

So, this completely contradicts the assertion that surgeons make surgical decisions based on financial considerations, and not what's in the best interest of the patient. That's just not the case.

In further support of the ethical conduct of physician-owned distributorship surgeons, the OIG report found that the re-surgery rate was slightly lower among distributorship surgeons, five percent versus six percent. So it's not a huge difference.

What that tells us is a lower reoperation rate runs counter to the assertion that surgeons are making medical decisions based on financial incentives.

If I wanted to make more money, I would have recommended more surgery. But, the fact that the OIG study showed that, that is not the case contradicts the assertion that physicians cannot be

trusted to do what is right for their patients. And, I find that offensive as you might agree, and as you might understand.

Now, finally the OIG report shows that spinal-fusion surgeries did increase at hospitals once they brought on a physician-owned distributorship, but by the Department of Health and Human Services admission report does not provide sufficient information to explain why there were more spinal fusion surgeries at their hospitals. Was it because maybe the surgeons moved more business to that hospital to consolidate their inventory, rather than having inventory at several hospitals they consolidated their distributorship at one, or perhaps maybe the hospitals partnered with those surgeons to provide service of excellence. There are many of reasons, but the study doesn't provide that insight.

So, again, it would be wrong for us to conclude that physicians and surgeons are unethical based on an increase surgery rate at the hospitals. This just doesn't give us insight into that. So, my hope is that my observation of the OIG report and from my own personal experience show you that physicians are a very important part of the

solution to our healthcare crisis.

Removing physicians and surgeons from participation in the marketplace is not only unwise, but it runs counter to the proven effectiveness of small business as the creative engine to the solutions and progress in America.

I would be pleased to answer any questions, or provide any additional information. Thank you.

DR. IRENE FARQUHAR: Thank you, Dr. Edwards. Any dissertation on the matter, would you please entertain any questions from the Board members or audience?

MS. CHARLOTTE MARKVA: I just have one question. How is full disclosure done, and what seems to be the reaction of the hospital through the patients?

DR. CHARLES EDWARDS: In my office, I talk to patients about surgery. I share with them that I am going to -- in certain cases need to use implants. I tell them that these implants are provided by a company that I am a part owner. I explain why I've done that. That it provides tremendous cost savings to my hospital and to the society as a whole. They are really impressed.

They are really grateful for that.

Also, we have posted in our surgery counseling room a sheet that describes my ownership and interest and my partners in our distribution company. They are asked to sign that sheet acknowledging that they understand that I have this potential conflict of interest. They are given a copy of that to take home.

Finally, my hospital is very aware of this relationship and they scrutinize it. I am a member of the American Association Distributing Distributors. My practice is audited by that organization to see that I am doing appropriate surgeries. My hospital appreciates that. So, there is a full disclosure.

Actually, my patients think more of me because I have taken the time to explain this to them. That I am mindful of our national healthcare needs.

MS. CHARLOTTE MARKVA: Thank you.

DR. IRENE FARQUHAR: Thank you.

Dr. Carter.

DR. ELIZABETH CARTER: I just have one question. Should a patient want to use another device, do they have that option?

DR. CHARLES EDWARDS: Yes, of course. And I have had -- This is funny, but one of the major manufacturing companies, one of their local reps is a friend of mine. He will often will send his friends to me. They will often ask if I would use the implants that my friend distributor provides. I say, of course, I am happy to do that. That's fine.

My distribution company doesn't provide all implants for all scenarios. If there is an unusual cancer case, then of course, I am going to use the best implants for that patient. That's the ethical thing to do, but also let's say that I didn't do the right thing. I had some terrible complications. Well, there is a malpractice attorney who would love to point their finger at me and say, Dr. Edwards, did a sub-operable surgery for a financial interest. So, there is already the malpractice attorneys out there that are proving some structure to this issue.

DR. IRENE FARQUHAR: May I ask a question. But, do you subsidize for the devices provided to you by your friend rather than other companies?

DR. CHARLES EDWARDS: In this case,

the implants are sold directly to the hospital. They are not sold through our distribution company. The hospital always calls me when I do one of their surgeries because they are now paying over double the price for the implants by a major manufacturer.

So, I always get a phone call from the Vice President of supplies saying, Dr. Edwards, why are you using these expensive implants. I provide an explanation, but they do call me to ask that.

DR. IRENE FARQUHAR: Any analysis that was made by your hospital about how much it would cost? How much extra it would cost them to use the devices from one of your companies?

DR. CHARLES EDWARDS: Yes. So, at my hospital, we have a few neurosurgeons who prefer to use the implants by one of the major medical manufacturers. So, it provides a very nice internal comparison of the three surgeons that use the distribution companies versus the neurosurgeons who do not at the same hospital in the same city.

That comparison showed that last year for three surgeons we saved the hospital 2.6 million dollars, relative to how we use implants by the neurosurgeons. For three surgeons, we saved 2.6

million dollars. So, it's a huge amount of cost savings in one year alone.

DR. IRENE FARQUHAR: Any logic from neurosurgeons, why they wouldn't use your devices?

DR. CHARLES EDWARDS: Well --

DR. IRENE FARQUHAR: Is it because you don't distribute them, or for some other reason?

DR. CHARLES EDWARDS: Well, I think there are perhaps there are a few reasons. In some ways, they are competitive with me for patients, and they don't want to support a distribution company that is owned by their competitor.

They also have our consultants for the larger manufacturing companies. They provide advice and are paid for that. There are other reasons that perhaps I don't understand, but my hospital continues to encourage them to use our distribution companies.

DR. IRENE FARQUHAR: Competition?

DR. CHARLES EDWARDS: Yes. But, I would say if we were not there, there would be no -- Then the prices might rise by the competition, but we are providing leadership in this area.

DR. IRENE FARQUHAR: You just mentioned provide leadership in the area. So, how

do you feel geographically wise? Do you lead the trend? Were you able to establish a trend geographically where other hospitals or surgeons will look up to your leadership in terms of utilization?

DR. CHARLES EDWARDS: Well, I tell you my hospital very much appreciates the fact that I helped them to save 2.6 million dollars a year. They are very appreciative of that. What makes them nervous is the lack of clarity as to what direction Maryland, Virginia, and in the Federal government will go with respect to physician-owned distributorships.

My hospital wants to do everything appropriately. That's why they are very careful in making sure that we follow the Stark laws and the anti-kickback laws. So, they are looking at that very carefully. They do not want to be audited. So, they document everything to a "T". So, it actually does create a whole nother level of scrutiny that obviously our company is subjective that I think that most other companies are not.

So, my hospital is reflective if the State of Maryland and the Federal Government would provide some clear standards, or some clear

directive that, yes, this is not only okay, but this is sanctioned if you follow some defined and ethical and legal standards. Right now, those standards are not as well defined as they should be.

I try to do a really good job. I try to be very virtuous an act in the best interest of our company. Of course, there are some bad apples out there. So, I strongly support the adoption of standards that physician distributor companies should be measured by, but they be allowed to flourish and compete within those standards, but don't kick them out the marketplace, just give them some rules by which they can play.

DR. IRENE FARQUHAR: Thank you.

Any further questions, please?

Thank you, Dr. Edwards. We very much appreciate your statement and thank you. Thank you for that.

The next speaker is Dr. Kate McDermott.

MS. KATHLEEN MCDERMOTT: Thank you, Madam Chairwoman. I must tell you I am not a doctor. I am a lawyer.

DR. IRENE FARQUHAR: Judicial doctor.

MS. KATHLEEN MCDERMOTT: Thank you

kindly for the opportunity, Chairwoman and the Board, to present perspective to the consideration that is being undertaken on clinical devices.

I am an attorney. I am at a law firm Morgan, Lewis & Bockius that has a substantial life science practice. I have been representing the health industry for 23 some odd years, though eight of those was as a prosecutor with the U.S. Attorney's Office in Maryland where I prosecuted healthcare fraud and ran the healthcare fraud program in Maryland.

I prosecuted hospitals, doctors, labs, nursing homes, really just a full spectrum, and participated on policy Committees in Washington related to the HIPPA fraud and abuse program.

In the last 14 years, I have been in private sector doing only healthcare principally in fraud and abuse. In that context, I operate in a compliance environment where I advise folks in the health industry on how to comply with the fraud and abuse laws.

I also where a defense counsel hat when entities and individuals make and get subpoenas, or come under investigation for not being compliant with fraud and abuse laws. I represent

medical societies and defend device companies and defend hospitals, laboratories, a whole host of folks in the health industry today. So, I have some perspective to this particular controversy, and the consideration that is being undertaken to potentially regulate physician-ownership in implantable devices. I offer some perspective to that today.

That perspective would be I think to urge regulations and consider urging prohibition in the context of that to consider State funded programs and whether they should allow reimbursement. Why would that be a perspective.

Physician-ownership investment and compensation has been regulated. It's not new and it's not a new concept. It's regulated for one singular reason. Physicians are the gatekeepers to medical decision making and they control utilization. They impact the type of procedures and services provided. They have a unique role in our healthcare system that has been long noted. For that reason, their medical-decision making as it impacts their own financial interest has been regulated.

There are, you know, in my

experience, I represented folks for 14 years now. Most doctors are honest. I frankly say 99.9 percent. Most companies are honest. This is not about whether someone is good or bad. It isn't about whether somebody is big or small in a particular environment. I am going to suggest to you it's not about healthcare cost savings either as the Senate Finance Committee and some of the Federal regulators have noted.

It's always been about regulating financial conflict of interest that can corrupt and taint medical decision making. It has a host of medical characteristics that can castigate from that scenario.

So, when you look at the Federal anti-kickback and statute and the Stark Regulation, they attempt to regulate that for a good reason; not because they are pointing their finger at a medical professional who is lawfully licensed in the Commonwealth or anywhere else, but because they know that if you don't regulate conflict of interest you will have patient harm. You will undermine the public interest and untainted medical decision making. That's really the big picture here.

You know, people can come in here and

debate how they are saving costs, but there is empirical evidence over the last 40 decades of anti-fraud legislation that shows when doctors get a piece of the action utilization and medically unnecessary procedures go up.

Is there one doctor who may appear today and tell you that he doesn't do that, sure. That's totally believable. But, you have to regulate and legislate for the public interest as a whole, not for one anecdotal or subjective presentation of information.

When we look at our experience, we know that medical decision making can be tainted by financial conflict of interest. If you look at the California experience where the American Association of Surgical Distributorships, as was created in 2011, you will see that California has their own concern about implantable devices, which are very unique devices because they are so dependent on surgeon preference. It is such a unique and complex surgical service that they can drive product selection and product purchases.

In the California workers' comp program there was a staggering increase in utilization once PODs, Physician-Owned Distributors

started providing, or being allowed to provide the implantable devices for surgeries. So, they band them.

We see the OIG October of 2013 report. It's not a perfect report. I think it's a good point that's been made about it, but it confirms what we all know is that when you have a financial stake, a personal financial stake in the procedures you are recommending that there is a potential for increase utilization. The OIG report confirmed increased utilization with PODs. That's what is taken from their report.

Now, is it every hospital in the country and every doctor, no. It was a sample. So, it has some utility. It has important utility for regulators when they are trying to assess. Is it more likely than not that a financial conflict of interest can undermine the public interest. When you are trying to forecast protecting the public is it better to air on the side a diminishing, or eliminating conflict of interest, or do you allow it to flourish without regulation. I think that in our experience we know that if it's unregulated there will be public harm. That's the fundamental premise I think of assessing these issues.

Now, the OIG did this report really as a part of a two-year evaluation that started with the Senate Finance Committee, which has jurisdiction over the Medical Program. They raised a lot of questions about the conflict of interest because it's foundational to a lot of the fraud and abuse regulations.

I think it's important that the Senate Finance Committee in their report said it doesn't matter if you save money on an implant, which is arguable and dubious, and if you have done so because of tainted medical decision making. It doesn't matter if you saved money by using a POD if the patient didn't need the procedure to begin with.

So, this is why I would urge your consideration on sort of broader issues besides dollars. First of all, it's not proven that it's cheaper. What the Senate Finance Committee said is do we care if it's cheaper or unethical. I think that's a powerful question for your study consideration.

I think the next thing that's really important to think about is should medical conflict of interest be happenstance. We just heard that in one practice patients are advised of a potential

conflict of interest and the use of implantable devices that may be used by the surgeon.

Well, I would submit to you that's not a potential conflict of interest. It's an actual conflict of interest. Again, I would take a step back and not being subjective or anecdotal and think about that patient/doctor interaction.

It's long known that whitecoat marketing has undoing influence on patience. So, when your doctor says use my implant because I think it's better for you. Is that really protecting the patient from medical conflict of interest in that private dialogue. Are they really given a list of other device implants that can be used. You can use your common sense and answer that question. But, what I think what's important to consider isn't whether one doctor or most doctors are handling that private interaction well.

I would suggest to you from at least from the witnesses we have seen today that they probably are handling that dialogue well. Let's presume that because we should give everyone the benefit of the doubt. That isn't sufficient to protect the interest because protecting a patient from medical conflict of interest shouldn't be

happenstance. It shouldn't be voluntary. It should be required.

The OIG has noted that disclosure to the patient that, frankly, I don't believe is happening on a regular basis, but let's assume it is. Let's assume there is disclosure to a patient on a regular basis of conflict of interest. Where the doctor gets money from using the implants in their surgical procedure in treating that particular patient.

How do you know what's being said in the patient's office? Do you really want to have to worry about that and regulate that communication.

When you think about whether these types of arrangements should be allowed and whether State taxpayers money should be funding the financial conflict of interest. Do you really want to have to worry about whether in every physicians' office at any hour of the day that conversation is occurring in the public interest.

I would suggest to you that the reason for good legislation and regulation is so that it's not happenstance. That the patient is foremost being protected by regulation that promotes ethical behavior and assures it. It's really a

prophylactic objective standard. It's not a subjective standard based on the experience, or the subjectivity of the particular communication.

So, when we think about the disclosure and the happenstance and the voluntary nature of this disclosure, I think it's sort of important to consider what the OIG, the Office of Inspector General, has been the guardian on the fraud and abuse laws on the Federal level. And, frankly, has been influential in many of the states anti-fraud legislative efforts.

What they said about disclosure is not sufficient. We don't believe that disclosure to a patient to a physician's financial interest in a POD is sufficient to address the concerns. That is the financial conflict of the interest. It doesn't provide assurance against fraud. It doesn't provide assurance against unfair competition, or billing irregularities, or utilization.

But, here is the most important thing they said in their report. They have great expertise in this area. They said that the disclosure of the financial interest is often part of the testimonial, a reason why the patient should patronize the facility. I think it's important when

a patient is in a doctor's office and they say use my product it's okay. I said it's okay. That is a testimonial.

So, I don't think we can presume that interaction is safe for the patient, even though the intension of the physician is presumptively valid, because you shouldn't leave it to happenstance.

Now, I would just like to sort of address a couple of other issues on cost. When we look at the issue of cost, I don't think the OIG report fully address the issues of cost. What they addressed was utilization. They confirmed that where there is a POD there was an increase in utilization.

That fact alone is similar to the OIG's experience and the regulators and enforcer experience and other similar scenarios where the physician having the opportunity to profit from their service or procedure with a patient. Imaging centers and other types of scenarios have all been brought with this utilization problem when doctors have had a piece of the action.

I would suggest to you that will happen, is happening when you look at PODs, you know, physician-owned entities and distributors.

So, you are simply confronted with an opportunity to look at a trend. You asked about trends. I think there is a trend in PODs. They have been very much gaining ground in some jurisdictions.

The question is, is that the type of financial conflict of interest that the Commonwealth wants to grow by itself unregulated and without consideration of the public interest. I think that's really your fundamental challenge in considering this particular issue. Thank you.

DR. IRENE FARQUHAR: Thank you.

Ms. Markva.

MS. CHARLOTTE MARKVA: What statistics do you have that patient harm has already occurred? That there have already been lawsuits that have proven conflict of interest? What's the percentage of that in Virginia that you are aware of also?

MS. KATHLEEN MCDERMOTT: I am not aware of the percentage of lawsuits in Virginia that could be related to medical malpractice and things of that nature. I don't know if we could do a study of that, or if I personally wouldn't undertake a study of that.

I think that when you are looking at fraud and abuse legislation, for example, the federal anti-kickback statute regulation which is 40 years old. They presume the opportunity for patient harm from the medical conflict of interest largely attributable to unnecessary procedures.

I think this is particularly a compelling issue in procedures where you have implantables. You know if somebody is having an office visit and it's medically unnecessary then maybe the patient isn't at harm to have a consult. But, if somebody is actually doing an invasive procedure that is medically unnecessary and there has been countless medical procedures in the device arena then I think that's almost irrefutable harm.

If only one occurs, is that okay? I think that's the concern. Overutilization is tantamount to patient harm if you have medically unnecessary procedures.

MS. CHARLOTTE MARKVA: I just want to be clear. Is what I am hearing you say is that there really hasn't been any kind of study or statistics that is connected to actual harm that has occurred because of conflict of interest in this area?

MS. KATHLEEN MCDERMOTT: Well, I do think that for PODs I think that would be correct. I think that there were some Virginia hospitals that were included in the OIG report. I think approximately four. But, there is not -- I don't believe that I would read the report to conclude actual patient harm.

MS. CHARLOTTE MARKVA: Okay. So, a lot of what we are talking about here is more of speculation that harm could occur, not that research shows that harm has occurred.

MS. KATHLEEN MCDERMOTT: I think that is true that none of these reports are confirming patient harm, because they haven't looked at that. But, I believe that there is a presumption in all of these fraud and abuse laws that medically unnecessary procedures are harmful to a patient.

MS. CHARLOTTE MARKVA: But, it has not unnecessarily been tied directly to PODs?

MS. KATHLEEN MCDERMOTT: Well, I think the OIG report does raise that and confirm that issue of overutilization.

MS. CHARLOTTE MARKVA: But, not necessarily that they can tie to patient harm because of it?

MS. KATHLEEN MCDERMOTT: They did not identify instances of patient harm, but I don't think they want to wait for a patient to be harmed. I do think there is a foundational premise that if a procedure is unnecessary for a patient then that is presumptuously harmful.

MS. CHARLOTTE MARKVA: I understand. I was just trying to figure out if there were any facts out of statistics.

MS. KATHLEEN MCDERMOTT: I think it's a public fact and public underlying issue when you look at the rationale for the anti-kickback statute and a lot of the fraud and abuse regulations.

I think sometimes people say, well, the procedure was medically necessary, but under the law if it's tainted or corrupted then it's still a criminal violation. So, there has been some broad principles that have been identified in fraud and abuse laws that say we don't take the risk of that.

And, so under the anti-kickback statute, even the people focused on cost and medical necessity, which I think is really key for utilization. The reality under the Federal anti-kickback statute the procedure could be necessary. You could actually have a good outcome

for the patient, and you still have committed a crime if you have done that in violation of the statute.

So, being a good doctor is not the same as not violating the anti-kickback statute in the eyes of the Government when they are regulating this for public healthcare reasons.

MS. CHARLOTTE MARKVA: But, it doesn't sound like it has been a lot of lawsuits to show that connection.

MS. KATHLEEN MCDERMOTT: Well, there has been some product liability type of things that explored the conflict of interest. There are certainly investigations that explore conflict of interest and potential violations of the kickback statute. That's what I do for a living.

So, I think that everyone understands and the OIG found that PODs is subjected to kickback statutes. They say these arrangements are inherently suspect for fraud. So, I think that that is the concern.

The OIG looks at four issues. They look at foremost patient harm, but that's not the only consideration. They look also as to whether medical judgment can be compromised or tainted.

They look as to whether overutilization has occurred, because they view that as a patient harm issue, as well as a fiscal issue for medically funded programs. They also look at whether in the totality, you know, this is going to induce improperly the provision of services that are federally funded.

One point that I don't think I didn't mention, which I think is an interesting trend. It's occurring a little bit in Virginia but nationally. I do have a national healthcare practice.

You see a lot of hospitals not wanting to take the risk of PODs. First, the Government has made it clear at the Federal level these are suspect arrangements. They are not ethical and they potentially are not legal.

So, you know, hospitals are looking at this after having to, you know, to assure that their own arrangements are lawful in saying it's nice for someone to say they are okay, but when the Government is saying they are inherently fraudulent, then they don't want to take the risks of these arrangements.

Some of the hospitals have updated, I

would say, finally, updated their conflict of interest policies to prohibit or band PODs in their hospital, or to regulate them, because what they are concerned about is what has been noted is because it's a special preference item, implantables, and surgeons are highly influential in the procurement process. I don't think anyone misunderstands that. That there is an opportunity to unduly influence the purchase of products.

So, the hospitals don't want to be tainted by the conflict of interest. They don't want to be accused of violating the anti-kickback statute because they are using a POD, only because a doctor said I will take my business elsewhere. So, yes, that does happen.

So, they want to have transparentical [SIC] ethical relationships. So, that's causing a lot of them to say I don't want the conflict of interest in my hospital.

In our Power-point, it lists a lot of the institutions that have decided they don't participate in POD arrangements. I think that's wise in public policy. Now, this isn't to cast disparage on a particular professional or a particular hospital if they did allow it

unregulated, but the harm and the potential harm to the public has increased. I would say at an unacceptable risk.

MS. CHARLOTTE MARKVA: Thank you very much.

MS. YVONNE HAYNES: Just a point of clarification for me. When you speak of procedures being tainted and corrupted, you are referring to the fraud that's inherent to the victim or? Please explain, please.

MS. KATHLEEN MCDERMOTT: I think when physicians are different than other healthcare professionals, because of their compensation and their investment and their ability to own, they have an ownership interest in an entity related to their procedures is regulated by the kickback statute.

The foundation of kickback statute is medical conflict of interest. The Federal anti-kickback statute is concerned about undermining and corruption of medical decision making because of the financial interest and the treatment of the patient.

In that context, that is what the OIG report has noted about PODs are concerned in that regards. They have noted it undermines the, you

know, the gatekeeper role of the physician and utilization.

Honestly, I, you know, am a little clasp when they say get a piece of the action. I am an old Government attorney. So, that's how I look at it. I think, you know, when I try to counsel professionals in this, you know, people will say, well, you know, academically you can have a POD that meets the entire Federal punch list of a safe practice.

It is virtually impossible to achieve that and who regulates it and where is the accountability. Self regulation has not been that successful. That's why we have a war on healthcare fraud in this country. That's why entities and individuals are indicted everyday, because they are violating the kickback statute. It's a pervasive issue.

I don't know why PODs are any different than any imaging centers, or other types of activities where the physician gets a piece of the action. Would a physician own a POD if they weren't performing the procedures and couldn't influence the hospitals and the purchase of them. I don't know. I would suggest human behavior is what

it is.

I think you have to really consider the issue not on the dimension of good doctor, bad doctor because that is just not a practical analysis, because every doctor I've ever met I liked and thought was honorable. That's just the reality. That's why they are so influential. That's why white-coat marketing is such a danger.

So, you really have to regulate conflict of interest on a multi-dimensional level that says what is the risk. It is okay to have a small percentage that aren't good at managing PODs and don't make disclosures to their patients, and, you know, strong-arm their hospitals to get their products. Is that okay because most may be all right. Thank you.

DR. IRENE FARQUHAR: Thank you.

I would like to ask if you are aware of cost incentives evidence and studies that would clearly ascertain the trends in overutilization within the trends of overuse in surgical procedures and trends in PODs?

MS. KATHLEEN MCDERMOTT: I don't think -- I doubt there is anything that is scientific as a statistically a valley random sample

at certainly confident levels. I think the OIG is the first Agency that has sought to be somewhat scientific in their examining of this issue. They did take a sample. I did confirm overutilization.

Is that a trend I would argue that is a predictable trend and anything that has a financial conflict of interest you will see an increase in utilization.

The only other one that -- There are actually two. There was the New England Journal of Medicine article in 2002 that identified overutilization. I've cited in a life paper that I have written that cited imaging center ownership and the dramatically increases in medical unnecessary services. That's probably the most credible study that has been done, but it was not on PODs. It was on imaging centers. But, I think the principles underlying that are predictable for this type of arrangement.

Then you have the California workers' compensation situation where because of a dramatic increase in utilization attributable to PODs, I banned them. I think in that context limited to workers' compensation they probably looked at it as fiscal issue that they have to get control on their

cost.

So, those reports, the OIG report and the New England Journal of Medicine study from 2002 and the California Legislation related to workmens' comp, I think are the three that I am most familiar with.

I think when you look at the rationale of the fraud and abuse statutes, which I don't think relied necessarily on statistical studies, but they took a regulator's view of public health in addressing conflict of interest. That conflict of interest regulation has been around for almost 40 years.

DR. IRENE FARQUHAR: Thank you.

Any further questions from the audience or from the Board?

MR. DAVID BROWN: I do. I might have missed this at the beginning. I am curious how you ended up here today. Are you representing someone?

MS. KATHLEEN MCDERMOTT: I am not representing any particular company. I do, however, represent device companies and medical societies, such as the American Academy of Orthopedic Surgeons. I don't generally reveal my clients publicly and am not authorized to do so. But, I am absolutely

involved in these issues from a compliance and other perspective.

MR. DAVID BROWN: Just looking at your website, while I was sitting here listening to you, it says that you have a national corporate defense practice. Does that accurately characterized?

MS. KATHLEEN MCDERMOTT: It does. I represent small, medium and large companies when they get in trouble.

MR. DAVID BROWN: Yes.

MS. KATHLEEN MCDERMOTT: And when they get subpoenas. They frequently get subpoenas for allegations of fraud and abuse. They hire me to help them navigate through physicians.

MR. DAVID BROWN: But, your presence here today, did we invite you to come down here today, or did you decide this is an interesting topic?

MS. KATHLEEN MCDERMOTT: No, I am --

MR. DAVID BROWN: Are you representing someone here today?

MS. KATHLEEN MCDERMOTT: I am not representing a particular entity here today. I have been asked by an entity to participate.

MR. DAVID BROWN: Okay. Thank you.

DR. IRENE FARQUHAR: Would you advise us if whether there are scientific studies, which we can tap into to understand the most potential harm, but evidence of this harm. The question has been asked already. I think you are avoiding it.

MS. KATHLEEN MCDERMOTT: Okay. Other than what I have cited, I think I would go back. There is a lot of articles on this. I can't tell you whether they are empirical studies. I have offered a life paper on this that's got about 105 footnotes. I think it might be helpful to go back and look at some of those footnotes and see if any would be helpful to that question. But, I think what I cited so far is helpful to that particular question.

DR. IRENE FARQUHAR: Thank you.

Any further questions? Thank you.

MS. KATHLEEN MCDERMOTT: Thank you.

DR. IRENE FARQUHAR: Senator Steve Martin, please.

SENATOR STEVE MARTIN: Good morning.

DR. IRENE FARQUHAR: Good morning.

SENATOR STEVE MARTIN: I am Steve

Martin. I represent the 11th Senate District, which is the most of Chesterfield County and all of the City of Colonial Heights and all of the County of Amelia.

I don't come in here with fresh news about healthcare discussions. Even before I became a legislator some 27 years ago, I was actively involved in the mental health community, and also working with the corporate world on providing employee benefits and to the healthcare industry as well.

For all of my 27 years as a legislator, almost 27 years, I have been focusing on healthcare issues. I am the Senior Minority member of the Senate on the Educational Health, former Chairman. A Chairman for a good number of years of Health Professions Committee, which I also held licensing Committee towards which deals with the turf wars between medical interest.

I am the Senior member of all of the 50 states on each of the two major national task forces of healthcare to convince yourself and American Exchange Council.

I am the only State Legislator in the entire nation asked to serve on the Healthcare

Reform Commission that was established by President Bush in the early 2000's.

So, I don't come to you as someone who has not looked at this issue fully. I fully understand that there are two marketplaces, in which the issues of market places, competitive markets, so I fully understand. There are two market places that don't really reap the benefits like they should. Market forces involves supply and demand. Healthcare is one. Education is the other.

I would like for it to be different than that. I have worked hard for it to be. So, regardless of opinions on this, this Board here, the fact is that I believe that we can handle the concerns of COPN without there being COPN. The reason I raise COPN is because of the arguments I heard made so far.

The arguments that were made before us on COPN over the years has been that an oversupply without COPN regulating that marketplace, and an oversupply of such things as MRIs and CAT scans, and all of these sorts of machinery will drive up costs.

Now, they use the word "cost", even though what they really mean is "demand" and the

total cost as a result in this demand. The fact is that can't be possible given the laws of supplies and demand, unless and oversupply of a product never drives up cost, unless it's being driven by the supply. That's the only set of circumstances. So, that's the problem in dealing with that. Dealing with what can happen in the medical world as far as driving referrals.

Now, we have representing before us right here arguments of mixed messages that is, one, opposite of that. Saying that somehow that a physician who can drive the demands, as a result of it somehow could drive down the cost, but then turns around -- and I heard this. I was stunned at this argument. I know I heard the first speaker. This is a quote, the distributor -- The suppliers only reduce the cost when the demand for the product is down.

Now, if you think that through and then put it with what they are arguing here. First of all, that is an absolute. That is the way the market is supposed to work, the laws of supply and demand. The demand is down relative to the supply. Yes, you lower your cost. That's what happens.

Now, let's move to generics. Yes,

generics are in the marketplace. Generics cost less. Generics need to find their way into the marketplace because that's helpful. But, to say that the way in which generics must find its way into the market way is through byway of PODs whereas Ms. McDermott said just a few minutes ago. I think she might have a Juris Doctor.

But, Ms. McDermott said a little while ago, there is a conflict of interest, not a potential. If you are in that POD whether it causes harm or not, the very fact that you reap financial residual reward as a result of your role is a conflict of interest. It is not a potential conflict of interest, it is.

And does it cause harm? Yes, it might not cause harm. It does cause harm because it causes harm to the credibility and the integrity of the system that such a situation could be allowed. It does cause harm because it exists.

The fact that there is not a lawsuit that says that, no, I not only was referred unnecessarily, but because I was referred unnecessarily then these physical damages were caused to me. I have the resources and the will and residual to pursue remedy. Maybe that doesn't get

it, if that's what you are looking for. Then we have a problem with most of our laws that exist on the books, because our laws exist on the books are looking for victims. They are looking to prevent them from being victims.

But, yet the questions I am hearing asked here as looking for scientific evidence as to and legal cases as to whether it led you to something, when absolute common sense tells you it exists. Absolute common sense tells you it exists.

How could you on one hand say that we want more competition in the marketplace, then not in your very argument recognize the facts of the laws of supplies and demand. They are as I just stated them. The fact is if you allow a situation.

Now, you come to a dealership to buy a car. Well, you came there because you wanted a car. There is no doctor prescribing that for you. There is no one telling you that your life depends on this, or your health. You came there. That guy might recommend a particular car. There is no conflict of interest. It exist, but it's a different thing, okay.

Those market forces I wish they were allowed to benefit the medical profession for what

it does, but, we've set it. We set up laws and regulations because we are concerned about the actual health and safety of the public. We are not willing to take the chance that you might on your own free will buy a car that might not have been the best one for you. All right. There is a difference and you cannot make argument with that analogy.

So, this came to my attention. I introduced it to legislation because I became aware of the OIG report. I didn't know such things happened. As a matter of fact, we've worked so hard to prohibit things like this. I bet you folks that are aware of this.

An optometrist, if you look to an optometrist that is associated in any way whatsoever with a retail outlet that there can't be a door that allows you to pass from that optometrist into the retail outlet. You have to go outside back out to the parking lot before you can come back into the retail outlet.

We've gone pretty far to make sure this sort of thing doesn't happen. When I heard it was a possibility it was happening here, I had said, no, we have to prevent that. Another reason why we are here before you is because I became convinced

that, okay, look, this is poor oversee of the medical profession in the State of Virginia. Let them pass judgment on it, okay. I would be appalled if you folks think this is okay. It's not okay.

The OIG would not have been expressing their concerns if it was within the realm of reason. It's not. I have heard the arguments. I heard it from the arguments from a few people here today. It's another way that a physician can make money in a stressed marketplace where they are not making money. Yes, and there are lots of ways that can happen, and lots of those ways are wrong, okay.

No, not every doctor is not a bad doctor. That's absorb. Most of them are not, by far most of them are not. Most of them they are honest people. They are going to do business right.

But, you've heard way too many cases, around this country, way too many big cases, in which there is fraud abuse and there is conflict of interest, big cases. Then there are a whole lot of little ones that don't get flagged so much. Then we know there are even more that's going on. So, don't tell me it's not happening. It's common sense. It's total common sense that it would. It's the way markets work. There is a conflict of interest

simply because it exists. Not because of a particular outcome that might find its way into Court with a certain ruling at the end.

So, I thank you for this opportunity to be before you. I certainly hope that you find that this is not a practice we want in the Commonwealth of Virginia.

I had all of my notes here. I hope y'all don't mind here. I talked from a big legal pad.

DR. IRENE FARQUHAR: Thank you, Senator.

SENATOR STEVE MARTIN: Thank you.

DR. IRENE FARQUHAR: Thank you for introducing that piece of legislature [SIC]. That gives us, the Board, and the public to consider the matter of the public safety. I would like to ask for questions.

SENATOR STEVE MARTIN: If I might just close. My involvement in the healthcare debate is then to create more competition. If you look at my records, I have had one hundred of thousands of dollars spent against me in one session alone because of legislation that I introduced, not in a campaign, but in one session because I introduced

legislation that would allow for competition in the healthcare marketplace. There are TV ads and radio ads ran for months relative to COPN.

So, the idea that in some way, shape, or form that this is helpful to the laws of supplies and demand is absolutely absorb. Yes, generics cost less. Generics need to be in the marketplace. It is wrong for it to find its way to the marketplace this way. I thank you.

DR. IRENE FARQUHAR: Thank you.

Next person to speak is Dr. Tom Tremble.

MR. THOMAS TREMBLE: Yes, ma'am. Good morning. It's still morning. Thank you, Chair and Members of the Committee.

My name is Thomas Tremble. I am with the Advanced Medical Technology Association. We are the primary trade association that manufactures medical equipment. I want to take a few minutes to address some of our concerns, and hopefully not repeat too much of what others have said.

So, I want to give you a little more background on our association, Adva the company I am referring to. We are comprised of about 40 manufacturers of a wide range of medical equipment,

syringes and needles to surgical tools, MT equipment, and implantable devices as well.

Some large members, but most of our members are about two thirds are small companies. Included in our membership, our the primary manufacturers of implantable orthopedic devices that allow patients to regain some of their mobility.

But, I want to leave you with four points today about PODs that has been generally referred to. And going along with the OIG has said both in their study and their special fraud work that they released.

PODs are inherently suspect as the OIG has cited. PODs have inherent conflict of interest because their success is based on referrals primarily by their investors. HHS studies have shown that PODs can threaten patient safety by performing a higher rate of surgeries and increasing healthcare cost. As the OIG has advised, it is not possible to create a good POD where the purpose of the investment is inducing or rewarding referrals.

So, it might be a little more helpful if I gave background on medical device development process. One of the unique characteristics of our industry is that, many, not most of the place

innovation occurs in the field of professional practice with companies working closely with physicians to incorporate their recommendations for improvements to existing devices. Such collaborations have resulted in numerous technologies that have proved to patient care.

In some cases, physicians have created a company to develop their idea for a device innovation. Often, if a physician has been instrumental in the development of a new medical device, the manufacturer will pay the physician a royalty for his or her contribution.

So, we are totally supportive of the ability of physician-innovators to develop and bring to market their ideas to improving healthcare devices. We support physicians having the ability to invest in innovative device manufacturing companies, where the model is not predicated on the physician's recommendation of/or referral of the entities products.

In fact, small and start-up device firms are often the incubators of new technologies, and those companies really help to drive innovation that can save lives and reduce costs to our healthcare system.

So, to ensure that interactions between companies and physicians meet high ethical standards, they must be conducted in a transparent manner and must comply with applicable laws, regulations and government guidance.

That's why AdvaMed several years ago developed its Code of Ethics on interactions with healthcare professionals. AdvaMed's Code distinguishes the interactions that contribute to the advancement of healthcare and interactions that may be perceived as inappropriately influencing physician decision-making.

We support and proactively has embraced appropriate disclosure of relationships between companies and physicians.

We recognize, for some types of physician relationships, disclosure is not sufficient. Some Federal and State laws aim to prevent or eliminate any conflict by prohibiting doctors from referring patients to entities that they have ownership interest in.

The Federal anti-kickback law that has been cited a few times is that law is intended to protect patients from inappropriate medical referrals by healthcare may be unduly influenced by

financial incentives.

So, over the past several years, a new type of entity has developed in southern California and has spread across the country. These arrangements come under two different names. POCs (physician-owned companies) or PODs (physician-owned distributors), are designed to include equity investments by physicians who are major revenue generators for the companies.

As PODs proliferated, evidence of inappropriate surgeries with the potential harm to patients in increase in healthcare costs by Congress and the Federal regulators to take a closer look at the practice.

In fact, that question came up earlier, I don't have it with me now, but a few years ago there was a series of articles done by the Wall Street Journal why physicians who were doing a high number of surgeries much more than their colleagues. Those physicians were in the PODs. They were showing patient harm that had been caused. I think in some cases there was death with some patients. So, I wish I had brought that today, but I can get that to the Committee later.

So, in March of last year, as I had

mentioned, the Office of Inspector General came out with their special crime alert, calling the POD "inherently suspect".

The introduction pointed out that in prior guidance OIG specifically cited: "the strong potential for improper inducements between entity and among the physician-investor, the entities, device vendors, and device purchasers."

In March 2013, fraud alert of PODs that are problematic described eight characteristics of PODs that are problematic. It goes through a few of them: Selecting investors because they are able to generate substantial business for the entity; the size of investment offered to physicians varies with the expected or actual volume of POD devices used by the physician; physician-owners conditioning their referrals to hospitals on their purchase of PODs devices through promise or coercion; requiring investors who stop practicing in the service area to divest ownership interest; and distributing extraordinary returns on investment compared to the level of risks involved.

So, Special Fraud Alert PODs exhibiting these or other questionable features raise four significant concerns usually associated

with PODs. Corruption of medical judgment; overutilization; increased costs to Federal health programs and beneficiaries; and unfair competition.

The Special Fraud Alert expressed particular concerns about such arrangements involving implantable devices because those type of devices are generally known as "physician preference devices", which unlike many devices, surgeons of implantable devices will request that a hospital provide a particular brand, or type of device. In some cases, it may be that they had more training on that device and more familiar with it.

So, it pretty much because of that and those implantables the physician-preference items where the facility will defer to the surgeon's preference. They are certainly able to dictate to the type of brand the hospital must purchase.

Finally, I want to particularly emphasize two points from Special Fraud Alert: They said we do not believe that disclosure to a patient of the physician's financial interest in a POD is sufficient to address these concerns." These criteria are not intended to serve as a blueprint for how to structure a lawful POD, as an arrangement may not exhibit any of the above suspect

characteristics and yet still be found to be unlawful."

Back in last October, the OIG came out with a report that examined the use and prevalence of spinal devices supplied by PODs, and among their findings: PODs supplied devices for 19 percent of spinal fusion surgeries that was billed to Medicare in 2011. Sixteen percent of the spinal fusion surgeries in Virginia involved POD devices.

Surgeries involving POD devices did use fewer devices, but did not have lower costs than non-POD surgeries. Generally, POD devices can cost the same or more than non-POD devices. But, they did find the growth rate of spinal surgery hospitals purchasing from PODs was three times that of all hospitals.

Not to insult you-all, I think that is where the the growth rate of spinal surgeries and hospital purchasing from PODs was three times of that of other hospitals. The cost of the POD devices and the increased volume at POD hospitals may increase the cost of spinal surgery to the Medicare program and beneficiaries over time.

So, I am concluding in no way do we want to question the integrity of the many Virginian

physicians who are acting in the best interest of their patients. The perception and reality, in some cases, is that healthcare decisions are being made for economic reasons as opposed to what is in the best interest of the patient.

I ask the Board to consider the findings of the Special Fraud Alert and its strong admonition that "PODs are inherently suspect under the anti-kickback statute" and that they are concerned about their proliferation.

Hopefully, after reading the alert, that the Board will agree with our findings and can play some role in helping to educate the community of physicians about their concerns and consider it during it's deliberation. Thank you.

I can answer any questions.

DR. IRENE FARQUHAR: Thank you.

Questions, please.

You did mention a few references to scientific study and that can be brought into consideration and cited and concluding the study in the report. Could you please so kind as to share with us. I look through your statement I didn't see these submitted to those specific references, so if you would.

MR. THOMAS TREMBLE: I think there is lack of scientific studies. I will find the data that I am aware of and provide that.

DR. IRENE FARQUHAR: Thank you.

Mr. Brown.

MR. DAVID BROWN: Are you aware of others states that have taken steps to regulate PODs?

MR. THOMAS TREMBLE: Yes, a couple of years ago, the Legislator of New Hampshire presented a bill that passed the House of Representatives. I think it was similar to the legislation here in Virginia.

In the Senate they decided to study Committee. So, they studied over the session and reported back to the Legislator, but I don't think they took any further action on it.

It was mentioned that California has acted a law on PODs. Oklahoma has also weighed in with the legislation. I am not familiar with the specifics on that, but I can get that.

DR. IRENE FARQUHAR: Thank you.

From the audience, any comments? Any comments from those persons who did not sign in on the sign-in sheet? Is there anyone who wants to

speak come forward. It will be recorded and very helpful for our consideration.

Also any comments will be accepted until 5:00 p.m. June 20, 2014. We will be accepted and very much appreciate it.

If there are no further questions, no further comments, no further issues that wish to be discussed at this moment, I want to thank all of you for your time to come today. We will consider all comments prior to recommendations concerning further study.

We, once again, I would like to ask for written comments. You still have a month ahead of you.

Again, thank you very much for being here and for participating. That is our concluding for this hearing. Thank you. So this concludes our public hearing Regulatory Research Committee will start shortly after this, after the conclusion of this meeting. We will take a five minute break and we will reconvene. Thank you.

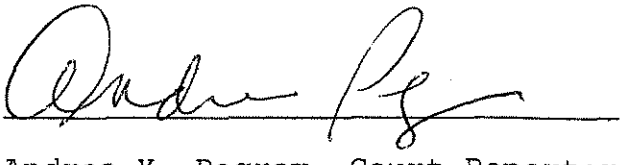
MAY 20, 2014: 11:34 A.M.

CERTIFICATE OF COURT REPORTER

I, Andrea Pegram, hereby certify that I was the Court Reporter in the hearing held at the Department of Health Professions, on May 20, 2014, at the time of the public hearing herein.

I further certify that the foregoing transcript is a true and accurate record of the hearing herein to the best of my ability.

Given under my hand this 20th day of May, 2014.



Andrea Y. Pegram, Court Reporter