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PHYSICIAN-OWNED DISTRIBUTORS: ARE THEY HARMFUL TO PATIENTS AND PAYERS?

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

FIRST SESSION

NOVEMBER 17, 2015



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PHYSICIAN-OWNED DISTRIBUTORS: ARE THEY HARMFUL TO PATIENTS AND PAYERS?

TUESDAY, NOVEMBER 17, 2015

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 2:30 p.m., in room SD–215, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Present: Senators Grassley, Thune, Scott, Wyden, Stabenow, Brown, and Bennet.

Also present: Republican Staff: Kimberly Brandt, Chief Oversight Counsel; Justin Coon, Detailee; and Jill Wright, Detailee. Democratic Staff: Dave Berick, Chief Investigator; and Matt Kazan, Health Policy Advisor.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. The committee will come to order. I want to welcome everyone to this afternoon's hearing.

Today we are here to explore the various issues surrounding the growth and prevalence of Physician-Owned Distributors, or what we call PODs. Simply put, PODs are medical device businesses in which a physician is both an investor and a distributor, essentially a salesperson, of either the devices or of some of the components.

And while these arrangements are not always problematic, we are seeing more and more of these physician salespeople using the very devices they sell in the surgeries and procedures they perform. Many critics have argued, with significant evidence to support their case, that this practice creates a financial incentive for these physicians to recommend and perform more and more unnecessary surgeries.

Typically, the more devices or hardware a POD physician implants in their patients, the larger the payment he or she receives from the POD. So an incentive clearly exists to these surgeons to perform a steady stream of procedures, increasing the use of products supplied by their POD, thereby increasing their own incomes.

The question we will address today is whether these arrangements and the apparent conflicts of interest that exist among POD physicians have had a negative impact on our health-care system and, of course, the well-being of patients.

As some of you may recall, in June 2011 the Republican staff of the Finance Committee issued a report on PODs, outlining key issues and potential areas for congressional oversight. In response

to some of the concerns outlined in the report, former Chairman Baucus and I, along with Senators Kohl, Grassley, and Corker, wrote to the Inspector General of the Department of Health and Human Services to share our concerns about the proliferation of PODs and the lack of guidance as to how these arrangements square with existing Federal law.

For years, the HHS Inspector General has warned about the conflict of interest created by a joint partnership between physicians and companies, including device manufacturers that depend on them for referrals or new business. In March 2013, the Office of the Inspector General issued a special fraud alert calling PODs, quote, "inherently suspect" under the government's anti-kickback laws. Later that year, the Inspector General reported that the number of spinal surgeries in hospitals that purchase implantable devices from PODs grows at a faster rate compared to other hospitals.

The OIG also found that for nearly one in five spinal fusion surgeries billed to Medicare, the device was supplied by a POD, indicating a potentially significant link between PODs and Federal health-care costs. Most notably, this same report found that physicians with investments in PODs perform on average 20 percent more surgeries than their counterparts who do not have these kinds of financial relationships.

Needless to say, these findings confirm much of my skepticism about PODs. And while the OIG's guidance helped to persuade many in the industry that PODs were a risky business model, we continue to see reports in the media and from our constituents that these types of arrangements are still prevalent in our health-care systems. And because the Federal Government does not regulate these types of business arrangements, it is difficult to determine just how many PODs exist or where they all are. This lack of accountability is one reason why the issue is, at least to me, so complicated.

Anecdotally, we received reports of PODs operating in every State represented on the committee. From what we have heard, the growth rate of PODs has slowed since the Inspector General's March 2013 alert. However, the total number of PODs remains roughly the same as before the report.

Now, our information indicates that PODs are no longer concentrated in large hospital chains, as many chains have adopted policies forbidding or strictly curtailing POD usage. As a result, many PODs have migrated to smaller and more rural hospitals.

Some proponents of PODs have argued that some of our hardline statements and positions regarding their business arrangements go too far. They claim that implementing a sweeping prohibition on physician ownership in medical technology companies might have an unintended chilling effect on legitimate business practices as well as medical breakthroughs and research.

Nevertheless, we note that a number of POD physicians have abused their positions of trust and have put their own personal financial gain above the safety of their patients. According to Department of Justice filings, one such physician was Dr. Aria Sabit, who, within months of accepting a lucrative investment offer from a POD, more than doubled his number of instrumented spinal fusion surgeries.

Prior to making his investment, Dr. Sabit had never used the POD's product before. After his investment, he used their products in more than 90 percent of his spinal fusion surgeries. All told, Dr. Sabit had invested $5,000 in the POD. In just over 2 years, he saw a return of over $438,000.

Now, I am not typically one to decry investments with a high rate of return, but those numbers alone should be enough to, at the very least, raise a few eyebrows. In the end, Dr. Sabit pled guilty to more than $11 million in health-care fraud, and to causing bodily harm to his patients. One of our witnesses today, Kevin Reynolds, will tell us about his mother's experience under Dr. Sabit's care.

As part of our ongoing inquiry into these issues, the Finance Committee has become aware of additional cases that warrant further review. As a result, Ranking Member Wyden and I will be making a formal referral to the HHS Office of Inspector General and the Department of Justice on at least one case we feel deserves review for potential criminal action. We will be submitting additional information to the HHS OIG and to CMS about the rate at which PODs report their ownership interests. We believe these findings will say quite a bit about the lack of accountability for these types of business relationships or arrangements.

I hope that today's hearing will be another important step in our ongoing efforts to provide appropriate oversight and enforcement on this issue.

[The prepared statement of Chairman Hatch appears in the appendix.]

The CHAIRMAN. Now, I want to especially thank our witnesses for appearing today. I look forward to hearing their insights on these complex matters. And when Senator Wyden gets here, we will turn to him for his opening statement.

We are grateful to have all of you here today, and we will look forward to taking your testimony. And I guess we will begin with you, Doctor, all right?

Dr. LEDERHAUS. Well, thank you very much. I am honored to be here——

The Chairman. Well, let me take a second to introduce you. [Laughter.]

Dr. LEDERHAUS. All right.

The CHAIRMAN. There are four witnesses at today's hearing. The first one is Dr. Scott Lederhaus. Dr. Lederhaus is a neurosurgeon from California who has been concerned about the potential negative effects of PODs on the health-care industry.

Dr. Lederhaus is president of the Association for Medical Ethics. And we want to thank you for being here today.

And let me just announce the other witnesses. Our second witness today is Dr. John Steinmann. Dr. Steinmann is a POD physician from California. Dr. Steinmann serves as chairman of the board of the American Association of Surgical Distributors, which is the POD industry group. And we want to thank you, Dr. Steinmann, for being here today.

Our third witness is Ms. Suzie Draper. Ms. Draper is the vice president of business ethics and compliance at Intermountain Healthcare, the major hospital chain in my home State of Utah,

and one that has been constantly referred to as a chain that does a really good job. So I want to thank you, Ms. Draper, for being with us today, once more, and we will get to you in just a few minutes.

The final witness today is Mr. Kevin Reynolds. Mr. Reynolds is a Navy veteran, a certified medical assistant, and a massage therapist. Mr. Reynolds's mother, Lillian Kaulbach, died after receiving spinal fusion from a POD doctor. So we are grateful to have you here as well.

And we will begin with you, Dr. Lederhaus.

STATEMENT OF SCOTT LEDERHAUS, M.D., PRESIDENT, ASSOCIATION FOR MEDICAL ETHICS, MONARCH BEACH, CA

Dr. LEDERHAUS. Thank you very much for allowing me to speak today. As you mentioned, I am part of the Association for Medical Ethics, which was a group formed in 2005 essentially to address issues regarding spine fraud. It was formed by Gemma Cunningham and Chuck Rosen, who is an orthopedic spine surgeon at UC-Irvine Medical Center and also instrumental in passage of the Sunshine Act.

I became involved in POD evaluation simply because of what I was observing at my own hospital and area. I was witnessing patients who had multilevel fusions for no reason; people in their mid-80s being treated for back pain with a 12-level fusion operation. Many of these people, of course, did not do well, and many of the docs in the area were also doing surgeries that did not seem to make sense to me. And this was before the issue of PODs even really came out in the press or anybody really knew anything about what they were. It appeared as though everybody who suffered from back pain became a surgical candidate.

Over time, Mr. John Carreyrou began writing articles in the *Wall Street Journal* which highlighted some of the Physician-Owned Distributors, and it became more apparent to me what was going on in my own area. And that information fit with what I was witnessing on a regular basis.

In some instances, I looked for information regarding these Physician-Owned Distributors. There was no information on the Internet. There were no salespeople to talk about the product. There was no reason to understand why anyone would use these products unless they were getting money from financial kickbacks.

There was secrecy among the surgeons themselves. Nobody was admitting to being involved in a POD. They were not telling their patients they were involved in a POD, and the community at large had no idea what was going on. And to date, these PODs are still kept in a rather stealthy, secret mode.

A few years ago, the Department of Justice began investigating the Reliance Medical POD, and they discovered a number of things, one of which was that many of these surgeons were making in excess of $50,000 a month simply for implanting their POD hardware. And this did not include the fee that the surgeons were charging to actually do the surgery.

One of the owners of this particular POD made close to $4 million in a 6-year period from the implantation of his POD hardware. The POD investigation done by Mr. Carreyrou of the *Wall Street*

Journal discovered that there were 11 PODs in six different States which involved 32 spine surgeons. There were only two owners of this group, and only one salesperson, which led to even more curiosity and speculation about what was being done.

Once this POD evaluation was under scrutiny by the Department of Justice, it became apparent that some of these POD surgeons switched to a different POD, because they knew the one they were using was no longer available. The issue about saving money on PODs also is erroneous. One of the physicians who was using a POD put in $4.6 million worth of implants in 2011. My neurosurgery group, myself and three partners, implanted $1.3 million worth of implants in the same time period. So this one individual put in 3.5 times the volume of myself and my three partners combined. So claiming savings does not make any sense if there is a high volume of implants being implanted for the sake of enhancing income.

How does this affect the patients? Many of the patients I have seen in second opinions are worse off and in more pain. They have been using narcotics on a chronic basis. They have had multiple operations. Some of them have had infections, many of them being life-threatening infections. They have been unable to work, had a loss of income. Patients feel as though they have been abused and abandoned, and this adds to the burden of the Federal Government. The Federal Government becomes financially responsible to care for these patients.

Another issue is one I have termed "predatory pricing." A physician who is a member of a POD can go into a geographic area and obtain all of the health-care contracts because they can underbid the non-POD physicians. Thus, one POD physician may be able to sign a health-care contract at 40 percent of Medicare reimbursement, whereas the non-POD docs cannot survive on that reimbursement. So this becomes an issue about preselecting the POD docs over the non-POD docs, and rewarding the people who, in many instances, are doing harm to the patients.

Our societies, the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the AMA, and the American Academy of Orthopedic Surgeons (AAOS), in their code of ethics state it is unethical to receive compensation from a manufacturer for using a particular device or product.

Are these PODs ethical? I believe the reason we talk about ethical PODs is because PODs are not legal. Safe harbor laws negate legality, as no POD can satisfy the restrictions of the safe harbor restrictions. Since PODs cannot fulfill these legal requirements, those who are involved in a POD then simply try to be or appear ethical.

In conclusion, I feel that some hospitals have ignored the warnings and continue to use PODs. In my opinion, there have been no cost savings. The FDA approval has been meaningless, as implants can be made in foreign countries or anywhere else, and one can obtain FDA approval via "substantial equivalency." And there is also a big question of quality with POD implants—where are these implants made, and who is making them? This is not an issue that can be ignored. It can and will affect everyone to some extent.

Thank you.

[The prepared statement of Dr. Lederhaus appears in the appendix.]

The CHAIRMAN. Dr. Steinmann, we will turn to you.

STATEMENT OF JOHN STEINMANN, D.O., BOARD ADVISOR, AMERICAN ASSOCIATION OF SURGICAL DISTRIBUTORS, REDLANDS, CA

Dr. STEINMANN. Chairman Hatch, Ranking Member Wyden, honorable Senators, and valued staff, it is my honor to be here to speak with you today on the subject of surgeon ownership in medical device distributorships. I am an orthopedic surgeon in practice for 25 years. I am a senior partner in one of California's largest orthopedic groups and a board member of the California Orthopedic Association.

I want to make it clear that I am not here to defend any of the individuals or stories that are portrayed by the other witnesses. I am here because I offer another side to this story, a side that shows the potential value of this model, when the distributorship is structured in a manner that deeply protects patients.

You will hear testimony today that raises valid concerns about distributorships that are not structured correctly. You will hear from a family member of a patient with a terrible outcome following a spinal surgery performed by a surgeon with severely compromised ethics. And, Mr. Reynolds, on behalf of the medical profession, I am truly sorry we cannot do a better job of removing bad doctors from our ranks.

This is why, as we bring necessary change to our health-care system, we need to support models with strong standards that protect patients' health. We must reduce waste in our system and correct the serious flaws that enrich certain industries to the detriment of our country.

Ask yourselves, please, why in this country do we pay twice what Europe pays for our own U.S.-manufactured products? We need to address this market failure and fix it. We owe that to the 1.7 million Americans who are affected by a medical bankruptcy every year.

In this country, we acquire medical devices in a horribly inefficient and very expensive manner. First, when ordering medical devices, surgeons bear no financial burden for their decision, and hence the choice of the implant is most often based on rep relationship or brand loyalty, never on value. There is no incentive for surgeons to create or support a competitive environment—a better-controlled price.

Second, we missed the opportunity to create competition and purchase in volume. We must move from this highly inefficient commission distribution system to a stocking distribution system where surgeons and hospitals prospectively derive a consensus on product designs and features, identify competitive manufacturers, and create an environment that rewards the products of highest value. Ownership of this stocking distribution company can be either the surgeon or the hospital, depending upon the circumstance.

We have proven that this model can work in a manner that protects patients and can result in savings in excess of 35 percent, a

number that could, in theory, gain us back the $7 to $10 billion a year we waste in this country on orthopedic and spinal devices.

The American Association of Surgeon Distributors has promoted a structure that ensures transparency, protects patients, and ensures cost savings. The distributorship we developed 8 years ago has served four hospitals. Our main hospital has documented over $8 million in savings, all in a manner that is fully transparent to our patients, to our colleagues, to our hospitals, and to our government, and with no increase in surgeries performed. That is nearly $250,000 in savings per surgeon per year.

The conflict of interest associated with surgeon ownership and distribution is a serious and a valid concern. We have proven those concerns can be countered and patients protected with high, clear, enforceable standards such as those of the AASD. We should derive confidence that conflicts such as fee-for-service and bundled payments, which offer a far stronger incentive, are safely managed by these very same principles.

In closing, the health-care industry is finally starting to innovate methods to increase value by finding means to enhance the patient experience at a lower cost. And it would be a shame for our country's leadership not to endorse in some manner any model that is proven to effectively produce these goals.

This is why, policymakers, I ask you to please request of the Office of the Inspector General affirmative program guidance along the lines of those standards outlined by the AASD so that patients can be protected and the American public can start to see the benefits of effective, well-structured innovations in health-care delivery.

Again, I thank you for the opportunity to discuss these standards and welcome any questions you may have.

The CHAIRMAN. Well, thank you, Dr. Steinmann. We appreciate your testimony.

[The prepared statement of Dr. Steinmann appears in the appendix.]

The CHAIRMAN. Ms. Draper, we will take your testimony now.

STATEMENT OF SUZIE DRAPER, VICE PRESIDENT OF BUSINESS ETHICS AND COMPLIANCE, INTERMOUNTAIN HEALTHCARE, SALT LAKE CITY, UT

Ms. DRAPER. Thank you very much. Intermountain Healthcare appreciates the opportunity to describe our policy for dealing with Physician-Owned Entities. My name is Suzie Draper, and I am vice president of business ethics and compliance at Intermountain Healthcare.

Based in Salt Lake City, Intermountain is a not-for-profit healthcare system that operates 22 hospitals in Utah and Idaho, more than 185 physician clinics, and an insurance plan called SelectHealth. Intermountain has become well-known internationally and nationally for identifying best clinical practices and applying them consistently. Our focus is on providing high-value health care, and our mission is to help people live the healthiest lives possible.

My testimony will describe Intermountain's challenges in implementing policies and procedures regarding both Physician-Owned Distributors and Physician-Owned Entities as vendors.

Intermountain Healthcare's supply chain organization is responsible for over $1.5 billion annually and oversees the distribution of over 2 million medical devices annually. In the early years of our supply chain, we sought information about physician ownership for vendors, even though these relationships were not viewed as an absolute impediment to contracting. Over time, however, we received increasing reports from the field regarding suspected and nondisclosed financial relationships between vendors and physicians who were in the position to order products.

Prior to the OIG's Special Fraud Alert in 2013, Intermountain internally struggled to reach consensus on the proper way to approach PODs and then strike a balance between competing interests. With the publication of the Special Fraud Alert, consensus at Intermountain crystalized around a bright-line policy that would be straightforward to implement. We thus were able to create our Physician-Owned Entities Financial Arrangements Policy—that is a mouthful—or our POE policy. This policy prohibits Intermountain from purchasing from a POE any product or service other than those that were personally furnished by a physician owner or health professional employee.

Our policy does have two exceptions. The first exception applies to POEs in which the physicians are not in a position to generate business for Intermountain. This exception requires a written contract in which the POE attests that its physicians do not generate such business and that the POE does not have any of the eight suspect characteristics identified in the Special Fraud Alert.

The second exception to our POE policy is made for useful, disruptive technologies that are preapproved by Intermountain's senior management team. This exception gives us the flexibility to make available new products and services that are beneficial to the patients.

Finally, our POE policy has also required a great deal of coordination between our compliance and our supply chain staffs to ensure that our policy is appropriately applied.

Our first priority was to terminate non-compliant arrangements for implantable medical devices. Our policy has helped Intermountain comply with the Anti-Kickback Statute when dealing with POEs, and it has helped us avoid relationships with the type of suspect PODs identified in the Special Fraud Alert.

However, the implementation of our policy has not been without challenges. I will discuss three. The first challenge concerns the trade-off between standardization and competition.

To some degree, our POE policy has narrowed the field of qualified suppliers. Standardization is generally viewed as a positive cost-saving measure. However, in this situation, we may be standardizing on a legacy group of products, a practice some argue is inefficient, anti-competitive, and potentially subject to abuse. Our challenge is to strike the right balance between competition and standardization while ensuring the products we source are the best for our patients.

The second challenge concerns medical innovation. As I mentioned, our POE policy provides an exception for certain POEs with products or services that are potentially groundbreaking, from a therapeutic perspective. This exception applies in the infrequent

circumstance where disruptive technology is only available through a POE and is approved by a panel of three non-conflicted clinicians and then ratified by our senior management. The challenge with this exception is that it is very narrow in scope, and there have only been a few instances where suppliers have met these requirements. This is not because the suppliers were unwilling to comply with the Special Fraud Alert, but rather their products or services were not truly disruptive.

The third challenge that we have with our POE policy is our need to preserve innovation and collaboration at Intermountain. We are considering adding a third policy exception for technologies that are co-developed by Intermountain and its employees. We recognize that many of our own physicians are in the best position to invent beneficial technologies, and we hope that this exception will provide a compliant model for those activities.

In conclusion, I should note that we have included some of the specifics of our implementation steps in my written testimony.

Thank you for the opportunity to share our process.

The CHAIRMAN. Well, thank you, and we appreciate you, Ms. Draper. And I know that Intermountain does a terrific job and is well-recognized all over the country.

[The prepared statement of Ms. Draper appears in the appendix.]

The CHAIRMAN. Mr. Reynolds, we will take your testimony now.

STATEMENT OF KEVIN REYNOLDS, SON OF A PATIENT OF A SURGEON AFFILIATED WITH A PHYSICIAN-OWNED DISTRIBUTOR, VENTURA, CA

Mr. REYNOLDS. Thank you. Good afternoon, Chairman Hatch, Ranking Member Wyden, and distinguished members of the Finance Committee. I would also like to thank you for your comments, Dr. Steinmann.

I, Kevin Reynolds, stand before this committee on behalf of my mother, Lillian Kaulbach, and patients across the country who have been harmed by Physician-Owned Distributorships, or PODs.

My testimony today describes my family's involvement with PODs, specifically a POD called Apex Medical Technology, LLC, that was owned by Dr. Aria Sabit. Based on my mother's experience with the POD, I believe that PODs are a serious threat to patient health and must be stopped immediately.

PODs are a conflict of interest with the oath that doctors take that states they must do no harm. Beyond that oath, there is an unspoken trust and belief in our health-care system that doctors make decisions based on the patient's best interest. When doctors recommend surgery, patients put their trust in that judgment.

My mother's medical problem started in 2002 when she called me to tell me that she was having a hard time taking care of her paralyzed mother and her brother, who had recently had his skull removed after an accident. I dropped everything to go help my mother. With my help, my mother continued to take care of her mother and brother for several years. During this time, she had several major surgeries due to conditions brought on by the physical and mental stress of caretaking for her family.

After several surgeries, my mother still suffered from severe and persistent back pain. She turned to Dr. Aria Sabit for help in the

fall of 2010. I went with my mother as she met with Dr. Sabit in his office, and our meeting with him was very brief. It lasted probably only 3 to 5 minutes. Dr. Sabit did not perform any physical examination of my mother. Nevertheless, at the end of the meeting, Dr. Sabit recommended that she have spinal fusion surgery.

My mother and I trusted Dr. Sabit's judgment and decided she would have the spinal surgery. At that time, when we met with Dr. Sabit, we had no indication that he had an ownership interest in any products that might be used in her surgery.

Dr. Sabit performed surgery on my mother in October of 2010. My mother and I signed a consent form authorizing one level of fusion. However, Dr. Sabit performed four levels of surgery on his own without asking the family or my mother for consent. After surgery, my mother developed five to six different infections. The hospital staff told me there was nothing they could do.

They asked me not once, but twice, to pull the plug. I said "no." Miraculously, my mother showed some improvement, but she was never able to walk again. Instead, she became bedridden and was sent to a nursing home to battle these infections, taking up to 25 pills a day. On May 31, 2011, my mother passed away from complications related to Dr. Sabit's spinal fusion surgery. She was only 68 years old.

It was only after my mother died that I learned of Dr. Sabit's involvement with Apex Medical Technology, LLC, a company that manufactures screws and rods that were used in my mother's surgery. A single screw used in that type of surgery can cost around $100 to make and sell for upwards of $1,000 to $10,000 each.

As has been reported, Dr. Sabit had a 20-percent stake in Apex. It has also been reported that from May 2010 to August 2012, Dr. Sabit's share of the profits in Apex was approximately over $400,000. Simply put, I believe that Dr. Sabit had a clear financial incentive to use more screws and rods in my mom's back surgery than what was needed. And I believe this is a financial incentive that played a role in his decision to perform a more complex surgery on her than was medically necessary.

Some people have asked me if I would do anything differently if I had known that Dr. Sabit had ownership and interest in the products he planned to use in my mother's back surgery. Looking back, the answer is "yes."

Knowing that information and understanding the conflict of interest, we would have sought a second opinion before authorizing any surgery. Of course, we were not given the opportunity, because we did not know that Dr. Sabit was involved in PODs.

Since my mother's death, I have tried to tell her story. I have spoken out locally and nationally to news organizations, I have testified in Dr. Sabit's criminal proceedings, and it is my privilege to appear before this Senate Finance Committee.

But I know, even if Dr. Sabit goes to prison, patients will not be protected from the same dangers that claimed my mother's life and so many others. There are still other doctors who participate in PODs and have the same financial incentive that Dr. Sabit had for performing unnecessary and dangerous surgeries on a daily basis.

On behalf of my mother, Lillian Kaulbach, once again, I ask and demand this committee to stop these doctors. Please do whatever

is necessary to ensure that doctors make decisions based on what is best for the patient, not the doctors' wallets. Doctors should do no harm.

And the last statement is a mantra. PODs no more. Thank you for letting me go over, Mr. Chairman.

The CHAIRMAN. Well, thank you, sir.

[The prepared statement of Mr. Reynolds appears in the appendix.]

The CHAIRMAN. I apologize to the vice chairman. I should have called on him before anybody else, and we are going to turn to him now for his statement. And he will be the first to ask any questions.

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

Senator WYDEN. Mr. Chairman, no apology necessary. It has been a pleasure to work with you on this as we have worked together on so many issues. And I look forward to our pursuing this again in a bipartisan fashion, and today we put some bipartisan sunlight on it.

I want to apologize to all our guests as well. I am on the Intelligence Committee—obviously, we face great challenges there—and also on the transportation conference. So I am going to touch on a few issues here now.

I have been involved in these kinds of issues since my days as co-director of the Gray Panthers, and I think this is some of the most egregious and offensive behavior I have seen in a long, long time. And here is what concerns me. What is going on here are double-dip payments that are also a conflict of interest that puts American patients at risk. And let me be very specific.

The first dip is for the payment made by Medicare or a private insurer for the surgery. The second dip is the cut that the doctor gets from the manufacturer for implanting the device. So what we are talking about here is a system that creates these new incentives for more surgeries and more implantable devices.

And the chairman and I—because we have been working very closely together on a bipartisan basis—have looked at a number of these cases. The Inspector General wrote some time ago that these distributorships are inherently suspect under the Anti-Kickback Statute.

In my own home State, Dr. James Makker had his medical license revoked in 2012 after a long string of questionable surgeries and malpractice suits. News reports have indicated Dr. Makker was also affiliated with a Physician-Owned Distributorship. Before he lost his license, Dr. Makker had one of the highest number of spinal fusion surgeries of any surgeon in the Nation. He would sometimes operate six or seven times on the same patient.

Now, as Chairman Hatch and I have noted in so many of our inquiries that have been bipartisan, not all the practitioners in this field are involved in this kind of activity. And you all have highlighted that: that there are so many very responsible practitioners in the medical profession.

But the fact is, with respect to this type of business, too often the business practices of these distributorships are simply in the

dark, out of any kind of sunshine or transparency. The patients, the hospitals, the regulators, frequently do not know when a doctor is part of a distributorship.

So clearly, we need to do far more to ensure that the public is aware, which is how I see this. The patient has a right to know, and then, of course, taxpayers, because you have public payers, the people of this country, through the Medicare program. There is really an urgent need for more transparency.

Now, the Finance Committee has also gotten some troubling information from industry sources. Distributorships, under the Sunshine Act, are required to report doctors' ownership interests as well as their own payments to doctors. But neither seems to happen, again, when it comes to many of these distributorships. The committee got one report of a device manufacturer offering to make payments to doctors through a third party to avoid disclosure.

So Chairman Hatch and I are going to work very closely together with respect to these allegations and possible Sunshine Act violations that ought to go to the Inspector General.

But you are going to see, on this committee, Democrats and Republicans working together. These are extraordinarily important issues. And as far as I am concerned—and I feel badly, because now I have to go to yet another meeting in the Capitol—I want you to know that I am going to work very closely with the chairman. And I can tell you, Democratic Senators are very much committed to pursuing this with Chairman Hatch and our colleagues on the other side of the aisle.

And I apologize to our guests for three things, essentially, all at once.

Thank you very much, Mr. Chairman.

[The prepared statement of Senator Wyden appears in the appendix.]

The CHAIRMAN. Thanks, Senator. I appreciate you very much.

Well, let me just say that my colleagues and I are very concerned about the conflicts of interest that exist when physician owners of PODs receive revenues from the sale of devices that they order for procedures they perform on their own patients. Typically, surgeons, not hospitals, choose the devices that they will use in their surgeries, which increases the potential for abuse by POD surgeons. And without controls, this position of power gives POD surgeons the opportunity to grant themselves a steady stream of income by increasing the use of devices supplied by their POD.

Now, my concern is that POD ownership may affect the physicians' clinical decision-making by influencing them to perform unnecessary surgeries or to choose devices in which they have financial interests, rather than another device that might be even more appropriate for the patient.

So I would like to ask each of you to explain very briefly, if you would, in just a few sentences, whether you believe that this particular conflict of interest compromises medical judgment.

We will start with you, Dr. Lederhaus.

Dr. LEDERHAUS. Well, I think it certainly does, and it is a conflict of interest. And why would I say that? Because I am a physician. I could stand to make money on a Physician-Owned Distributor-

ship; why not just join a Physician-Owned Distributorship and enhance my income?

And the reason is, I fully believe they are a conflict of interest due to the fact that I have seen a lot of harm done to patients, as you have already heard about. This is a public safety issue, and to be involved in a POD presents a huge conflict of interest.

The CHAIRMAN. How about you, Dr. Steinmann? What do you have to say about it? You have used PODs. What do you think?

Dr. STEINMANN. I believe that an ethical surgeon will not be changed into an unethical surgeon by this model. I believe that the data that we have shown—and if you will look at the CMS data on our distributorship alone, the three spine surgeons in our distributorship order spinal fusions at a rate that is half the national average.

I do not believe that Scott Lederhaus would change his surgical indications tomorrow if he owned a distributorship. I do not believe it is powerful enough to change a person's ethics.

We have, and are met with, a powerful conflict of interest in every patient we see. We are paid on a back-pain patient $100 to recommend a conservative regimen of exercise and safe medication, or we are paid $5,000 to operate on their back.

Dr. Lederhaus and myself both see 20 to 30 patients before we select one that is appropriate for an operation. Our indications for surgery have never changed in the 8 years that we have been in a distributorship, and I can say that is true for every one of the distributorships that we have been involved in helping to develop.

We do this for the right reason, and it does not change our decision-making.

The CHAIRMAN. Good.

Ms. Draper?

Ms. DRAPER. The relationship between a physician and his patient is kind of a sacred relationship, and you are putting your trust in that physician to make the best decisions for you. We would hope that, just like my two esteemed physicians here, that they would not be compromised by a financial interest.

But like any potential conflict of interest, transparency is key. And making sure that everyone involved understands a physician's potential additional financial advantage for the prescribing of a surgery or any other medical device is essential if we are going to help maintain this ethical relationship.

The CHAIRMAN. Thank you.

Mr. Reynolds, do you have anything you would care to add?

Mr. REYNOLDS. Yes. I believe this is a conflict of interest and becomes blood money. When protocols follow therapy, medication, reconstruction, when all those avenues have been pursued, then possibly surgery should be considered.

This POD system, I believe, is just a simple cash cow, fraudulent money above and beyond any expectations that anybody could ever imagine. I just find it unacceptable how this has gone on for so long, and it does affect the Nation on so many different levels.

Thank you.

The CHAIRMAN. Well, thank you.

Now, this is an interesting panel, as far as I am concerned. I used to be, in my early life, a medical liability defense lawyer, de-

fending doctors and hospitals and health-care providers and nurses, et cetera. So naturally I take a real interest in this.

And let me just ask this question, and I will ask it of you, Dr. Lederhaus. Your testimony here has been very persuasive.

Some have suggested changing the Sunshine Act to add reporting requirements for physicians who have ownership interests in pharmaceuticals, biologicals, devices and, of course, medical supplies. Do you believe that this would eliminate the conflict of interest, and is it enough to protect patients from physicians with a financial interest in PODs?

Dr. LEDERHAUS. I think it would be difficult to control. There are certainly enough dishonest physicians who will hide their involvement with pharmaceuticals or implant companies, and I just do not know of a good way of monitoring that, even with respect to Dr. Steinmann's way of monitoring his POD physicians. I think a large group of physicians throughout the country just cannot be effectively monitored or, unfortunately, trusted.

The CHAIRMAN. All right.

Mr. Reynolds, you have endured a tremendous loss as a result of an unscrupulous POD physician. And it sounds like the surgeon in her case performed an unnecessary surgery and then implanted a bunch of unnecessary hardware, or at least too much hardware.

When helping your mother plan for her medical care, you said that you had no idea that Dr. Sabit might have had a financial interest in the devices used in the surgery. Now, given your experience, what would have been the best and easiest way for you to learn that the doctor was part of a POD?

Mr. REYNOLDS. I think, from an ethical standpoint, the doctor should disclose that, whenever he is going to surgery and putting hardware into somebody.

I had been with my mother through seven major surgeries. She had a knee reconstruction and knee replacement following protocol, shoulder reconstruction and shoulder replacement following protocol, hernia operation, gall bladder operation. She had each one of these in consecutive years leading up to this surgery.

It got to the point where medication for the pain management had got up to morphine, and it was too much. So I decided—I had had so much success with Medicare and Medi-Cal, had spent so much money, and she recovered and gained and got better, but it got to the point where back surgery was needed.

The simple fact—once again, doctors: do no harm. Disclose your ownership in materials and hardware that are going into your patients. So I had so much success that in hindsight, I just took a leap of faith with this doctor and not knowing—because I am not a big one to be on the Internet, I am not a big one to be looking up and checking out people—because I had had so much success in the system, I took him upon his word that he would do the right thing.

I would like to see it disclosed. I would like to see it policed and audited a little bit better. And reform is a must, and it must happen as soon as possible.

Thank you.

The CHAIRMAN. Well, thank you.

Dr. Steinmann, the AASD believes that PODs can implement various safeguards that eliminate any legal barriers to operation. Can you explain how you believe that these safeguards are sufficient to protect patients when their surgeon has a financial interest in the devices that he or she chooses for the surgeries? Could you help me to understand that a little bit?

Dr. STEINMANN. Yes. The AASD has published 12 standards, and they are very comprehensive. They go beyond the eight issues that the OIG brought up.

As was brought up earlier today, when met with a conflict of interest—which exists everywhere in health care, politics, law—they are managed best with transparency. And so one of the AASD standards requires transparency; requires disclosure to patients, to colleagues and to hospitals; requires that products are evaluated in a systematic manner for quality; and requires utilization reporting from the 12 months before you start your distributorship every year thereafter. It requires every 12 months an audit on all the 12 standards to ensure that you are compliant.

The CHAIRMAN. Well, Dr. Lederhaus, do you agree with Dr. Steinmann on what he has suggested here?

Dr. LEDERHAUS. Well, there would certainly be ways that these companies could be made compliant, if you will, although I still see that, despite some groups claiming to be ethical, they are anything but ethical and have ways of getting around some of these requirements.

I think, in Dr. Steinmann's group, they use primarily Renovis POD implants. I cannot tell from looking at his website where they are made or who makes them. I do not think his company makes them. In the past, I have attended two of Dr. Steinmann's discussions regarding his POD set-up. In theory, there are ways of improving the ways PODs are set up and monitored, but in practice, I think it would be difficult to finalize and manage and oversee.

The CHAIRMAN. All right. From what the OIG, the Office of Inspector General, said about PODs, it seems that it is very difficult to determine how many PODs there are and who actually owns them.

Dr. Steinmann, you represent a group of PODs that promotes ethics. That is why you are testifying here today. Do you have any recommendations, any additional recommendations, for dealing with the confusing web of entities, from manufacturers to distributors, that may be involved in paying physician investors?

Dr. STEINMANN. I believe that we have proven that AASD standards absolutely can work, and, if we were to receive affirmative program guidance from the OIG, that would bring transparency to every one of these relationships, and it would bring transparency to every one of these relationships' conduct.

And really, that is what it comes down to, because you have to be transparent and you have to conduct yourself appropriately.

The CHAIRMAN. Well, thank you.

Ms. Draper, we are grateful to have you here, and from my own State. And we have had you testify before, and you have always done a very good job.

But one of your roles is to advise hospitals about how to comply with the laws governing the Federal health-care system. Do you

feel that existing laws, regulations, and guidance from the Federal Government provide enough clarity for hospitals to design POD policies that comply with the law, or is more guidance needed?

Ms. DRAPER. We felt that the Special Fraud Alert was enough to give us enough guidance so that we could set a policy that was consistent with how we like to focus on the patient and proven clinical protocols and practices. The challenge that we have, which I think has been alluded to, is whether there is enough transparency or whether through the Sunshine Act all of these physician financial arrangements are truly disclosed so that we can appropriately manage the policies that we already have in place.

We hear anecdotal stories similar to what was already talked about of payments done through other entities or employment relationships, et cetera. So, as we continue to be vigilant in implementing sustainable controls, increased knowledge of these relationships is essential for us to set the best policy.

The CHAIRMAN. Well, thank you.

I want to thank all of you witnesses here today. This has been a very interesting hearing to me. And these are important issues. I hope we can all work together to find solutions to ensure an appropriate balance between physician entrepreneurship and safeguards to protect beneficiaries from unintended harm.

I think this is something we owe to the patients and to America's seniors and to the health-care system as a whole.

So with that, this hearing is adjourned. But I want to thank all of our witnesses for appearing here today to discuss these important issues, as well as all of our colleagues who have participated in this hearing. It is my hope that we can all work together to find solutions to ensure an appropriate balance between physician entrepreneurship and safeguards to protect beneficiaries from unintended harm. I think this is something that we owe to America's seniors and to the health-care system as a whole.

And, as a former medical liability defense lawyer, I have to say that a lot of the great ideas that have improved the profession, that have solved a lot of future problems well in advance of their origination, really come from good physicians and good managers who really care about these issues and who really want to make sure that everything is ethical and aboveboard and appropriate.

So I appreciate the testimony each of you has given here today, and I am going to ask that any written questions by any member of this panel be submitted by Tuesday, December 1st.

So with that, we will adjourn this hearing, and thank you once again for appearing and helping us to understand these things a little bit better. Thank you so much. This was great. With that, we will adjourn.

[Whereupon, at 3:20 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF SUZIE DRAPER, VICE PRESIDENT OF BUSINESS ETHICS AND COMPLIANCE, INTERMOUNTAIN HEALTHCARE

Intermountain Healthcare appreciates the opportunity to describe its experience with the development and implementation of policies for dealing with Physician-Owned Entities. My name is Suzie Draper, and I am the Vice President of Business Ethics and Compliance at Intermountain Healthcare in Salt Lake City, Utah. Intermountain is a not-for-profit 501(c)(3) integrated healthcare system that operates 22 hospitals in Utah and Idaho; more than 185 clinics; and an insurance plan, SelectHealth, which covers more than 750,000 lives in Utah and Idaho. Intermountain's Medical Group employs approximately 1,200 physicians, and about 4,000 other physicians affiliate with Intermountain.

Intermountain has become well-known nationally and internationally for identifying best clinical practices and applying them consistently. Dr. John E. Wennberg of the Dartmouth Institute for Health Policy and Clinical Practice said, "Intermountain is the best model in the country of how you can actually change healthcare for the better." Dartmouth estimated that if healthcare were provided nationally in the way it is provided at Intermountain, "the nation could reduce healthcare spending for acute and chronic illnesses by more than 40 percent."

Intermountain's focus is on providing high-value healthcare and helping people live the healthiest lives possible. To that end:

- We have developed physician-led clinical programs so that medicine at Intermountain is practiced by collaborative teams and is based on the best available data.
- We establish specific clinical improvement goals, with accountability for accomplishing these goals reaching all the way to Intermountain's Board of Trustees.
- We have developed information technology that allows us to track, compare, and improve outcomes—and eliminate inappropriate variation.
- We view variation as an opportunity to improve, whether we find it in our clinical processes, our business processes, or our supply chain.

1. OBJECTIVE

This testimony describes Intermountain Healthcare's challenges in implementing policies and procedures regarding Physician-Owned Distributors (PODs) and Physician-Owned Entities (POEs).

2. PROCESS AND HISTORY

2.1 The Evolution of a Centralized Supply Chain Organization (SCO)

Originally, Intermountain's supply chain processes were largely decentralized, with contracting authority at the individual facility level. In 2006, Intermountain created a Supply Chain Organization (SCO) to more effectively manage its annual spend on goods and services purchased from outside vendors. The SCO is responsible for more than $1.5 billion in annual spending and oversees the distribution of more than 2 million medical devices annually. Creation of the SCO has resulted in significant efficiencies, and Intermountain's SCO was ranked third in the United States in the most recent annual top 25 list of healthcare supply chains ranked by Gartner, Inc.

2.2 Contracting Challenges and PODs

In the early years of the SCO, resources were devoted to centralizing the purchasing process and to significantly increasing the evaluation of current and potential vendors. Typically, information regarding physician ownership of vendors was sought, but physician ownership was not viewed as an absolute impediment to contracting. Over time, however, there were increasing reports from the field regarding suspected and non-disclosed financial arrangements between vendors and physicians who were in a position to order the vendor's products.

2.3 The POD Regulatory Landscape Prior to the Special Fraud Alert

Prior to the issuance of the Special Fraud Alert on March 26, 2013, there was no statute, regulation, or clear agency guidance limiting hospitals from contracting with PODs. In 2006, AdvaMed requested additional guidance from the Office of Inspector General (OIG), which replied only that OIG "would take [AdvaMed's] views . . . into consideration as we contemplate future OIG guidance projects." In 2008, CMS was asked by a commenter on the CY 2008 PFS proposed rule (identified by CMS as a "large medical device manufacturer") to define PODs to be designated health services (DHS) entities subject to the Stark Law; in the 2009 Inpatient Prospective Payment System (IPPS) final rule, CMS declined to do so. In response to a Senate inquiry to CMS and OIG on PODs, in 2011 CMS stated it would "consider this issue carefully" but at that time declined to define PODs to be GPOs subject to the Sunshine Act. OIG similarly responded in 2011 that it would initiate a study but that "OIG's ability to issue guidance about the application of the [kickback] statute to these business structures is limited."

2.4 Intermountain's Evolving Approach to PODs Prior to the Special Fraud Alert

As the 2011 Senate Finance Committee Minority analysis (the Hatch Report) noted, there was a general lack of clear regulatory guidance to hospitals in this area. In connection with Intermountain's self-disclosure and ongoing discussions with the DOJ and OIG, a policy review of all hospital-physician arrangements was undertaken. Intermountain struggled to reach consensus on the proper approach to PODs that struck the appropriate balance of competing interests. The Hatch Report identified potential vulnerabilities in the typical POD model, while the Sunshine Act viewed disclosure as a means to limit the risk of abuse. A May 2012 Food and Drug Policy Forum article by Joseph Truhe, Esq., arguing that PODs were not only lawful but beneficial to the supply chain, was widely disseminated. From a strictly legal perspective, fair market arrangements between PODs and hospitals arguably satisfied the discount safe harbor to the Kickback Law and the relevant Stark Law rules, but there was growing discomfort with the potential conflicts of interest involved.

2.5 Special Fraud Alert

With the publication of the Special Fraud Alert, consensus at Intermountain crystallized around a bright-line policy that would be straightforward to implement. Prior to March of 2013, Intermountain was still unclear on how to best minimize the uneasiness caused by all the factors identified above. Intermountain's uneasiness was greatly alleviated by the OIG's Special Fraud Alert: Physician-Owned Entities (the "SFA"). The SFA stated that the OIG was particularly concerned about the financial incentives present in Physician-Owned Distributorships ("PODs") of implantable medical devices "because such devices typically are 'physician preference items,' meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed."

The SFA went on to identify eight "suspect characteristics" of PODs that might run afoul of the Anti-kickback Statute, which characteristics are as follows:

1. The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
2. Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
3. Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.

4. Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (*e.g.,* decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
5. The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.
6. The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
7. The POD does not maintain continuous oversight of all distribution functions.
8. When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

The SFA also stated that "hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute." Based on the SFA's warning, Intermountain elected to follow the course of action suggested in Footnote 1 of the SFA and develop a revised policy governing Intermountain's relationships with not just PODs but all Physician-Owned Entities ("POEs").

2.6 Policy Revision

In May 2013, Intermountain revised its policy entitled the "Physician-Owned Entities Financial Arrangements Policy" (the "POE Policy"). Under the POE Policy, Intermountain will not enter into any agreement to purchase from a POE any item or service other than professional medical services personally furnished by the physician owner or other health professional employed by the POE, unless the POE falls into one of two exceptions. The first exception applies to POEs whose physician owner (or physician who is an immediate family member of any owner) is not in a position to generate business for Intermountain. This exception also requires that prior to purchasing any item or service that meets the exception, Intermountain must enter into a written contract with the POE that includes the following representations and warranties and ongoing covenants from the POE: (1) that the entity does not have and will not have any of the eight suspect characteristics identified in the SFA, and (2) that no physician owner or physician who is an immediate family member of an owner in the POE be in a position to generate business for Intermountain, and that the POE will notify Intermountain if that representation is no longer true.

The second exception to the POE Policy is an exception made for disruptive technologies that are pre-approved by Intermountain's Senior Management Team in accordance with Intermountain's Disruptive Technologies Exception Guideline. This exception allows Intermountain the flexibility to make exceptions for products and services that if not purchased by Intermountain may pose a risk to the quality of care an Intermountain patient may receive as more fully described in Section 2.8 below.

Finally, the POE Policy also requires Intermountain's compliance team to work with Intermountain's Supply Chain staff to develop a plan to terminate or not renew existing arrangements that do not meet the requirements of the POE Policy, with first priority given to terminating and not renewing non-compliant arrangements for implantable medical devices. The implementation of the POE Policy has helped Intermountain to avoid relationships with the types of suspect POE identified in the SFA; however, the implementation has not been without costs to Intermountain. Implementation of the POE Policy has also led to other obstacles and challenges that were not present prior to the OIG's release of the SFA and Intermountain's implementation of its policy as a response to the SFA.

2.7 Balancing Competition and Standardization

In many instances Intermountain's implementation of the POE Policy narrows the field of suppliers that are qualified to receive and respond to RFPs for certain products and services. This decrease in qualified suppliers naturally increases product and supplier rationalization and standardization. These are generally viewed as positive, cost-saving measures. However, in this situation Intermountain may be standardizing on a legacy supply chain, which some argue is anti-competitive and potentially subject to abuse. Extending RFPs to compliant POEs may resolve those flaws, but that extension is often prohibited by the POE Policy.

2.8 The Disruptive Technologies Exception

Intermountain's Disruptive Technology Exception is limited to the disruptive technology in question (not the POE's entire catalog of items or services) and does not apply where a substantially equivalent product or service is available from a non-POE or, for example, where a device obtains 510k clearance. The challenge with this exception is its narrow scope. There have been only a handful of products and suppliers that have met these requirements—not because the suppliers are unwilling to comply with the Special Fraud Alert but, rather, because their items or services are not truly disruptive technologies.

2.9 Promoting Innovation and Collaboration

Another challenge is the potential chilling effect the POE Policy might have on Intermountain's innovative and collaborative culture. In an effort to reaffirm that culture and to insert appropriate safeguards, Intermountain is considering adding another exception to the POE Policy for technologies that are co-developed by the POE and Intermountain. This new exception would be available for items or services that are innovative, distinguishable, potentially superior, and otherwise compliant with the exception and Intermountain policy. We recognize that many of Intermountain's own physicians are in the best position to invent disruptive and innovative technologies, and we hope that this exception will provide a compliant model for those activities.

3. ONGOING IMPLEMENTATION

3.1 Attestation Form

Defining the policy prohibiting purchasing products or services from Physician-Owned Entities was only the first step; implementing the policy presented additional challenges and opportunities. One challenge was to determine the process for inquiring regarding an entity's ownership. In collaboration with legal counsel, Intermountain developed a form letter that references the OIG Special Fraud Alert and outlines Intermountain's policy regarding purchasing from Physician-Owned Entities. The letter then asks the supplier to attest to not having physician ownership and to meeting the policy's other provisions; the supplier makes this attestation by completing and signing a Compliance and Attestation form.

3.2 Implants, Then What?

Due to the large number of suppliers Intermountain purchases from, the attestation form is being implemented in several phases beginning with total joint and spinal implants and then other categories of implants. The next area of specific focus is being developed.

3.3 AP Database and AP Payments—Invoices, Contracts

When Intermountain sets up a supplier in its payment database, there is a field to indicate whether the supplier has physician ownership. That information may have come from an Intermountain Supply Chain employee, the supplier, or a local sales representative (who may not have actual knowledge of the supplier's ownership). There is ongoing effort to ensure the database is accurate and complete.

3.4 Exceptions to the Policy

As noted above, Intermountain's policy includes two exceptions to prohibiting purchases for POEs: (1) the physician-owner is not in a position to generate business for intermountain, and (2) the product purchased is a "disruptive technology." Additionally, professional services provided personally by a physician are categorically exempt from the policy. The first exception presumes that any physician practicing within Intermountain's service area is in a position to generate business for Intermountain Healthcare. For a supplier to meet the first exception, the supplier must attest to the physician-owner's not being in a position to generate business and must adduce sufficient supporting evidence.

3.5 Divestitures

Implementation of this policy by Intermountain has affected the local medical device market. A few physician-owned companies have chosen to have their physician-owners divest in order to continue supplying Intermountain. Other companies have combined divestiture with ongoing financial arrangements with the divesting physician owners, including employment. Analyzing these evolving arrangements under the POE Policy is an ongoing challenge.

3.6 Operational Wind Down

In a system the size of Intermountain, it is very difficult to simply stop purchasing a product for reasons outside the normal procurement channels. In the case of ending purchases from POEs, we chose to stop purchasing products that are, in some instances, widely used and possibly the preferred product. Prior to telling a supplier that we would no longer purchase items or services because of physician ownership, we worked through a process to notify all the users of those items or services of the change—particularly physicians—and to find satisfactory replacements. After those notifications are made, we then notify the manufacturer that we will discontinue purchases from them due to their being a Physician-Owned Entity. Additionally, all stock on hand that was not already purchased from the POE is removed and returned.

We discovered a few issues with discontinuing some purchases. Primarily, orthopedic surgeons prefer to replace an implant, if replacement is necessary, with the same device from the same manufacturer. Similarly, orthopedic surgeons prefer to implant the same device in the bilateral body part after the first implant is placed. For example, if a patient has had a hip replacement using a device from a POE and then requires a hip replacement on the other hip, the surgeon prefers to use the same device from the same manufacturer for the second hip. To meet these demands, we have authorized one-time purchases of those devices and maintained contracts with the suppliers in order to make those purchases. Some flexibility is needed to meet the medical needs of patients.

In addition to the issue of orthopedic surgeon preferences, some items or services are arguably superior to their supposed equivalents and yet do not meet the high bar of a disruptive technology. To date we have not finalized a satisfactory resolution to this issue.

Exhibits

- Office of Inspector General—Special Fraud Alert: Physician-Owned Entities
- Intermountain's Physician-Owned Entities Financial Arrangements Policy
- Intermountain's letter and attestation that is sent to Physician-Owned Entities

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Washington, DC 20201

Special Fraud Alert: Physician-Owned Entities

March 26, 2013

I. Introduction

This Special Fraud Alert addresses Physician-Owned Entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs). These entities frequently are referred to as Physician-Owned Distributorships, or "PODs."[1] The Office of Inspector General (OIG) has issued a number ofguidance documents on the general subject of physician investments in entities to which they refer, including the 1989 Special Fraud Alert on Joint Venture Arrangements[2] and various other publications. OIG also provided guidance specifically addressing physician investments in medical device manufacturers and distributors in an October 6, 2006 let-

[1] The Physician-Owned Entities addressed in this Special Fraud Alert are sometimes referred to as "physician-owned companies" or by other terminology. For purposes of this Special Fraud Alert, a "POD" is any Physician-Owned Entity that derives revenue from selling, or arranging for the sale of, implantable medical devices and includes Physician-Owned Entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation. Although this Special Fraud Alert focuses on PODs that derive revenue from selling, or arranging for the sale of, implantable medical devices, the same principles would apply when evaluating arrangements involving other types of Physician-Owned Entities.

[2] Special Fraud Alert: Joint Venture Arrangements (August 1989), *reprinted at* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

ter.[3] In that letter, we noted "the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" and stated that such ventures "should be closely scrutinized under the fraud and abuse laws."[4] This Special Fraud Alert focuses on the specific attributes and practices of PODs that we believe produce substantial fraud and abuse risk and pose dangers to patient safety.

II. The Anti-Kickback Statute

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. Section 1128B(b) of the Social Security Act (the Act) makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. Conviction will also lead to exclusion from Federal healthcare programs, including Medicare and Medicaid. OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs or to impose civil money penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

III. Physician-Owned Distributorships

Longstanding OIG guidance makes clear 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 illegal remuneration under the anti-kickback statute. The anti-kickback statute is violated if even one purpose of the remuneration is to induce such referrals.

OIG has repeatedly expressed concerns about arrangements that exhibit questionable features with regard to the selection and retention of investors, the solicitation of capital contributions, and the distribution of profits. Such questionable features may include, but are not limited to: (1) selecting investors because they are in a position to generate substantial business for the entity, (2) requiring investors who cease practicing in the service area to divest their ownership interests, and (3) distributing extraordinary returns on investment compared to the level of risk involved.

PODs that exhibit any of these or other questionable features potentially raise four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. This is because the financial incentives PODs offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices. We are particularly concerned about the presence of such financial incentives in the implantable medical device context because such devices typically are "physician preference items," meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed.

We do not believe that disclosure to a patient of the physician's financial interest in a POD is sufficient to address these concerns. As we noted in the preamble to the final regulation for the safe harbor relating to ASCs:

> . . . disclosure in and of itself does not provide sufficient assurance against fraud and abuse . . . [because] disclosure of financial interest is often part of a testimonial, *i.e.,* a reason why the patient should patronize that facility. Thus, often patients are not put on guard against the potential conflict of interest, *i.e.,* the possible effect of financial considerations on the physician's medical judgment.

See 64 Fed. Reg. 63,518, 63,536 (Nov. 19, 1999). Although these statements were made with respect to ASCs, the same principles apply in the POD context.

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[3] Letter from Vicki Robinson, Chief, Industry Guidance Branch, Department of Health and Human Services, OIG, Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2006).

[4] *Id.*

OIG recognizes that the lawfulness of any particular POD under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by a POD's characteristics, including the details of its legal structure; its operational safeguards; and the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. Nonetheless, we believe that PODs are inherently suspect under the anti-kickback statute. We are particularly concerned when PODs, or their physician-owners, exhibit any of the following suspect characteristics:

- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
- Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (*e.g.,* decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POD does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

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. Other characteristics not listed above may increase the risk of fraud and abuse associated with a particular POD or provide evidence of unlawful intent. For example, a POD that exclusively serves its physician-owners' patient base poses a higher risk of fraud and abuse than a POD that sells to hospitals and ASCs on the basis of referrals from nonowner physicians.

The anti-kickback statute is not a prohibition on the generation of profits; however, PODs that generate disproportionately high rates of return for physician-owners may trigger heightened scrutiny. Because the investment risk associated with PODs is often minimal, a high rate of return increases both the likelihood that one purpose of the arrangement is to enable the physician-owners to profit from their ability to dictate the implantable devices to be purchasedfor their patients and the potential that the physician-owner's medical judgment will be distorted by financial incentives. Our concerns are magnified in cases when the physician-owners: (1) are few in number, such that the volume or value of a particular physician-owner's recommendations or referrals closely correlates to that physician-owner's return on investment, or (2) alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs' devices on an exclusive, or nearly exclusive basis).

We are aware that some PODs purport to design or manufacture their own devices. OIG does not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent. The risk of fraud and abuse is particularly high in circumstances when such physicians-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute. In evaluating these arrangements, OIG will consider whether one purpose underlying a hospital's or an ASC's decision to purchase devices from a POD is to maintain or secure referrals from the POD's physician-owners.

IV. Conclusion

OIG is concerned about the proliferation of PODs. This Special Fraud Alert reiterates our longstanding position 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 illegal remuneration under the anti-kickback statute. OIG views PODs as inherently suspect under the anti-kickback statute. Should a POD, or an actual or potential physician-owner, continue to have questions about the structure of a particular POD arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: *http://oig.hhs.gov/faqs/advisory-opinions-faq.asp.*

To report suspected fraud involving Physician-Owned Entities, contact the OIG Hotline at *http://oig.hhs.gov/fraud/report-fraud/index.asp* or by phone at 1–800–447–8477 (1–800–HHS–TIPS).

Physician-Owned Entities Financial Arrangements Policy

Policy Statement

Except as set forth in this Policy, Intermountain will not enter into any agreement to purchase from a Physician-Owned Entity any item or service other than a professional medical service personally furnished by a Physician or by an allied health professional employed by the Physician-Owned Entity under a Physician's supervision.

Scope

IHC Health Services, Inc.

Definitions

Immediate Family Member—Husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of grandparent or grandchild.

Ownership or Investment Interest—Has the same meaning set forth in 42 CFR § 411.354(b) or any successor regulation. For these purposes, ownership may be direct or indirect, and may be by means of equity or debt. There is no minimum percentage ownership below which this policy would not apply. Investments in publicly-traded securities or mutual funds are excluded from the definition so long as they meet the requirements of 42 CFR § 411.356(a) or (b) or any successor regulation.

Royalty Interest—Payments made to the creator/owner of an item or intellectual property for each unit/copy of the property sold.

Physician—A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.

Physician-Owned Entity (POE)—Any entity in which a Physician or Immediate Family Member of a Physician holds an ownership, investment, or royalty interest if royalties are paid on purchases resulting from the royalty holder's order.

Provisions

1 If no Physician owner (or Physician who is an Immediate Family Member of any owner) of the POE is in a position to generate business for Intermountain, the prohibition does not apply. Utah-based physicians are presumed to be in a position to generate business for Intermountain.

1.1 Evidence that the POE satisfies provision 1 above must be submitted to and approved by the Anti-Kickback Statue (AKS) Committee before entering into any financial arrangement with the POE.

1.2 Intermountain may contract for an item or service meeting this exception so long as the contract:

1.2.1 is in writing;

1.2.2 is fully executed and effective prior to the first purchase;

1.2.3 includes a representation and warranty and ongoing covenant from the Physician-Owned Entity that the entity does not and will not have any of the following eight suspect characteristics identified in the Department of Health and Human Services' Office of Inspector General's "Special Fraud Alert: Physician-Owned Entities" or later related regulations or guidance;

- The size of the investment offered to each Physician varies with the expected or actual volume or value of devices used by the Physician.
- Distributions are not made in proportion to ownership interest, or Physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the Physicians.
- Physician-owners condition their referrals to hospitals or ambulatory surgical centers (ASCs) on their purchase of the POE's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POE, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POE, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POE.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POE or, conversely, are threatened with, or experience, negative repercussions (*e.g.,* decreased distributions, required divestiture) for failing to use the POE's devices for their patients.
- The POE retains the right to repurchase a Physician-owner's interest for the Physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POE's devices.
- The POE is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POE does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires Physicians to disclose conflicts of interest, the POE's Physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POE.

1.2.4 includes a representation and warranty and ongoing covenant that no Physician-owner or Physician who is an Immediate Family Member of any owner of the POE is in a position to generate business for Intermountain, and requires immediate notice to Intermountain if that is no longer true; and

1.2.5 provides for the right of Intermountain to terminate the agreement no later than ten (10) days after any such notice.

2 An exception to this policy may also be made for disruptive technologies when approved by the Intermountain President/Chief Executive Officer, Chief Medical Officer, and General Counsel (see *Disruptive Technologies Exception Guideline*).

3 The Vice President of Business Ethics and Compliance works with Supply Chain Organization staff to terminate or non-renew existing arrangements that do not meet the requirements of this Policy in an orderly fashion, with first priority given to implantable medical devices.

Exceptions

None

Primary Sources

Special Fraud Alert: Physician-Owned Entities

42 CFR § 411.354(b)

42 CFR § 411.356(a) and (b)

Secondary Materials

"Physician Investment in Medical Device Manufacturers and Distributors" (Letter from the OIG) (Oct. 6, 2006)

Disruptive Technologies Exception Guideline

Confidential and proprietary to Intermountain Health Care, Inc. If Intermountain Healthcare authorizes a person to access policies, procedures, and guidelines (PPGs), it also authorizes that person to disclose information from PPGs—not copies—but only as reasonably necessary for healthcare matters related to Intermountain Healthcare.

Reasonable efforts will be made to keep employees informed of policy changes; however, Intermountain Healthcare reserves the right in its sole discretion to amend, replace, and/or terminate this policy at any time.

Intermountain Healthcare is an At-Will Employer. The terms of this policy do not, either directly or indirectly, constitute any form of employment contract or other binding agreement between any employee and Intermountain.

Contact Intermountain Healthcare's Legal Department for questions.

Intermountain Healthcare
36 South State Street, Tenth floor
Salt Lake City, UT 84111–1486
801–442–2000

Re: *Action Required: Intermountain Policy on Physician-Owned Entities*

To Whom It May Concern:

As you may know, on March 26, 2013, the Office of Inspector General, U.S. Department of Health and Human Services (OIG) published a fraud Alert entitled "Special Fraud Alert: Physician-Owned Entities." A copy is attached for your reference. The Fraud Alert addresses Physician-Owned Entities that derive revenue from "selling. or arranging for the sale of, implantable medical devices" and "includes Physician-Owned Entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices, or instrumentation." The OIG refers to such entities as "PODs," but notes that the same principles would apply when evaluating arrangements involving other types of Physician-Owned Entities (POEs).

Prior guidance from the OIG on the subject of POEs had been equivocal, indicating only that such arrangements could potentially implicate the Federal anti-kickback statute and should be evaluated based on the particular facts and circumstances. By contrast, the Fraud Alert suggests heightened concern about POEs, which the OIG describes as "inherently suspect under the anti-kickback statute."

In response, under the direction of Intermountain's President and CEO, Intermountain has adopted an updated policy regarding contracting with POEs. A copy of the policy is attached for your reference.

The basic thrust of the policy is quite simple: Intermountain will no longer contract with POEs and will discontinue purchases under existing contracts with POEs.

Under the policy, a POE includes any entity owned in any part by a physician or an immediate family member of a physician. There is no minimum percentage required to trigger the prohibition. "Ownership" can mean shares, partnership units. bonds and other forms of debt, or royalties based on purchases by the ordering physician.

We are writing you to reconfirm that <<Company_Name>> is not a POE under the policy's definition, as you have previously represented. <<Company_Name>> will qualify as a POE if it has any owner who is a physician, or whose immediate family member is a physician. Under the policy, "immediate family member" means husband or wife; birth or adoptive parent, child or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of grandparent or grandchild.

Please take a moment to review the policy and, if <<Company_Name>> is not a POE, sign the attached attestation. Other than filling in information where denoted by a blank line, please do not modify the attestation. False or incomplete attesta-

tions will be taken seriously, and will be treated both as a breach of the purchase agreement between <<Company_Name>> and Intermountain and, depending on the facts, unprofessional conduct that may result in disciplinary action through the medical staff process. **If Intermountain does not receive a signed copy of the attached attestation prior to <<Company_Name>>, Intermountain will initiate a process to terminate any further purchases from <<Company_Name>>.**

If <<Company_Name>> is a POE, but you believe the prohibition should not apply as set forth in Provision 1 (no physician owner is in a position to generate business for Intermountain) or Provision 2 (disruptive technologies) of the policy, please contact Mr. Jeramy Green at (801) 442–3557 to discuss the procedures under the policy to allow purchases to continue.

We recognize that this Policy will change some existing arrangements, but believe that ultimately this is the right thing to do. We very much value <<Company_Name>>'s contribution over the years, and the contribution made by every supplier and physician at Intermountain in providing the care for which Intermountain is known.

If you have any questions about this letter or the policy, please contact Mr. Green at the number referenced above or me at (801) 442–1502.

Sincerely,

Suzie Draper
Vice President of Business Ethics and Compliance
Intermountain Healthcare

cc: Jeramy Green, Esq., Intermountain Healthcare

ATTESTATION AND COMPLIANCE CERTIFICATE

I, _____, hereby attest as an authorized officer of _____ ("Supplier") that :

- I have read the Intermountain Policy entitled "Financial Arrangements with Physician-Owned Entities." I understand that it is my responsibility to read and understand the Policy or seek guidance should I require clarification about the standards and requirements set forth in the Policy.
- I hereby certify that Supplier does not meet the definition of a Physician-Owned Entity as described in the Policy.
- If at any time Supplier becomes a Physician-Owned Entity, I agree to report that change within five (5) working days to the Intermountain Healthcare Compliance Hotline at (800) 442–4845.
- I understand and acknowledge that failure to complete this Certificate truthfully and accurately or to update this Certificate as required constitutes a breach of Supplier's agreement with Intermountain, and may also subject its physician owners to disciplinary review and action.

I have read this Attestation and Compliance Certificate and do hereby demonstrate my understanding and agreement to abide by its terms by affixing my signature on the date indicated below.

Company Name: _____
Signature: _____ Date: _____
Name: _____
Title: _____

Please return a signed copy electronically to *brad.nokes@imail.org* and the signed original to

Attn: Brad Nokes
Intermountain Healthcare
Central Office—Corporate Compliance
36 South State Street, Tenth floor
Salt Lake City, UT 84111–1486

PREPARED STATEMENT OF HON. ORRIN G. HATCH,
A U.S. SENATOR FROM UTAH

WASHINGTON—Senate Finance Committee Chairman Orrin Hatch (R–Utah) today delivered the following opening statement at a Committee hearing to examine Physician-Owned Distributorships (PODs), entities in which physicians derive revenue from the sale of medical devices they prescribe to patients:

Today, we are here to explore the various issues surrounding the growth and prevalence of Physician-Owned Distributors, or PODs.

Simply put, PODs are medical device businesses in which a physician is both an investor and a distributor—essentially a salesperson—of either the devices or some of the components.

While these arrangements are not always problematic, we are seeing more and more of these physician-salespeople using the very devices they sell in the surgeries and procedures they perform. Many critics have argued—with significant evidence to support their case—that this practice creates a financial incentive for these physicians to recommend and perform more and more unnecessary surgeries.

Typically, the more devices or hardware a POD physician implants in their patients, the larger the payment he or she receives from the POD. So, an incentive clearly exists for these surgeons to perform a steady stream of procedures, increasing the use of products supplied by their POD, thereby increasing their own income.

The question we'll address today is whether these arrangements and the apparent conflicts of interest that exist among POD physicians have had a negative impact on our health-care system and the well-being of patients.

As some of you may recall, in June 2011, the Republican staff of the Finance Committee issued a report on PODs outlining key issues and potential areas for congressional oversight. In response to some of the concerns outlined in the report, former Chairman Baucus and I, along with Senators Kohl, Grassley, and Corker, wrote to the Inspector General of the Department of Health and Human Services to share our concerns about the proliferation of PODs and the lack of guidance as to how these arrangements square with existing Federal law.

For years, the HHS Inspector General has warned about the conflict of interest created by joint partnerships between physicians and companies—including device manufacturers—that depend on them for referrals or new business. In March 2013, the OIG issued an alert calling PODs "inherently suspect" under the government's anti-kickback laws.

Later that year, the Inspector General reported that the number of spinal surgeries in hospitals that purchase implantable devices from PODs grows at a faster rate compared to other hospitals. The OIG also found that, for nearly one in five spinal fusion surgeries billed to Medicare, the device was supplied by a POD, indicating a potentially significant link between PODs and Federal healthcare costs.

Most notably, this same report found that physicians with investments in PODs perform, on average, 20 percent more surgeries than their counterparts who don't have these kinds of financial relationships.

Needless to say, these findings confirmed much of my skepticism about PODs.

And, while the OIG's guidance helped to persuade many in the industry that PODs were a risky business model, we continue to see reports in the media and from our constituents that these types of arrangements are still prevalent in our health-care system.

Because the Federal Government does not regulate these types of business arrangements, it is difficult to determine just how many PODs exist or where they all are. This lack of accountability is one reason why this issue so complicated.

Anecdotally, we've received reports of PODs operating in every State represented on the committee.

From what we've heard, the growth rate of PODs has slowed since the Inspector General's March 2013 alert. However, the total number of PODs remains roughly the same as before the report.

Our information also suggests that PODs are no longer concentrated in large hospital chains, as many chains have adopted policies forbidding or strictly curtailing POD usage. As a result, many PODs have migrated to smaller and more rural hospitals.

Some proponents of PODs have argued that some of our hardline statements and positions regarding their business arrangements go too far. They claim that implementing a sweeping prohibition on physician ownership in medical technology companies might have an unintended chilling effect on legitimate business practices as well as medical breakthroughs and research.

Nevertheless, we know that a number of POD physicians have abused their positions of trust and have put their own personal financial gain above the safety of their patients.

According to Department of Justice filings, one such physician was Dr. Aria Sabit, who, within months of accepting a lucrative investment offer from a POD, more than doubled his number of instrumented spinal fusion surgeries.

Prior to making his investment, Dr. Sabit had never used the POD's products before. After his investment, he used their products in more than 90 percent of his spinal fusion surgeries.

All told, Dr. Sabit invested $5,000 in the POD. In just over 2 years, he saw a return of over $438,000.

Now, I'm not typically one to decry investments with a high rate of return. But, those numbers alone should be enough to, at the very least, raise a few eyebrows.

In the end, Dr. Sabit pled guilty to more than $11 million in health care fraud and to causing bodily harm to patients. One of our witnesses today, Kevin Reynolds, will tell us about his mother's experience under Dr. Sabit's care.

As part of our ongoing inquiry into these issues, the Finance Committee has become aware of additional cases that warrant further review. As a result, Ranking Member Wyden and I will be making a formal referral to the HHS OIG and the Department of Justice on at least one case we feel deserves review for potential criminal action.

We will be submitting additional information to the HHS OIG and to CMS about the rate at which PODs report their ownership interests. We believe these findings will say quite a bit about the lack of accountability for these types of business arrangements.

I hope that today's hearing will be another important step in our ongoing efforts to provide appropriate oversight and enforcement on this issue.

PREPARED STATEMENT OF SCOTT LEDERHAUS, M.D., PRESIDENT, ASSOCIATION FOR MEDICAL ETHICS

INTRODUCTION

Chairman Hatch and committee members, it is an honor to be invited to testify before the Senate Committee on Finance's hearing on "Physician-Owned Distributors: Are They Harmful to Patients and Payers?" As a neurosurgeon, spine surgeon, and president of the Association for Medical Ethics, I have spent the last several years speaking out about the pervasive effect Physician-Owned Distributorships of implantable medical devices, also known as PODs, on the medical community to my colleagues, patients and the media.

The Association for Medical Ethics is a grass roots group that was established by Ms. Gemma Cunningham and Dr. Charles Rosen at University of California, Irvine. The group formed in 2005 due to concerns regarding excessive and unnecessary spinal surgery being done in the United States. Initially consisting of orthopedic surgeons and neurosurgeons, the Association is now a national group and has expanded to include a variety of medical and surgical specialties. The members believe there is a need to address the rampant physician financial conflicts of interest contributing to the overuse and misuse of spine surgery in America. Dr. Charles Rosen was the only physician who testified in 2007 before Senate hearings about these abuses, which helped push through the Sunshine Act. Our current efforts have been directed towards the abuses and conflicts of interest with Physician-Owned Distributors. I have been a member since 2007, a board member and now president of the group in 2014 and 2015.

In my testimony for the committee, I will define how PODs are affecting patients, physicians and the American medical community.

UNDERSTANDING PHYSICIAN-OWNED DISTRIBUTORS (PODS)

There are approximately 13.6 million patient visits for neck or low back conditions per year costing about $950 per patient per year. Between 49 percent and 70 percent of all adults will experience back pain during their lifetime and 12–30 percent of all adults have an active back problem. Back pain is the second most common reason adults consult a primary care provider and it is estimated that the total cost of spine related problems is approximately $90 billion per year with $10 to $20 billion in economic losses each year. Low back pain is the number one cause of disability in the United States and worldwide. Spinal fusion surgery is one of the most common surgical procedures done in the United States, roughly 500,000 operations per year. These 500,000 operations a year are where the opportunity arose for many spine surgeons to exploit the American medical system and endanger their patients.

Extensive spinal fusion surgery in the United States has exploded over the last decade often without indication and for no reason other than to enhance the income of some greedy and misguided spine surgeons. Outcomes are often poor. This behavior by some spine surgeons borders on criminal behavior, yet is largely ignored by most physicians and generally unrecognized by the public. The development of all types of spinal implants has dramatically increased over the last decade, enabling these spine surgeons to run amok by performing un-indicated multilevel spinal fusion operations. Due to the vast array of spinal implants now available—and the large amount of money to be made—spine surgeons have consciously and subconsciously loosened their "indications" for the use of these new implants. When you have a hammer, everything looks like a nail. The profit from the "sale" of these screws, rods, and cages to the hospital is often more money to the surgeon than received for the surgical fee.

At present there are more types, shapes, sizes, materials and ways of putting implants into the spine from almost any direction; front, back or side, than ever before. The signature turn of the further explosion of operative spine procedures occurred when spine surgeons began performing operations to treat low back pain. Low back pain became the key ingredient for spinal fusion operations that initially seemed to make sense with limited and specific indications. However, over time the "surgical candidate" became anyone with a backache. Due to the evolution of thought processes regarding the treatment of back disorders, the spinal surgeon can now simply rationalize almost any back complaint as a surgical indication by grossly expanding the accepted criteria. Some patients may benefit by this shotgun approach, but the improvement may be more on the basis of luck than following evidenced-based medicine and good surgical guidelines.

Another reason for the surgical aggressiveness can be attributed to the continued financial cuts to a physician's income. Any cut in payments from Medicare directly translates into cuts in commercial insurance across the board. In order to maintain the same level of income, many doctors have made a conscious effort to see more patients and do more surgery, and some have become more "aggressive" with their surgical indications. The stage was set for some spine surgeons to enhance their income by increasing the numbers and levels of spine fusion procedures with the plethora of spinal implants available, particularly with the loosening of indications for spinal surgery.

With the further advent of PODs around 2003, doctors could now enhance their income far beyond what was imaginable prior to being involved in a POD. A POD is an entity whereby the physician purchases an ownership in an implant company. The POD buys the implants wholesale and then sells those implants to the hospital at retail. The surgeon inserts the POD implants into their patients and the doctor and POD organizers pocket the difference. Thus, the POD-docs can make additional income on each and every implant inserted in their patients creating obvious conflicts of interest. This has resulted in thousands of patients being treated by some overly aggressive spine surgeons, which have resulted in many un-indicated, multilevel spinal fusion operations, many of whom have suffered injuries, horrific infections and even death.

As a result of what my partners and I witnessed for years, we felt something had to do be done. I was compelled to notify the appropriate authorities and have some resolution to the horrible acts of neglect and malpractice that my partners and I witnessed on a regular basis. However, going after these individuals legally is a quagmire of issues, which is bogged down and largely impotent. The peer review (hospital physician oversight) process is generally useless and powerless. Too often, doctors who sit on peer review committees may choose to look the other way to avoid being tied up in legal proceedings. Hospital administrators often close their

eyes to the abuses since the extensive spinal fusion operations bring huge profits into the hospital. The State Medical Boards have done little to protect the public.

WHAT ARE THE POSITIONS OF OUR SURGICAL SOCIETIES AND THE AMERICAN MEDICAL ASSOCIATION ON INVESTING IN PODS AND CONFLICTS OF INTEREST?

AMERICAN MEDICAL ASSOCIATION (AMA)

(http://www.amednews.com/article/20130408/government/130409964/7/). The American Medical Association (AMA) Code of Ethics, Opinion 8.06 issued in 2002 under Prescribing and Dispensing Drugs and Devices on the AMA website states: "Physicians may not accept any kind of payment or compensation from a drug company or device manufacturer for prescribing its products." "Furthermore, physicians should not be influenced in the prescribing of drugs, devices, or appliances by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or re-packager of the products involved."
(http://www.ama-assn.org//ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion806.page).

NORTH AMERICAN SPINE SOCIETY (NASS): ETHICAL STANCE ON INDUSTRY AND PODS

According to the North American Spine Society (NASS) Code of Ethics *(http://www.spine.org/Pages/PracticePolicy/EthicsProfConduct/CodeofEthics.aspx)* revised March 2012: "A NASS member should not enter into any academic or consulting relationship with industry that might influence his or her care of patients. If a conflict or apparent conflict develops between the physician's financial interest and the physician's responsibilities to the patient, the conflict must be resolved to the patient's benefit. A NASS member must disclose to colleagues and patients, in a professional context, any financial relationships that he or she has with industry. A NASS member who fails to disclose financial or other significant relationships with industry in accordance with NASS' current Disclosure Policy is in violation of this Code of Ethics. NASS does not prevent or restrict its members from participating in a POD, but requires POD owners to disclose their ownership to their patients. Level 1 compliance for all NASS committee chairs and board members cannot have any POD involvement."

AMERICAN ACADEMY OF ORTHOPEDIC SURGEONS (AAOS): ETHICAL STANCE ON INDUSTRY

According to the American Academy of Orthopedic Surgeons (AAOS) Code of Ethics, revised 2011, section IIIC: *(http://www.aaos.org/about/papers/ethics.asp):* "When an orthopedic surgeon receives anything of value including royalties, from a manufacturer, the orthopedic surgeon must disclose this fact to the patient. It is unethical for an orthopedic surgeon to receive compensation (excluding royalties) from a manufacturer for using a particular device or product. Fair market reimbursement for reasonable administrative costs in conducting or participating in a scientifically sound research clinical trial is acceptable."

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS (AANS): ETHICAL STANCE ON INDUSTRY

The American Association of Neurological Surgeons Position Statement: 2008 May 5, *http://www.aans.org//link.aspx?_id=360DCEF0D6464BA3A086EF32819B1DD6&_z=z.* Guidelines on Neurosurgeon-Industry Conflicts of Interest, Article 51297 states in their 2008 Code of Ethics: "It is unethical for a neurosurgeon to receive compensation of any kind from industry in exchange for using a particular device or medication in clinical practice. A neurosurgeon who has influence in selecting a particular product or service for an entity (organization, institution) shall disclose any relationship with industry to colleagues, the institution and other affected entities. A 'conflict of interest' occurs when a neurosurgeon or an immediate family member has, directly or indirectly, a financial interest or positional interest or other relationship with industry that could be perceived as influencing the neurosurgeon's obligation to act in the best interest of the patient."

CALIFORNIA ASSOCIATION OF NEUROLOGICAL SURGEONS (CANS): CALIFORNIA ASSOCIATION OF NEUROLOGICAL SURGEONS NEWSLETTER, VOLUME 40, NUMBER 3, MARCH 2013 AND VOLUME 40, NUMBER 4, APRIL 2013

The California Association of Neurological Surgeons (CANS) in 2012 requested of "the AANS and the Congress of Neurological Surgeons (CNS) a Conflict of Interest Statement to include Physician-Owned Distributorships (PODs)." CANS requested

that the position statement should affirm that the neurosurgeon should disclose to the patient his or her financial interest that is related to any aspect of the patient's evaluation and care related to the use of POD products.

AANS: CODE OF ETHICS: REVISED NOVEMBER 22, 2014

http://www.aans.org/en/About%20AANS/~/media/4A6862BB037742FF99B833D609D23B1E.ashx. The AANS finally included Physician-Owned "Enterprise" in their updated Code of Ethics. "The AANS Member who has influence in selecting a particular device, product or service for an entity shall disclose any relationship(s) with industry to colleagues, the institution and other affected entities prior to the entity's selection or purchase of the device, product or service. If a AANS Member has a financial or ownership interest in a **physician-owned enterprise,** or any other entity that sells, or arranges to sell, implantable medical devices, and/or in a durable medical goods provider, imaging center, surgery center or other health care facility where the neurological surgeon's financial interest is not immediately obvious, the AANS Member **must disclose that financial interest to the patient and the institution where the patient is being treated.** The financial or ownership interest must be disclosed on a timely basis so as to allow the patient to take the interest(s) into account when making his or her health care decisions. The AANS Member has an obligation to be aware of the applicable laws regarding physician ownership, compensation and control of these entities. Disclosure of professionally-related commercial interests and any other interests that may influence clinical decision-making is required in communications to patients, the public and colleagues."

Dr. Gerald Rodts, 2010 Congress of Neurological Surgeon (CNS) President stated in his 2010 CNS Presidential Address: **"Findings of disk dehydration or degeneration at greater than or equal to 3 levels in a patient without deformity and only back pain do not justify a 3- or 4-level fusion. Without any medical evidence to support such extensive fusions, it is unethical to perform them. We all have a responsibility in our own practices, in our own hospitals and in our own communities to police ourselves. We need to get the issue out in the open and discuss it openly and honestly at regional or national neurosurgery meetings. It can no longer be the 800 pound gorilla in the room that everyone is ignoring."** Dr. Gerald E. Rodts, M.D. 2010 CNS Presidential Address. Neurosurgical Pioneers: Foundation for Future Innovation. Clinical Neurosurgery, Volume 58, 2011.
https://www.cns.org/sites/default/files/clinical_neuro/Chapter1_0.pdf.

SUMMARY OF ETHICAL PROBLEMS WITH PODS

Every reputable physician association states that physicians must not be influenced in their choice of medical product by a financial interest. But it is difficult to believe that even physicians with the best of intentions could avoid being influenced in their choice of product and procedure by POD ownership. This conflict of interest is not the same as the financial incentive that exists in all fee-for-service medicine: it's additive, and it's also qualitatively different. Not only is there potentially a lot more money involved for the physician-owners, but, the doctor's financial interest is likely to overwhelm any ability the hospital might otherwise have to exercise quality control. As Dr. James R. Bean, a former President of the American College of Neurosurgeons has said, "PODs invite an abuse that can neither be regulated nor prevented" (Bean, "Are Physician-Owned Distributorships (PODs) Ethical," AANS Neurosurgeon, Volume 21, No. 2, 2012). And while disclosure to patients of such a conflict-of-interest is an ethical requirement, it is not sufficient. Relying on sound social science evidence, the HHS Office of Inspector General (OIG) has noted that patients often will perceive disclosure as a testimonial in favor of the procedure or product, Special Fraud Alert on Physician-Owned Entities (2013), *http://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf; e.g.*

It has been my experience that patients have no idea what an implant looks like, where they are made, what they are made of, what kind of quality they may be or what would be best for them. That decision is left to the spine surgeon. As a result patients are blindly willing to accept whatever implant the surgeon would decide to use regardless of the quality of those implants or where they are made. A patient has no idea what a POD is or how a POD might affect their treatment or outcome. So a disclosure by the physician of the POD implants to be used is nothing more than the physician telling their patients what they will be inserting into their spines.

UNFAIR COMPETITION, PREDATORY PRICING, AND MARKET DISTORTION

In addition to the severe ethical problems posed by PODs, they adversely affect competition and distort the true price of healthcare services. On the basic question of competition, PODs eliminate it. Because implants are physician preference items, once physicians invest in a POD, the hospitals and ASCs where they perform their procedures either buy from the POD, or the physicians will take their cases elsewhere. Direct sale from an implant manufacturer to the facility is eliminated.

Moreover, through what might be described as "Predatory Pricing," PODs prevent the non-POD doctors from being able to compete on a level playing field when it comes to contract negotiations with insurance groups. Physicians whose income is supplemented by their self-referral earnings from a POD can agree to what would otherwise be unrealistically low insurance reimbursement rates for their physician services. Thus, the physicians who are members of a POD can simply eliminate competition between the POD and non-POD physicians by signing ridiculously low reimbursement healthcare contracts. This rewards the POD physicians, stifles competition, and has nothing to do with good or competitive care, but only about money. It can only hurt the market for health care services when inappropriate financial incentives hide the true costs that should be the basis for reimbursement rates and policies.

THE OIG AND PODS

I am not a lawyer, and fortunately the committee has not asked me here today to give legal advice. But you don't have to be a lawyer to understand something is illegal when the OIG describes self-referral to PODs as "inherently suspect" under the Federal health care programs anti-kickback law. According to OIG, the law is that if one purpose of offering a physician an opportunity to earn a return from a POD investment is to induce that doctor to order products from the POD, the law is violated. Can anyone seriously believe that there is any physician anywhere who has a POD ownership interest without at least "one purpose" being the financial reward from ordering POD products for his or her own patients?

I'm also not an economist. But you don't have to be an economist to understand that PODs don't save money when the OIG reports that from a study of almost 600 hospitals and almost 1,000 spinal fusion cases (*Physician-Owned Distributors of Spinal Devices: Overview of Prevalence and Utilization,* October 2013, *https://oig.hhs.gov/oei/reports/oei-01-11-00660.asp*). The OIG reported that the cost of implants purchased from PODs was not less, and in some cases was more, than from the purchase of non-POD devices. Also not surprising was the fact that the rate of growth of spinal surgeries at POD-purchasing hospitals was three times the rate at non-POD hospitals. POD Hospitals also performed 28 percent more surgeries than non-POD hospitals. If PODs present a serious conflict of interest, are "inherently suspect" under the anti-kickback law, don't save money and do lead to overutilization of medical services, it is hard to understand why any of them are still in business.

PODS IN THE REAL WORLD

The poor judgment and extensive surgeries are not just theoretical. Physicians with ownership in PODs have caused real harm to patients. I have personally seen patients in consultation who have been the brunt of a POD surgeon. Examples are numerous: The 85-year-old man who has back pain undergoes a T8 to S1 (10 spinal levels) fusion with pedicle screws and rods up and down the spine to treat the back pain. Needless to say this not indicated or supported in the literature, but in most instances detrimental and can be lethal. The 45-year-old woman who has a single level herniated disc in her back with radiating leg pain who may benefit by a one hour, limited lumbar discectomy, but undergoes a two level lumbar fusion operation. The patient who has a multilevel lumbar fusion for suspected nerve root pain who does not improve only to find out the POD doctor did not examine their arthritic hips, which was the actual source of the pain. The patient who presents with carpal tunnel syndrome in the hand, yet gets a multiple level fusion in the neck. The patient who has mild spinal canal narrowing in the neck without any spinal cord compression, but is told they need a multilevel neck fusion to avoid becoming paralyzed. The patient with back pain who undergoes a three level lumbar fusion operation, which does not help the pain, undergoes additional levels of fusion with still no improvement, who then undergoes a sacro-iliac joint fusion, still without resolution of the pain, only then to be referred to a pain management physician who puts in a spinal cord stimulator to help with the pain.

Mr. John Carreyrou authored an article for the *Wall Street Journal* about Dr. Aria Sabit, a neurosurgeon in Ventura, Calif., who used Apex Medical implants through Reliance Medical, the same Reliance Medical implants from Mr. Bret Berry and Mr. Adam Pike who claimed they had no financial dealings with the doctors. According to the *Wall Street Journal* articles by Mr. John Carreyrou on July 25, 2013 ("Surgeons Eyed Over Deals With Medical-Device Makers") and July 27, 2013 ("Does My Surgeon Profit From My Implants?"), the Reliance Medical network of Mr. Pike and Mr. Berry eventually grew to comprise at least 11 PODs operating in six States—Utah, California, Texas, Louisiana, Florida and South Carolina—thus, further evidence that Reliance Medical is a group of PODs that utilize one of their 26 LLCs for distribution purposes of the POD implants. Dr. Sabit worked in Ventura, CA for 17 months and somehow managed to acquire 30 malpractice lawsuits against him. It just so happened that in many of his cases he used Apex Medical Implants, which are Reliance Medical implants supplied by Mr. Pike, Mr. Berry and Mr. Hoffman (the owners and salesperson for Reliance Medical implants). The profits from Apex Medical POD included 20 percent of the proceeds each going to Mr. Adam Pike, Mr. Bret Berry, Mr. John Hoffman, Dr. Sean Xie (a neurosurgeon in Los Angeles who apparently trained with Dr. Sabit, as a co-owner in Apex POD) and Dr. Aria Sabit. Dr. Sabit's surgeries, often without indication and very extensive spine fusion procedures, caused injury to many patients including nerve root damage, spinal fluid leaks, failed fusions, and life threatening infections to mention a few complications. Dr. Sabit reportedly was paid $400,000 in just over a year for the use of the Apex POD implants. These issues were discussed in the articles by Mr. Carreyrou. Thankfully, the Department of Justice has brought cases against Dr. Sabit and against Reliance, bringing both criminal charges and claims under the False Claims Act, *e.g.,* United States District Court for the Eastern District of Michigan, *United States of America v. Aria O. Sabit* filed February 7, 2014, page 32 and 33, *http://projects.scpr.org/longreads/selling-the-spine/docs/doj_investigation.pdf. The USA v. Reliance Medical Systems, Mr. Adam Pike, Mr. Bret Berry, Mr. John Hoffman and Dr. Aria Sabit* is the first test case against a POD. However, what is really remarkable is that although OIG's report estimated that 20 percent of the spinal fusion operations done in America were done with POD implants in 2011, there currently do not appear to be any other enforcement cases.

HOSPITAL SYSTEMS REACT TO POD CONTROVERSY

Over time, many hospital systems have recognized that PODs represent additional liability exposure and perhaps increased abuse, expense, and inherent conflicts of interest. Especially following the OIG's 2013 Special Fraud Alert, many hospitals have taken the opinion that PODs are too risky and have eliminated them from their facilities. Some of the hospitals that no longer allow PODs are:

- Catholic Healthcare West, now Dignity Health (40 Hospitals)
- Scripps Hospital System in San Diego
- Martin Memorial Health System (Florida)
- Providence Health and Services (28 Hospitals)
- Loma Linda University
- University of California, Irvine
- The Memorial Care Health System in Orange County (6 Hospitals)
- Tenet Health Care (77 Hospitals in 14 States)
- Ascension Health (70 Hospitals, largest Catholic non-profit)
- Intermountain Healthcare (22 hospitals in Utah and Idaho)
- Hospital Corporation of America (HCA, 165 hospitals, 115 ASC's)
- Baylor Scott and White Health (43 hospitals in Texas)

It is encouraging that the private sector is stepping up to push back on PODs to fill the gap left by the absence of law enforcement. But there are still way too many hospitals that are dealing with PODs. The private sector alone is not enough to protect patients and the health care system.

CAN THERE BE AN "ETHICAL" POD?

In a word, "no." Surgery involving implantable medical devices is one of the great medical innovations of the 20th century. Millions of patients have received life-changing and life-prolonging relief from disabilities that crippled or killed previous generations. Physicians who provide this kind of care are justifiably proud of what they do. After long years of training to become specialists in these fields, many of the physicians in this country have been frustrated to watch as a health care system tries to "bend the cost curve" which continues to devalue their services. That the

physicians of this country are looking for an alternative should then be of no surprise.

But PODs cannot be the answer. Giving physicians a financial interest in the implants they order for their own patients creates a conflict of interest that is quantitatively greater and qualitatively different from the choice of whether to treat a patient in the first place. Medical ethics largely places the decision of whether an inappropriate financial interest exists in the hands of the physician. However, it is difficult to believe that any physician could fail to be influenced in choice of products based on the financial interest involved, or choice of facility based on whether the facility will deal with the POD. PODs adversely affect competition and distort the true cost of health care products and services. And while decreased health care costs and better controlled utilization of health care services would not eliminate the conflict interest, unfair competition, or market distortion, the OIG's research demonstrates that PODs fail to deliver even on these.

CONCLUSION

In conclusion, my experience as a neurosurgeon these past 30+ years, and my observations of the world around me from my position as President of the Association for Medical Ethics, leads me to believe that physicians should not be permitted to profit from the implants they order for their own patients by investment in a POD. PODs present doctors with an ethical conflict that realistically can't be overcome. They create unfair competition among implant sellers, hospitals, and physicians. They distort the true cost of medical products and services. And even if they did so in the transparent light of day, the potential for harm to patients and the integrity of the physician-patient relationship can't be put at risk in this way. The only answer in my opinion is that PODs cannot be allowed.

Supporting Addendum One

Physician-Owned Distributors: The Wave of the Future or the End of the Model?

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ABSTRACT: New business entities called Physician-Owned Distributors (PODs) have sprung up around the country. PODs, are business entities, that enhance the income of physicians who are investors via the recovery of money paid out for the implantation of medical devices in their patients. There have been a varying opinions among attorney groups and the Office of Inspector General as to their legality and what would constitute a legal entity. The legal opinion of attorneys employed by the major implant companies is that the PODs are illegal, whereas the legal opinion of those physicians setting up a POD is that the PODs are legal when properly and "legally" constructed. The Office of the Inspector General has been watching these businesses as possible violations of the Stark Laws and kickbacks being paid out to the physician owners in the PODs. Some hospital groups have been prohibiting PODs from doing business in their hospitals because of fear of the excessive use of implants and possible kickback violations. These are confusing issues and as of this time there is no clear and concise model that can be considered legal, yet the PODs persist and are becoming more prevalent.

KEY WORDS: physcian-owned distributors, PODs, OIG, kickback, Stark. safe harbors, alliance surgical distributors, omega solutions, implants, Sunshine Act, predatory pricing, False Claims Act, civil monetary penalty.

I. DEFINITION

Physician-Owned Distributors (PODs) are sometimes called physician-owned intermediaries or physician-owned companies by virtue of their place in the supply chain. PODs are groups of physicians, usually surgeons, who enter into a business relationship with a business entity that purchases implanted devices such as total joint prostheses or spinal hardware (*i.e.,* pedicle screws, cages, and rods that the owner physician ordered for their cases). The physicians in the POD profit financially by participating in the sale of medical devices intended for implantation in their own

patients. thus creating the opportunity for them to profit from their own referrals and implants.

II. INTENT AND DESIGN MODEL

Probably in large part because of the continued decline in reimbursement from Medicare and private payers, PODs have become increasingly widespread throughout the United States in an effort to increase physician income.[1] The design with which the PODs achieve their goal varies. The simplest model involves the POD business being set up by a entrepreneur, who could be a physician or nonphysician. The developer of this model then seeks investors who implant devices such as spinal implants, joint replacement, cardiac pacemakers, and spinal cord stimulators. The initial financial contribution to be a investor may vary, but it could exceed $50,000. The investor may own their implants, a percentage of the POD, or both. The hospital at which the surgery takes place pays the POD for the product after the investor implants the devices. The POD includes a shell—a second corporation or entity—that is used to facilitate payment to the investors, thus avoiding, direct payment from the POD which then sells its products to the physician investors. The investor may be involved as a solo physician in his own investment group or possibly could be involved in a small group of physicians who all share in the profits; both of these models are considered mini-PODs. Therefore, in most of these models there is a direct payment per implant to the POD.

III. CONFLICTS OF INTEREST

The Office of Inspector General (OIG) along with the Stark legislation have examined PODs as a source of kickbacks and conflicts of interest.[2,3] Kickbacks can be in the form of direct financial payments. consulting and royalty agreements, trips for doctors and their families, or consulting meetings. The conflict of interest is borne out in that an investor in a POD stands to make large sums of money for the implants used. The more extensive the surgery the higher the reimbursement, which may be a set up for egregious acts on the part of the surgeon. Unfortunately, all too often, greed becomes the determining factor in the extent of surgery and issues surrounding minimal or no indication for surgery.

IV. EXISTING LEGISLATION AGAINST THE POD MODEL

According to a OIG/Department of Health and Human Services (HHS) Fraud and Abuse Alert from January 23. 1989,[2] noted that Congress did not intend to bar absolutely any investment by physicians in other health care entities but has included a "safe harbor" for investment interests in large public corporations. The OIG and DHS have done this to ensure that the companies are sufficiently large enough so that the return on investment is, at most, tangentially related to any referrals or items or services made by a shareholder. Therefore, under the proposed rule, referrals by physicians to entities in which they have any kind of investment interest (other than in large corporations available to the general public), such as limited partnerships, would be subject to prosecution.

Safe harbors' protection of medical business entities makes it possible that certain business arrangements might violate the anti-kickback laws. Thus, if the business qualifies as a safe harbor then the doctors involved do not have to worry about being accused of making money from referrals. To be a "legal" POD entity under the safe harbor regulations a number of legal issues would need to be satisfied to avoid being held accountable under anti-kickback regulations.

Safe harbor regulation allow for certain arrangements when the business entity, a POD in this case, is not publicly traded, derives less than 40 percent income from physician investors, be no more than 40 percent physician-owned, receive no referrals from investing physicians, have terms for passive investors that are no different than those for physician investors, and require payments to physicians that are not directly related to volume or referrals. Passive physician owners are not required to make referrals to the POD and physicians are not required to divest their inter-

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[1] Physician-Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight. Printed by the United States Senate by U.S. Senator Orrin Hatch (R–Utah), Ranking Member, June 2011. Available from: *http://finance.senate.gov/news-room/ranking/release/?id=126c-415e-fla3-41e9-ab49-665a71188flc.*

[2] The 1989 Special Fraud Alert is available on the OIG's website. Available from: *http://oig.hhs.gov/fraud/docs/safeharborregulations/012389.htm.*

[3] Testimony of Gregory Demske, Assistant Inspector General for Legal Affairs, before the U.S. Senate Special Committee on Aging Examining the Relationship Between the Medical Device Industry and Physicians (Feb. 27, 2008), Available from:
http://oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

est if they retire or are no longer actively engaged in the practice of medicine in the POD market. It is doubtful if any of the PODs today would qualify as safe harbors because a large, publicly traded company does not fit the POD model. In general, then, safe harbor protection would not apply to a POD.

If the safe harbor classification does not apply, then the Ethics in Patient Referral Act (Stark law against self referrals) may apply. The theory behind the Stark law is to control unnecessary spending that arises from improper financial relationships with Federal programs. The statute applies to anyone who is connected financially under any federally funded health care program, not just Medicare or Medicaid. A physician is prohibited from referring Medicare-funded inpatient or outpatient services when the physician or anyone in their immediate family has a financial relationship with the associated hospital unless the relationship meets a Stark exception, for example, a possible indirect financial relationship.[4] To violate Stark laws, the *intent* to violate does not matter, whereas with anti-kickback regulations, *intent* to violate is critical.

Under the Stark law, anyone who fulfils either of the following criteria is potentially liable for prosecution:

> *A physician who has a "financial relationship," which is defined as (a) ownership of an entity, or (b) a compensation arrangement between physicians and the entity, including family member.*
>
> *The entity cannot make a claim to Medicare for a prohibited referral. This is done to prevent physicians from making referrals based on financial gain, thus preventing overutilization, which increases health care costs.*

Because PODs do not qualify as safe harbors, they must follow anti-kickback regulations and potentially Stark laws. A member of a POD then has to be concerned about whether the POD is a legal entity and if, as an investor, they would be potentially at fault for breaking these laws. The Stark laws prohibit Medicare payments for any hospital services *referred* by a physician with a prohibited financial relationship or who requires refunds are subject to penalties that increase with each new referral. This is especially true when the physician knows or should have known they are an investor in a POD. The Centers for Medicare and Medicaid Services has recognized the physician-POD-hospital connection and believe this is an *indirect financial relationship* under the Stark laws and would run afoul of the physician self-referral statute.[5] The Federal Register[5] reported that there is concern about possible program or patient abuse when physicians profit from the referrals they make to hospitals through physician-owned companies. In the Federal Register it is noted that many cases the physician investors bear little, if any, economic risk with respect to the medical devices. It is felt that some PODs 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. "The financial incentives paid to the physicians may foster an anticompetitive climate, raise quality of care concerns, and lead to overutilization of the device or other products to which the physician is linked."[5, 6]

If the Stark restrictions are not enough, the False Claims Act (FCA) can also be a legal avenue against a investor. The FCA is the Federal Government's primary civil enforcement tool for addressing health care fraud. Under the False Claims Act the government may enforce significant penalties against any person who *knowingly* submits a false claim for *unnecessary* medical services. Whisteblowers can report those violators who have defrauded the government, and many of the individuals who file these lawsuits are employees or former employees of the companies that committed the fraud. If there are violations of the anti-kickback or Stark laws, then there is a potential for a violation of the FCA, which is implicated in cases of the questionable medical necessity of procedures. In February 2008, Gregory Demske of the OIG stated that, "[PODs] will be closely scrutinized due to potential for abuse. These groups can be prosecuted under the Federal False Claims Act, Federal anti-

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[4] Ngai E, Oppenheim C, Regulatory and Structural Considerations for Physician-Owned Medical Device Companies, Health Law Perspectives 1 (February 2011). Available from: *http://health-law.com/health-law-perspectives/february-2011/#3.*

[5] The Federal Register, Volume 73, No. 84, Wednesday, April 30, 2008, Page # 23694. Available from: *http://www.copyright.gov/fedreg/2008/73fr23390.pdf.*

[6] The Federal Register, Volume 72, No. 133, Thursday, July 12, 2007, Page 38187. Available from: *http://www.rjg.com/ProposedAmendment.pdf.*

kickback statute, or civil monitories penalty law."[7] The Civil Monetary Penalty (CMP) refers to device manufacturers paying a physician to recommend the specific device for use in hospital procedures. Therefore, a physician owner in a POD is walking a tight rope with respect to believing they can navigate the potential laws designed to punish those involved in health care fraud and abuse.

V. GOVERNMENT LEGAL ISSUES

A June 2011 inquiry by the Senate Finance Committee provided an overview of key issues and potential areas for congressional oversight. This investigative report noted that PODs began developing around 2003 and have branched out from orthopedics to spinal implants, cardiac pacemakers, and other implants.[8,9] It was noted that there are multiple PODs in at least 20 states, with as many as 40 PODs in California alone.[1] On June 9, 2011, letters were sent to the U.S. Department of Health and Human Services and the CMS, both of which were authored by Senator Orrin Hatch (ranking member of the Finance Committee), Senator Herb Kohl (chairman of the Special Committee on Aging). Senator Charles Grassley (ranking member of the Judiciary Committee), Senator Max Baucus (chairman of the Finance Committee), and Senator Bob Corker (ranking member of the Special Committee on Aging). The authors requested that PODs be included in the Sunshine Act as far as making public the payments made to physicians through these POD groups. In addition, the letters requested that the DHS and CMS address potential loopholes in the POD model that may relate to the upcoming accountable care organizations and any potential conflicts of interest, safety concerns, and the impact on health care, all of which are considered "troubling issues about PODs."[8]

VI. GETTING AROUND THE GOVERNMENT LEGAL ISSUES

Bill Lockyer, Attorney General for the State of California, issued a opinion letter in February 2006.[10] He stated that a physician may prescribe a medical device distributed by a company in which a physician has an ownership provided that the return on investment is based on the physician's proportional ownership share and that the requisite disclosures are made. He goes on to point out that the company's profits are not dependent on the number of referrals that the physician has made if the physician complied with relevant patient disclosure requirements. The opinion mentions the Department of Health and Human Services regulations defining "financial interests" subject to the federal anti-kickback statute and that interest offered to passive investors would be no different than that offered to other investors. He states that the investment would be required to be lawful under the federal anti-kickback statute and implemented regulations. Regarding the Unfair Competition Law, which governs anticompetitive business practices as well as injuries to consumers, he notes that, "a business practice can be unfair if it offends and established public policy or is immoral. unethical, oppressive, unscrupulous. or substantially injurious to consumers."[11] The terms of financial interest, proportional return on investment, and passive investors are vague and not well defined in Lockyer's opinion letter. Despite his opinion, the Attorney General of the State of California has no jurisdiction over the federal laws regarding fraud and abuse, anti-kickback regulations, or the Stark laws.

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[7] Gregory Demske, Dept. of OIG, February 27, 2008, Examining the Relationship Between the Medical Device Industry and Physicians, hearing before the Senate Special Committee on Aging. U.S. Senate Assistant Inspector General for Legal Affairs of the OIG, February 27, 2008, testimony corrected May 22, 2008. Available from:
http://www.oig.hhs.gov/testimony/docs/2008/demske_testimony022708.pdf.

[8] The United States Senate, letter dated June 9, 2011 to Donald Berwick, M.D., Administrator for Medicare and Medicaid Services, from Senators Hatch, Kohl, Grassley, Baucus, and Corker. Available from: *http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-fla3-41e9-ab49-665a71188flc.*

[9] The United States Senate, letter dated June 6, 2011 to the Honorable Daniel R. Levinson, Inspector General of the U.S. Department of Health and Human Services, from Senators Hatch, Kohl, Grassley, Baucus, and Corker. Available from: *http://finance.senate.gov/newsroom/ranking/release/?id=126c415e-fla3-41e9-ab49-665a71188flc.*

[10] From the Office of the Attorney General of the State of California, opinion No. 05–614, dated February 27, 2006. Available from: *http://www.ag.ca.gov/opinions/pdfs/05-614.pdf.*

[11] Carreyrou, J, Hospital Bars Surgeon from Operating Room, Medical Board in Oregon Separately Investigates Doctor who Stood Out for High Rate of Multiple Spinal Procedures, *Wall Street Journal,* April 13, 2011. John Carreyrou and Tom McGinty. Available from: *http://online.wsj.com/article/SB10001424052748704336504576259142044058726.html.*

Many of the attorney groups that argue that PODs are illegal generally have some connection to the medical device companies and thus argue in favor of the illegal nature of PODs.[12, 13, 14] No different are the attorney groups that argue that PODs are legal.[15, 16] Thus, there seems to be no unbiased opinion when it comes to the legal views on either side of the argument. Hooper, Lundy, and Bookman, a law firm in California that has worked with PODs, including Alliance Surgical Distributors, a POD owned by Dr. John Steinmann in Redlands, California; Omega Solutions, a POD in Fresno, California; and Atlas Medical in Southern California. Hooper, Lundy, and Bookman have stated and recognize that a POD may be impacted by anti-kickback statutes and they point out that the OIG recognizes that these PODs are vulnerable to violations of anti-kickback laws, and the firm also states that, "following these guidelines does not guarantee the POD is lawful."[4] In an attempt to avoid the need for safe harbors, Hooper. Lundy and Bookman claim to have set up a potentially legal POD by using *indirect compensation* as an exception to the Stark self-referral laws: the products are sold at fair market value, and pricing competes with that of other companies. As reported by *Orthopedics This Week,*[17] the firm has established 19 requirements that must be met for a POD to be considered a legal entity; these requirements will in effect make the POD as legal because it can meet the current restrictive federal law. The Indirect Compensation Agreement is a Stark exception but is not relevant to the kickback laws. Therefore, the kickback laws can still be applied even with a Stark exception. Dr. Steinmann, owner of the POD Alliance Surgical Distributors, has opined that his model is a win-win for the doctor and hospital because he is able to supply the hospital with competitively priced implants and enable the physician members of the POD to enhance their income by using his model and his implants. His model does not take into account the surgeon who uses the POD implants and "saves the hospital money" but in actuality would increase costs by performing extensive surgery that may not be needed. According to Hooper, Lundy, and Bookman, using the 19 provisions, PODs can be as legal as possible although they still could be violating the anti-kickback laws.

The 19 steps for the formation of a POD[18] as required by Hooper, Lundy and Bookman include the following:

1. The company will hire and employ its own personnel.
2. The company will purchase products directly from manufacturers/distributors under its own contracts.
3. The company will sell products directly to its own customers such as hospitals or surgery centers under its own contracts.
4. The company will manage its own inventory.
5. The company will have its own distinct office and warehouse space for the operation of its own business.
6. Products will be shipped to the company by the manufacturer/distributor and will be separately warehoused by the company before resale to hospitals or surgery centers.

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[12] Immelt, SJ, Wisor, RL, Physician-Owned Intermediaries in the Medical Device Industry: Fraud and Abuse Compliance Risks Physicians, Hospitals and Manufacturers, Hogan and Hartson Law Firm, March 2010. Available from: *http://.www.jisrf.org/pdf_files/POI_WhitePaperMarch2010.pdf.*

[13] Author unknown, Hogan and Hartson Law Firm, Physician-Owned Distributors of Spinal Implants: The Impropriety of Physicians as Commissioned Sales Representatives, November 2009. Available from: *http://www.hoganlovells.com/files/upload/PODWhitePaper_Nov2009.pdf.*

[14] Immelt, SJ, "Psst! Have I got a deal for you," AAOS Now, July 2009 Issue. Available from: *http://www.aaos.org/news/aaosnow/jul09/managing6.asp.*

[15] Leahy, M, Managing Implant Distributions and Costs: Two Solutions that Put Surgeons and Hospitals in the Driver's Seat, AAOS Now, September 2010. Available from: *http://www.aaos.org/news/aaosnow/sep10/managing3.asp.*

[16] Physician-Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight, The United States Senate Committee on Finance, June 2011. An Inquiry by Senate Finance Committee Minority Staff, U.S. Senator Orrin Hatch (R–Utah), Ranking Member. Available from: *http://www.hoganlovells.com/files/Uploads/Documents/Senate%20POD%20report.pdf.*

[17] Eisner W, Orthopedics This Week: The Risks of PODs, May 9, 2011. Available from: *http://ryortho.com/index.php?s=56&p=52.*

[18] Carreyrou, J, Senators Request Probe of Surgeons, *Wall Street Journal,* June 9, 2011. Available from:
http://online.wsj.com/article/SB10001424052702304778304576373592455703056.html.

7. The company will hold any and all licenses or governmental approvals necessary for the operation of its business.
8. The investment price offered to physicians will not be based on the projected referrals from the physicians, nor will the amount being offered to physicians reflect the anticipated referrals generated from the physicians procedures.
9. No physician's investment interest will be subject to repurchase for failure to use the company's devices in their surgeries.
10. The investing physicians will not be pressured in any way to utilize the company's devices in their surgeries.
11. The investing physicians will not exert pressure on the hospitals or surgery centers to purchase the devices from the company.
12. The company will be adequately capitalized for its operations through the initial capital contributions of its members and the physician investments will not be nominal. The members' capital contributions will not come from the manufacturer or distributors that sell devices to the company, nor will the managers or its affiliates loan funds to the physician investor for their capital contributions.
13. The use of the devices will at all times be medically necessary.
14. The company will not bill patients or payers (including Medicare and Medi-Cal) for the devices.
15. The company will have written agreements with the manufacturers/distributors for purchase of the devices.
16. The company will have written agreements with the purchasers, hospitals. or surgery centers for the sale of the devices.
17. The purchasers, hospitals, or surgery centers will be charged a fixed price based on negotiations, which will not increase with the use of more devices.
18. The company will generally have a fixed list of prices that will be generally available to all purchasers, hospitals, or surgery centers.
19. However, the company may be willing to accept lower pricing if the purchaser dictates lower fixed pricing. The payments by the purchasers will not be higher than fair market value for the devices.

Omega Solutions was the distributor used by Dr. Vishal Makker, who was exposed by the *Wall Street Journal* in March,[17] April,[19] and June 2011;[11] the *Journal* highlighted that Makker was using implants from a POD and allegedly was performing multiple repeat surgeries while receiving $500,000 per year from Omega Solutions. As well, Makker's girlfriend was an Omega product representative. Omega Solutions closed its doors after the *Wall Street Journal* articles because the instrument manufacturers declined to do business with Omega any longer. Since the exposition of Dr. Makker the Oregon's Providence Health and Services Hospital, the Providence Health and Services have eliminated PODs from their 28 hospital system, which was implemented by John Koster, M.D. and President/CEO on February 9, 2012.

Regarding physician ownership in light of the OIG opinion mentioned earlier, Paul Hastings,[20] an attorney employed by Medtronic-Sofamore Danek, stated that, "this could be considered a 'referral,' which is applicable to the anti-kickback statutes. Return on investment to a physician from a medical device company to which the physician refers must be based solely on the value of the investment. The physician with a ownership must disclose the financial interest in writing to the patient at the time the referral is made. These referral companies may be permissible, but should not be considered a blanket permission to engage in such activities." Hastings concluding the following: (1) the physician must disclose ownership interest in writing to the patient; (2) physicians should remember that they must comply with the most restrictive federal laws, which may carry significant criminal penalties; (3) the return on investment must be solely on the value of the investment; (4) the attorney general seems to view solicitation by medical device companies of

[19] Medicare Records Reveal Troubling Train of Surgeries, *Wall Street Journal,* March 29, 2011, John Carreyrou and Tom McGinty. Available from:
http://online.wsj.com/article/SB10001424052748703858404576214642193925996.html.

[20] Hastings, Paul, memorandum, February 28, 2006, subject: Opinion of California Attorney General No. 05–614, *http://www.paul-hastings.com.*

physicians as investors to be a potential violation of the California Unfair Competition Law (hospitals have to use the physician implants); and (5) the physician should be careful not to commit in any way to using a company's products or to enter into a arrangement that guarantees return based on the volume of referrals.

Thomas Bulliet,[17, 21] an attorney in a firm that represents some large spinal implant companies, noted that PODs are entrepreneur-driven opportunities where doctors are seduced into kicking in a "little bit of money" in exchange for shares of the company. "There is no purpose for these companies but to give the doctor's a return. . . . The anti-kickback statute is violated if one purpose of the financial reward to a doctor is to get him to order a particular product or refer patients to a particular hospital."

Mr. Kevin McAnaney,[22] a attorney who specializes in healthcare fraud, claims physician ownership of medical device companies is legal providing that the physicians are buying their shares at fair market value and that their profits are based on their percentage of ownership of interest and not on the volume of business they generate for the company. The problem would arise if the money made is directly tied to his usage of the product.

VII. THE STANCE OF GOVERNMENT TODAY

Advanced Medical Technology, an organization representing the code of ethics of interaction with health care professionals, headed by Stephen Ubl, requested clarification from the OIG regarding guidance for certain physician investments in medical device manufacturers and distributors.[23] The OIG has taken the stance of closely scrutinizing PODs under the fraud and abuse laws (Dept HHS, Oct 6, 2006). The OIG considers these arrangements ripe for potential violations of fraud and abuse and that these models will be observed closely. More recently the Senate Finance Committees [12] have strongly requested clarification on PODs to draw a line in the sand so everyone can understand what is "legal." "You can't possibly think this is okay," said Tom Scully, senior counsel at the law firm Alston and Bird who headed the Medicare program from 2001 to 2004. "I understand that the docs feel squeezed and want to make more money, but they're racing toward a cliff. This can't possibly hold up." [18]

In September 2011 , Daniel Levinson, Inspector General of the OIG, gave the following response: [24]

> *We expect that our study will produce important information about PODs. We will consider this information in determining whether to issue additional guidance addressing phyician-owned entities, including PODs. However, as we have discussed a wide variety of POD models are being utilized, and different POD models can raise varying levels of legal concern; thus, the answer to many of the important legal questions posed about PODs depend on the specific facts of the case. The Federal Anti-Kickback Statute is a criminal, intent-based statute that plays a central role in addressing improprieties in physician-industy relationships. The legality of any individual Physician-Owned Entity under the Federal Anti-kickback Statute is highly dependent on each entity's particular characteristics, including the details of its legal structure; its operational safeguards; and, importantly, the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations For these reasons, the OIG's ability to issue guidance about the application of these business structures is limited.*
>
> *It has been OIG's longstanding view 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*

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[21] Bulleit, T, Physician-Owned "Distributors" of Spinal Implants: The Impropriety of Physicians as Commissioned Sales Representatives, November, 2009, Hogan and Hartson, LLP. Available from: *http://www.hoganlovells.com/files/upload/PODWhitePaper_Nov2009.pdf.*

[22] Author unknown, The Journal of Healthcare Contracting, Physician or supplier? When physicians own substantial portions of medical device companies, contracting professionals play a key role in keeping their IDNs on safe legal ground. Available from:
http://www.jhconline.com/article-sepoct2007-physicianorsupplier.asp.

[23] Letter from Stephen J. Ubl, President and CEO of AdvaMed to Ms. Vicki Robinson, Esq., Chief Industry Guidance Branch, Office of OIG, September 6, 2006, Request for Guidance Regarding Certain Physician Investments in Medical Device Manufacturers and Distributors. Available from: *https://www.crowell.com/pdf/MedicalDevice/AdvaMed-Letter.pdf.*

[24] Letter from Dan Levinson from the Department of Health and Human Services, September 13, 2011, to the Senate Finance Committee.

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 owner may be required to divest his or her ownership interest; the actual return or projected return on the physician's investment; and the amount of revenues generated for the entity by its physician investors. OIG has repeatedly expressed this view, and listed these factors, in various guidance documents, including Special Fraud Alerts, advisory opinions, and published letters to the industry.

It is clear from Levinson's response that there is no formal decision as to what constitutes a legal POD or whether a POD even can be legal. The "wait and watch," noncommittal attitude of the OIG continues to confuse proponents on either side.

VII.A. The Sunshine Act

The Sunshine Act, introduced in 2009 by Senator Chuck Grassley (R–IA) and Herb Kohl (D–Wl),[25] requires manufacturers and group purchasing organizations to report a wide variety of payments to physicians and Physician-Owned Entities. Penalties for not reporting include fines from $1,000 to $10,000 for each payment not reported, with a cap of $150,000 per year. For intentional failure to report, the penalties will be steeper, with fines of $10,000 to $100,000 for each payment not reported, with a cap of $1 million per year. For PODs, the Sunshine Act requires reporting physicians' ownership interests in private companies, including the dollar amount(s) invested, the current value, and any payment or transfer of value to the owner, including dividends or other payments. The information is to be published in a searchable website in 2013. The Sunshine Act alone does not imply that the PODs are illegal, only that items such as the dividends and payments are to be made public.

VII.B. The Stance of Some Hospital Groups

The Martin Memorial Health Systems in Stuart, Florida, have decided to stop doing business with PODs because in their opinion PODs are "inconsistent with the spirit and intent of the federal anti-kickback statute."[26] Other hospital groups are requiring their physician members to sign financial relationships with their suppliers to avoid anti-kickback and self-referral laws. The Scripps Hospital system in San Diego, California, has eliminated the use of PODs in their hospitals. According to Daniel Roach, Vice President of Compliance, except for very limited use the Catholic Healthcare West Hospital systems have eliminated PODs from their system of 40 hospitals throughout California, Arizona, and Nevada (Roach D, personal communication). As well, the 28-hospital Providence Health and Services have eliminated PODs where Dr. Makker had performed surgery.

VIII. OTHER POD ISSUES NOT PREVIOUSLY CONSIDERED

VIII.A. Predatory Pricing

If one considers health plan contracts including capitated payment issues to the physicians who are investors in a POD, the POD physicians cannot be competed with. Over the years, physicians have been competing to the point of who will accept the bottom dollar on a contract. Now, with the POD model available, one can consider predatory pricing when it comes to contract negotiations. Without the monies paid from a POD, a non-POD physician has little or no power to compete with a physician or group of physicians who utilize a POD model. In theory, the POD physicians could survive without being paid any fees for services or capitated money to provide care for their patients from their contracted insurance groups. The POD physicians can generate more income than would be possible with any insurance payment plan. Thus, the POD physician essentially could work without compensation when it comes to the insurers and could dominate their local provider market. How could anyone who is not part of a POD compete with this model? This could be considered a violation of California's unfair business practice under the Unfair Competition Law, section 17200.[20, 27] The antitrust laws were enacted to promote competition. Now we have gone to the other extreme to eliminate competition by reducing payments to amounts so low as to consider the POD model being almost free services to insurers. Although this is a new concept, it is occurring. This essentially

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[25] The Sunshine Act. Available from: *http://www.aging.senate.gov/record.cfm?id=307097.*

[26] Memorandum, from Martin Memorial Health Systems, Inc., and Affiliated Entities, Regarding Physician-Owned Intermediaries, May 6, 2011. Available from: *http://www.hoganlovells.com/files/Uploads/Documents/Hospital%20Policy%20on%20Physician%20Owned%20Intermediaries.pdf.*

[27] Strickland J, Simonetti L, Moritz A, An Overview of California's Unfair Competition Law. Available from: *http://www.stroock.com/SiteFiles/Pub168.pdf.*

promotes those physicians who may egregiously perform extensive and non indicated operations for the sake of enhancing income solely on the implants used. Gone are the days of lumbar discectomies when a multilevel fusion can be done instead. Thus, predatory pricing rewards those unscrupulous surgeons who have no sense of ethics or doing what is best for the patient.

VIII.B. Who Loses?

In a POD situation, if a surgeon performs more than that which needs to be done, the hospital loses because the costs of the implants generally are paid directly by the hospital. In some instances the costs may be paid by the health maintenance organization or insurance company, depending on the contracts the hospital may have with the insurer. In the instance of Medicare, the hospital loses because patients are admitted on a diagnosis-related group basis, multiple implants would be paid for by the hospital and Medicare would only pay based on the admitting diagnosis-related group. The other loser in this model is the patient, who unknowingly has submitted to a extensive operation with little or no indication for the treatment.

VIII.C. What Can Be Done?

It is doubtful that all physicians can be trusted enough to perform operations or provide services for only those patients who need surgery and do only what is best for their patients. There are too many financial enticements to keep those marginally ethical docs on the straight and narrow. It will be up to the hospitals to be proactive in their stance regarding PODs. At a minimum, hospitals should develop a conflict of interest statement that all physicians should sign. If a hospital's opinion is that the PODs do not coincide with the intent of the law, then it would be up to the individual hospital to decide whether or not PODs should be allowed at their facility. These efforts likely would eliminate the PODs ability to develop or gain a foothold at any given hospital.

VIII.D. Can a POD be Legal?

With the controversy regarding the legality of PODs, one must decide if sitting on the fence waiting for the federal government to formally declare PODs illegal or legal or if the risks of joining a POD are worth it. With time there may be more openly prosecuted cases involving PODs undergoing OIG investigations for fraud and abuse with surgeons performing egregious nonindicated, multilevel procedures.

It would seem that a POD cannot qualify for protection as a safe harbor. Thus, a indirect payment model, as a potential Stark exception, would be necessary, as outlined in part by Dr. Steinmann's 19-point compliance, with several important additions and differences.

1. The POD investors could only own a fixed, small percentage of the company and eliminate multiple small and individual or mini-PODs.
2. Reimbursement from a POD can be based only on the percentage ownership of a individual POD and not by individual use of a product.
3. A POD must have a large number of physician owners, perhaps 25 or more, all with equal percentages of ownership, who locally work in a close geographic area, so that one cannot construe that payment is based on volume as it would be in a smaller POD and an investor cannot choose heavy users throughout a large geographic area.
4. Any implant company potentially could compete for the business at any hospital from the POD.
5. The physician owners would not purchase specific implants because purchasing a implant would force a physician to use only one particular product that may be of inferior quality or not what would be best for the patient.
6. The POD would not accrue implants but would purchase implants from the most cost-conscious and quality options manufactured by any of the small or large implant companies.
7. Implants purchased by the hospital through any vendor would be no more expensive with a POD; a POD could not charge higher fees than other implant companies.
8. Each hospital that allows PODs must have a conflict of interest statement that each physician member or that hospital signs.
9. If any physician is egregiously performing nonindicated, multilevel operations (which would have to be monitored via a peer-review process and conflict of

interest declaration at each hospital), those individuals would be eliminated from the POD and potentially reported for possible fraud and abuse prosecution.

10. The POD owner would have to declare in writing to their patients that they have a financial interest in the company.
11. There would be no need for passive investors because the POD models would not qualify as safe harbors.
12. Physician investors who retire or move out of the area of a particular POD would sell their interests back to the POD.
13. POD investors who care for non-federally funded insurance, including workers compensation, should follow these same guidelines to avoid egregious acts and kickbacks.

IX. CONCLUSION

The POD model as described by John Steinmann and others has been looked at legally by Hooper, Lundy, and Bookman in California. Nevertheless, even this legal team, despite all efforts to develop a legal entity that complies with the most stringent federal legislation, recognizes and acknowledges that their efforts to make a legal POD still could be considered illegal under scrutiny by the federal government. It should be remembered that a legal opinion from an attorney or group of attorneys does not have legal jurisdiction over the OIG/DHS and the federally funded patients. It is ultimately up to the OIG and Fraud and Abuse to determine what is considered legal and what is deemed illegal and worthy of prosecution. For these reasons, one should be exceedingly careful when becoming involved in a POD. Only after a POD investor loses his license to practice medicine, incurs heavy fines, or faces potential prison time for egregious acts will these POD groups collapse, as they did in the case of the Omega Solutions group and Dr. Makker. Perhaps all hospitals should consider what the Stuart, Florida-based Martin Memorial Health Systems decided this year: stop doing business with such entities. Martin Memorial Health Systems told its staff that PODs are "inconsistent with the spirit and intent of the federal anti-kickhack statute." If a legal POD could be devised with stringent guidelines then perhaps there is a place in the market for such a model. Without strict guidelines the POD model will be poorly defined and lead to fragmentation of structure, and we will be back to our current dilemma of forming semi-legal or entirely illegal PODs and dealing with predatory pricing and kickbacks. Continuing on as we are is not acceptable and will eventually require the OlG to take a firm stance for or against PODs. It is up to physicians to practice responsible, ethical surgery for the benefit of their patients. However, if a legal POD entity can be developed that satisfies all the stringent federal laws and restrictions it also could be a revenue source for physicians in these difficult economic times.

Supporting Addendum Two

T10-S1 fusion for low back pain and bilateral Sacro-iliac fusion



Shown is an extensive POD fusion to treat low back pain. Unfortunately, despite a total of four operations, the patient is in worse pain than prior to the surgeries. This is not a unique case.

PREPARED STATEMENT OF KEVIN REYNOLDS, SON OF A PATIENT OF A SURGEON AFFILIATED WITH A PHYSICIAN-OWNED DISTRIBUTOR

I, Kevin Reynolds, stand before this committee on behalf of my mother Lillian Kaulbach and patients across the country who have been harmed by Physician-Owned Distributors (PODs). My testimony today describes my family's involvement with PODs, specifically a POD called Apex Medical Technologies LLC that was owned partly by Dr. Aria Sabit.

Based on my mother's experience with a POD, I believe that PODs are a serious threat to patient health and must be stopped immediately.

PODs pose a conflict of interest with the oath that doctors take, which states that they must "do no harm." Beyond that oath, there is an unspoken trust and belief in our healthcare system that doctors make decisions based on the patient's best interest. When doctors recommend surgery, patients put trust in their judgment.

My mother's medical problems started in 2002, when she called to tell me that she was having a hard time taking care of her paralyzed mother and her brother who recently had half of his skull removed after an accident. I dropped everything to go help my mom.

With my help, my mother continued to take care of her mother and brother for several years. During that time, she had several major surgeries due to conditions brought on by the physical and mental stress of taking care of her family.

After seven surgeries, my mother still suffered from severe and persistent back pain. She turned to Dr. Sabit for help in the fall of 2010.

I went with my mother when she met with Dr. Sabit in his office. Our meeting with him was very brief. It lasted no more than 3 to 5 minutes, and Dr. Sabit did

not perform any physical examination of my mother. Nonetheless, at the end of the meeting, Dr. Sabit recommended that she have spinal fusion surgery.

My mother and I trusted Dr. Sabit's judgement and decided that she should have the spinal fusion surgery. At the time when we met with Dr. Sabit, we had no indication that he had an ownership interest in any of the products that might be used in the surgery.

Dr. Sabit performed surgery on my mother in October 2010. My mother and I signed consent forms that authorized Level 1 spinal fusion. However, Dr. Sabit performed Level 4 surgery on his own without asking the family or my mother for consent.

After surgery, my mother developed 5 or 6 different infections. The hospital staff told me that they could do no more. They asked me to pull the plug not once, but twice. I said no.

Miraculously, my mother showed some improvement. But she was never able to walk again. Instead, she became bedridden and was sent to a nursing home to battle these infections, taking up to 25 pills a day.

On May 31, 2011, my mother passed away from complications related to Dr. Sabit's spinal fusion surgery. She was 68 years old.

It was only after my mother died that I learned about Dr. Sabit's involvement with Apex Medical Technologies LLC, a company that manufactures screws and rods that were used in my mother's surgery. A single screw used in this type of surgery costs around $100 to make and sells for $1,000.

It has been reported that Dr. Sabit had a 20 percent stake in Apex. It has also been reported that from May 2010 to August 2012, Dr. Sabit's share of profit in Apex was $330,000.

Simply put, I believe that Dr. Sabit had a clear financial incentive to use more screws and rods in my mother's back surgery. And I believe that this financial incentive played a role in his decision to perform more complex surgery on her that was not medically necessary.

Some people have asked if I would do anything differently if I had known that Dr. Sabit had an ownership interest in the products he planned to use in my mother's surgery. Looking back, I believe that the answer is "yes." Knowing that information, and understanding the conflict of interest, we would have sought a second opinion before authorizing any surgery.

Of course, we weren't given that opportunity because we didn't know that Dr. Sabit was involved with a POD.

Since my mother's death, I have tried to tell her story. I've spoken with local and national news organizations, have testified in Dr. Sabit's criminal proceedings, and it's my privilege to appear before the Senate Finance Committee today.

But I know that even if Dr. Sabit goes to prison, patients will not be protected from the same dangers that claimed my mother's life. There are still other doctors who participate in PODs and have the same financial incentives that Dr. Sabit had to perform unnecessary and dangerous surgery.

On behalf of myself and my mother, Lillian Kaulbach, I ask the committee to do everything in its power to stop these doctors. Please do whatever is necessary to ensure that doctors make decisions based on what is best for the patient, not the doctor's wallet.

From *The Wall Street Journal,* July 25, 2013

SURGEONS EYED OVER DEALS WITH MEDICAL-DEVICE MAKERS

Justice Department Investigation Shines Light on Federal Authorities' Broader Scrutiny of Physician-Owned Distributorships

By John Carreyrou

Ten months after an Afghan-born surgeon named Aria Sabit arrived in Ventura, California, local hospital staffers noticed he suddenly developed a preference for an

obscure brand of spinal implants for many of his surgeries. Soon his volume of operations increased, with sometimes-tragic results.

By the time he moved on less than a year later in late 2010, he had become embroiled in investigations by the California medical board and the Food and Drug Administration and more than two dozen medical malpractice lawsuits, including 12 involving surgeries he did with the new implants.

Now, the Department of Justice is investigating Dr. Sabit because it has emerged that he had an ownership interest in the company that distributed, and profited from, the surgical devices he switched to, people familiar with the matter say.

Federal prosecutors' scrutiny of Dr. Sabit is part of a broader civil investigation into a network of physician-owned spinal-implant distributorships operated by two former medical-device company employees, the people with knowledge of the matter say. This network, which was run out of Utah and comprised at least 11 Physician-Owned Distributorships in 6 States, generated tens of millions of dollars in profits for its investors over 6 years.

Physician-Owned Distributorships, or PODs, have proliferated in medicine. Distributorships, whether owned by physicians or not, act as intermediaries between medical-device makers and hospitals: In exchange for marketing and stocking devices, the distributors get a cut of each sale. When surgeons own the distributorship, that commission goes into their pockets. And since surgeons often dictate to their hospitals which devices to buy, they can effectively steer business to themselves.

Depending on how they are set up, such entities can be legal. But in March, the Department of Health and Human Services' Office of Inspector General issued a special fraud alert about PODs, warning that they "pose dangers to patient safety" by inducing surgeons to do more procedures than necessary and to favor devices they profit from over more "clinically appropriate" ones.

In Dr. Sabit's case, the Justice Department has been looking into whether his financial interest in the implants caused him to over-operate or contributed to a spate of alleged patient complications. Twenty-eight former patients or their families have sued Dr. Sabit in Ventura Superior Court, alleging negligent acts ranging from misplacing implants in their spines to performing surgeries that were unnecessarily extensive. Dr. Sabit has settled 11 of the suits, one has been dismissed and 16 are still pending against him.

Through his attorneys, Dr. Sabit, who is now practicing medicine in Michigan, declined to comment, citing the malpractice lawsuits and California's medical privacy laws. He has denied the suits' allegations in court filings and, in a deposition, blamed a surgeon who recruited him to Ventura for encouraging patients to sue him. Dr. Sabit has sued that surgeon and the Ventura hospital for wrongful termination.

In his malpractice depositions, Dr. Sabit has alternately denied receiving any monetary benefit from the implants he used in his surgeries or said he didn't know whether he did.

However, a person with knowledge of the matter says Dr. Sabit owned one-fifth of a spinal-implant distributor called Apex Medical Technologies LLC from May 2010 to August 2012. Over that period, which includes 8 months of his tenure in Ventura, he received profit distributions from Apex that averaged about $12,000 per month, this person says.

Dr. Sabit, 39, was born in Kabul, Afghanistan, but his family fled the country in 1979 during the Soviet invasion. In a deposition, he said they lived in a tent in Pakistan for 4 years until they emigrated to the U.S.

The family settled in Arlington, VA. Dr. Sabit's father, Abdul Jabbar Sabit, got a job as a reporter for Voice of America. He returned to Afghanistan after the fall of the Taliban and served as Afghanistan's attorney general from 2006 to 2008.

Dr. Sabit attended college and medical school at Virginia Commonwealth University and did his neurosurgery residency at the University of Medicine and Dentistry of New Jersey. He was recruited to Ventura by Moustapha Abou-Samra, a Syrian-born neurosurgeon who had practiced in the middle-class community north of Los Angeles for more than 3 decades.

Dr. Sabit raised eyebrows at Ventura's Community Memorial Hospital soon after he arrived in June 2009. An avid weight lifter, he said in one of his malpractice depositions that he used supplements such as creatine to build muscle mass. People who

worked with him say he was physically intimidating. In the operating room, he played loud heavy-metal music, several hospital nurses have testified.

At first, Dr. Abou-Samra portrayed his recruit as a young star on the cutting edge of neurosurgery who could perform sophisticated spinal procedures CMH had previously been forced to refer out to academic medical centers, several Ventura doctors say. Dr. Abou-Samra didn't return calls for comment. A spokesman for CMH declined to comment for this article.

Though he was fresh from his residency, Dr. Sabit said in a deposition that he quickly became one of the hospital's busiest surgeons and was billing four times as much as Dr. Abou-Samra within a year. He said this created tensions with Dr. Abou-Samra. During 18 months at CMH, Dr. Sabit performed 371 procedures, including 306 spine operations, according to a list of his cases the hospital provided in the malpractice litigation.

Dr. Sabit prided himself on working fast, according to Joan Kruse, a CMH nurse deposed in the malpractice litigation. "He would grab instruments. He'd shove them into the wound," she testified. "I've never seen any neurosurgeon be that rough and brutal with" tissue "that close to the spinal cord," she said.

In one of his depositions, Dr. Sabit said he found Ms. Kruse to be "very disagreeable" and had asked that she be barred from his surgeries.

Dr. Sabit used a variety of spinal-implant brands during his first 10 months in Ventura, but he switched to Apex in April 2010, according to Marilyn Harris, CMH's director of surgical services. In her deposition in the malpractice litigation, Ms. Harris said the switch prompted speculation at the hospital that Dr. Sabit had joined a POD and was profiting from his use of Apex implants.

Dr. Sabit denied to Ms. Harris that this was the case, and later testified he couldn't recall when he began using Apex products. Ms. Harris testified that he showed up in her office unannounced and told her: "I don't even know what a POD is. I'm not part of a POD." Ms. Harris said "he was in a heightened state of anxiety" and "very emphatic."

However, a person with knowledge of the matter says that Apex was in fact a POD and that Dr. Sabit purchased a one-fifth stake in it in May 2010, after a short trial period.

Apex was created by two men, Adam Pike and Bret Berry. Following a model they replicated at least 11 times across 6 States, Messrs. Pike and Berry recruited Dr. Sabit and a neurosurgeon in Los Angeles to become partners with them in Apex. Each surgeon bought a 20 percent interest in the company, with the remaining 60 percent going to Messrs. Pike and Berry and one of their business associates.

The two men are veterans of the medical-device industry who partnered up to create their own spinal-implant company, Reliance Medical Systems. From offices in Bountiful, Utah, Reliance contracts with machine shops to manufacture replicas of bigger companies' products that it sells under its own brand. The practice is legal under a streamlined FDA approval process for medical devices deemed "substantially equivalent" to ones already on the market.

To get their products adopted, Messrs. Pike and Berry created a series of distributorships similar to Apex and sold ownership stakes to groups of surgeons across the country, according to a person familiar with the operation. Each surgeon received a monthly profit distribution, this person said. The more Reliance implants the surgeons put in patients' backs, the more business their distributorship did and the more they earned.

Under California's anti-kickback statute, it is illegal to pay doctors to induce patient referrals, or for doctors to accept such payments. The practice is also illegal under Federal law if the patients are insured by health programs such as Medicare. According to the people familiar with its civil probe, the Justice Department is examining whether the distributorships Messrs. Pike and Berry created were effectively kickback mechanisms to induce surgeons to use Reliance implants.

The answer to that question hinges in part on whether the amount Dr. Sabit and the other surgeons paid for their distributorship stakes is too small to be considered a real investment, given the size of their returns, which in some cases reached $50,000 a month.

Federal prosecutors are looking into whether Dr. Sabit's financial interest in Apex made him more prone to operate or to do bigger and riskier surgeries than necessary, the people familiar with the matter say.

The printout of Dr. Sabit's surgeries at CMH shows that, before allegedly switching to Apex, he averaged 14 spine procedures a month and spine surgeries accounted for 76 percent of his operations. After he allegedly switched to Apex, he averaged 22 spine procedures a month and their share of his case load rose to 87 percent.

In a court filing, Dr. Sabit has pointed to deposition testimony from CMH Chief Executive Officer Gary Wilde, in which Mr. Wilde stated, "we believed that the vast majority of cases Dr. Sabit did were appropriate."

It is unclear how many patients Dr. Sabit used Apex implants on. Of the 28 patients who sued, he implanted Apex hardware in 12 of them, according to the malpractice depositions and people familiar with the matter. None of those suits allege that the Apex implants were defective.

A spokesperson for Reliance says the fact that Dr. Sabit didn't use Apex on more than half of the plaintiffs shows that there is no causal relationship between his use of Apex and the suits. "It is wholly inaccurate to assume that these claims are a result of the use of Apex products. To the best of our knowledge, there have never been any allegations by patients or doctors about faulty Apex products," the spokesperson said.

One of the patients Dr. Sabit operated on using Apex was Guanda Dusette, a 72-year-old retired nurse. Jack Padour, Ms. Dusette's primary-care doctor, says he referred her to Dr. Sabit after she complained of persistent back pain. Dr. Sabit proposed removing part of two disks in her spine, a relatively routine procedure designed to take pressure off the nerve root, Dr. Padour says.

Dr. Sabit operated on Ms. Dusette on July 8, 2010. However, the surgery he performed turned out to be much more extensive: Using Apex implants, he fused together eight vertebral levels in her spine, Dr. Padour says.

After the surgery, Ms. Dusette was "in agonizing pain," according to Dr. Padour. The metal screws and rods Dr. Sabit had drilled into her spine began coming loose, and the rods pressed against the skin of her back from the inside, according to Dr. Padour and Ms. Dusette's attorney.

Ms. Dusette was re-operated on at Cedars-Sinai Medical Center in Los Angeles, where all the hardware Dr. Sabit implanted was taken out, Dr. Padour says. She subsequently sued both Dr. Sabit and CMH. She recently reached a confidential settlement with the hospital, but her case against Dr. Sabit is still pending. Dr. Sabit has denied her suit's allegations.

Outside the hospital, Dr. Sabit's surgical outcomes caught the attention of Gary Proffett, the medical director of a physician association called SeaView that coordinates patients' care on behalf of health plans. Of 75 SeaView patients operated on by Dr. Sabit over his 18-month tenure in Ventura, 28 developed major complications, including two who died, Dr. Proffett said in an interview. Dr. Proffett reported the SeaView complications and deaths to the California Medical Board.

Many of Dr. Sabit's post-surgical complications involved infections, according to depositions by several nurses and Cary Savitch, an infectious diseases doctor at CMH.

Dr. Sabit has disputed this. In a court filing, he said CMH's infections control nurse "performed an exhaustive review of my infection rate" and concluded that it "was normal and acceptable."

One alleged victim of infection was Lillian Kaulback, an overweight woman in her late 60s with a number of health issues, ranging from diabetes to a history of ankle, shoulder and knee surgeries. Dr. Sabit operated on her on October 7, 2010, using Apex implants to fuse three vertebral levels in her spine, according to several people familiar with her case.

A person close to Ms. Kaulback says she was mobile and active before her surgery, playing bingo, attending family functions and going to a local club to watch couples dance. After the surgery, she never walked again and was in and out of the intensive care unit, this person says.

Dr. Savitch, who treated Ms. Kaulback after her surgery, recalled in his deposition that she had a big wound on her back that "was open" and "dripping pus" and had "six different bugs growing from" it.

To his astonishment, Dr. Sabit closed the infected wound and didn't document it in Ms. Kaulback's medical chart, Dr. Savitch testified. "Whenever you have an infected wound, you need it to drain. . . . The last thing you do is close it," he said.

The wound opened back up the following day, according to Dr. Savitch's deposition. The person close to Ms. Kaulback says she was eventually transferred to a nursing home, where she spent 6 months in acute pain. She died there on May 31, 2011.

Ms. Kaulback's son has filed a wrongful-death suit against Dr. Sabit and CMH. The case is pending. Dr. Sabit and CMH have denied the suit's allegations.

In their depositions, Ms. Kruse and other nurses testified that Dr. Sabit was cavalier about keeping the operating field sterile and would sometimes contaminate it by not scrubbing in properly or by letting his hair dangle over an open wound.

The Reliance spokesperson said, "There is absolutely no connection between allegations of infection and Reliance's products or its sterilization procedures."

When CMH confronted him about alleged post-surgical infections among his patients, Dr. Sabit blamed one of the hospital's two operating rooms, which he argued in a letter wasn't kept sufficiently clean and sterile.

On December 3, 2010, CMH suspended Dr. Sabit. Mr. Wilde, the CEO, handed him a letter stating that the hospital had decided "immediate action must be taken to protect the life or well-being of patients." The letter said the suspension was based in part on Dr. Sabit's alleged negligent treatment of two unidentified patients. In a subsequent court filing, a senior CMH staffer said one of those two patients died.

Dr. Sabit filed his own statement with the court in which he denied being negligent and said "there was no medical basis at all for the summary suspension." Instead, Dr. Sabit wrote, Dr. Abou-Samra and the hospital had conspired to suspend him so Dr. Abou-Samra could fire him and "avoid paying me the huge bonuses he would otherwise have to pay."

After Dr. Sabit threatened to sue the hospital, CMH reinstated him on December 7, 2010. But Dr. Abou-Samra refused to let him rejoin his practice, so Dr. Sabit voluntarily resigned his hospital privileges on December 21, 2010.

Following Dr. Sabit's departure, the California medical board launched an investigation, according to several CMH doctors and nurses interviewed by the board. A spokeswoman for the medical board declined to comment. The FDA also sent investigators to Ventura and audited Reliance's operations in Utah in May 2011. The results of the audit weren't made public. The Reliance spokesperson said: "Our products, which are certified by a third-party, meet the strict sterilization procedures and protocols established by the FDA."

Reliance discontinued its relationship with Dr. Sabit in August 2012 and stopped operating Apex as a POD, according to a person with knowledge of the company's operations. It has since bought out the ownership interests of surgeons in its other PODs but continues to pay many of them consulting fees, this person says.

Write to John Carreyrou at john.carreyrou@wsj.com

Spinal Fusion Surgery Spawns Lawsuits, Controversy

By Tom Kisken

February 15, 2012

Spinal fusion procedures that triggered many of the 17 lawsuits lodged against a former Ventura neurosurgeon regularly spawn litigation and are sometimes used on patients who have little chance of benefiting, according to surgeon specialists at USC and UCLA.

In fusions, metal rods and screws are used to anchor the spine in place while grafted bone or other material is employed to generate bone growth that fuses the vertebrae. The procedures are used to treat fractures, excessive curvature or other injuries, usually in the lower back.

The operations play a pivotal role in allegations facing Dr. Aria Sabit, a 36-year-old neurosurgeon who started operating at Community Memorial Hospital in Ventura in summer 2009, fresh out of a 7-year residency in New Jersey.

In the flood of lawsuits, patients allege he performed fusions in which the anchoring hardware was misplaced and screws pulled out of bone. They said they suffered from postoperative infections, that some of the surgeries were unnecessary or too much hardware was used.

Sabit was fired by Ventura County Neurosurgical Associates Medical Group after 17 months, in December 2010, according to a lawsuit filed by the physician against the group and then withdrawn. All of the lawsuits filed individually by patients against Sabit came after he stopped practicing in Ventura.

Now practicing in eastern Michigan, Sabit has refuted the allegations. Regulatory agencies reported no findings against him in Michigan, California or New Jersey. In his former lawsuit against the medical group, he disputed that his rates of complications and surgeries were high, blaming the group for generating untrue criticism against him.

Community Memorial officials said they initiated an investigation of Sabit by the California Medical Board. The hospital and a leader of the medical group—both targeted in some of the patient lawsuits—said they can't discuss the case but have defended themselves against accusations that they waited too long to take action against Sabit.

Tell Dr. Jeff Wang, a UCLA orthopedic surgeon who performs spinal fusion surgeries every week, about the 17 lawsuits and he offers an exclamation; the number surprises him. But fusion surgery is "very" litigious, and most doctors will face at least one lawsuit in their careers, he said.

"I think people have certain expectations," he said of patients with long histories of lower back pain. "The results can be mixed, and it's not necessarily the fault of the surgeon or the fault of the patients. We just don't have all the answers when it comes to nerves in the spine."

In the procedures, as many as a dozen vertebrae are fused together by bone. Pedicle screws, plates, small titanium or carbon fiber cages and other hardware are used to stabilize the spine in place until the graft takes hold.

The procedures are often used for fractured vertebrae or damage caused by scoliosis or tumors. But sometimes the procedures are used for patients with symptoms that show they are not likely to benefit from fusion, said Dr. Patrick Hsieh, a neurosurgeon at USC.

Elderly people who suffer from advanced conditions like heart problems, diabetes or some bone diseases like osteoporosis often are not the best candidates, Hsieh said.

Dr. Richard Deyo is an Oregon Health and Science University internist and researcher who studies back pain. He cited four studies from Europe that suggest patients who suffer from lower back pain because of worn-out disks in their spine but have no underlying spinal problems often see no more benefit from fusion than from nonsurgical care.

"And yet this is the fastest-growing reason for doing spinal fusions," he said, suggesting the procedures also push up the cost of care by generating more treatment that patients or insurers must cover.

"The U.S. does five times more spine surgery than the United Kingdom," he said. "We do twice as much spine surgery as other developing countries. There's no evidence that we're having better outcomes."

Hsieh said patients who suffer bone softening may not be good candidates for fusion.

Wang said the condition increases risk but said fusion may, in certain situations, still be appropriate.

"There are gray areas where you think it may be helpful or not helpful," said Dr. John Regan, a spine surgeon in Beverly Hills. "There are some physicians who overreach."

Sabit faces lawsuits filled with allegations that still must be proved in court. But if the cases reach trial, with one case set for an April start, spinal fusion could play a key role. His former patients allege he performed too many surgeries, relied on hardware that included rods, screws and interbody cages, and sometimes misused that equipment.

"He didn't know what he was doing," said Woodland Hills lawyer Steven Goldberg. He represents an Oxnard woman who underwent fusion surgery, only to have the

screws pull away from her bone. "When I met her, she was totally bent over like a paper clip."

Sabit's lawyer, Louis "Duke" DeHaas, branded the allegations of inappropriate procedures and faulty technique as common in malpractice litigation.

"That's what they allege in these lawsuits," he said. "It doesn't mean it's meritorious. You can allege anything you want. That's why we have trials."

Sabit has denied all the allegations. Once a refugee of Afghanistan whose father returned to the country and served 2 years as its attorney general, Sabit attended Virginia Commonwealth University. He went through 7 years of neurosurgery residency at the University of Medicine and Dentistry of New Jersey, in Newark, training at The University Hospital. In his final year, he served as chief resident.

"He successfully completed the residency," said Dr. Charles Prestigiacomo, who leads the neurosurgery residency program. "He did a fine job."

After finishing his residency in July 2009, he began operating at Community Memorial in Ventura, partnering with a highly regarded neurosurgeon, Dr. Moustapha Abou-Samra. In court papers, Sabit said he started to do some of the most difficult operations at the hospital, earning a reputation as a "go-to physician."

"He was introduced as the next generation of neurosurgery," said Dr. Jack Padour, a Ventura internist who has two patients who filed lawsuits against Sabit. "We thought, 'Great, we need a guy like that.'"

Complaints against the doctor involve infections after surgery, screws or rods that were improperly placed on patients and procedures that resulted in extreme pain and had to be redone.

Olivia Sawyer, 53, of Santa Paula said a doctor at USC took out everything Sabit put into her because the rods used for her spine were crooked. She tried to file a lawsuit but was told the 1-year statute of limitations had passed.

Charles Shinn, 46, of Ventura complained in court documents that Sabit told him he was going to do a minimally invasive procedure and then, without informing him, chose a much more involved procedure that included an interbody cage placed on his spine.

Guanda Dusette, 71, of Oxnard said she paid an online service $15 to research Sabit before choosing him for a spinal fusion. She alleged the screws pulled away from the bone after surgery, contributing to nonstop pain and leading to corrective surgery at Cedars Sinai Medical Center.

"What happened to me shouldn't happen to people," Dusette said.

But sometimes doctors can't prevent screws from loosening in the bone, said Wang of UCLA, adding that the problems can be caused by poor bone quality or a graft that failed to fully fuse the vertebrae. "Whenever you're putting the hardware in, there's always a certain risk," he said. "Even in the most skilled hands, the anatomy can cause the screws to be misplaced."

Surgeons fresh out of residency face a learning curve, said Hsieh, but a 7-year residency for neurosurgery means they should be ready to handle most fusions.

"Experience matters even if you're well trained," said Deyo, the researcher. "It's always true that the more you do, the more expert you become."

Hsieh said fusion surgery problems usually stem from the planning—choosing the right patients and figuring what strategy will bring the best result.

"As surgeons, we are experts, but who we operate on and who we make better is not based on just how good we are. It's also based on if we pick an appropriate patient," he said.

From CBS News, October 24, 2013

SURGEON SALESMEN? DOCTORS PROFIT FROM DEVICES THEY PUT IN PATIENTS

By the summer of 2010, 68-year-old Lillian Kaulback had developed severe back pain. She was referred to Dr. Aria Sabit, a spine surgeon in Ventura, Calif.

Her son Kevin Reynolds, who was at the appointment with her, says a few things struck him as strange from the start. There was no secretary or medical assistant

there to greet them—just Sabit. There was no physical exam, and Reynolds says Sabit told his mother she needed surgery within 3 to 5 minutes of meeting her.

Patients like Kaulback have a higher risk of complications—she was 68, overweight, and diabetic. Still, Sabit performed a three-level spine fusion, screwing together four of her vertebrae. Reynolds says within days, she developed a life-threatening infection. "The independent team asked me not once, but twice to pull the plug on her," he told "CBS This Morning." "I said 'no.'"

Lillian Kaulback never walked again. Seven months after the surgery, in May of 2011, she passed away.

Reynolds is now suing Sabit for wrongful death. One of his biggest questions centers on the screws and rods used to fuse the spine, which came from a company called Apex Medical Technologies LLC. Apex had no public phone number, website, or listing of its owners. "CBS This Morning" has learned one of its owners was Sabit himself, with a 20 percent stake. From May of 2010 to August of 2012, his share of the profit was about $330,000.

Reynolds claims the financial incentive caused Sabit to do a riskier procedure than necessary, so he could put in more hardware. A single screw used in spine fusion surgery can cost $100 to make, and can sell for $1,000. "I don't think he would've worked on as many levels or possibly did that type of invasive surgery," Reynolds told "CBS This Morning." He says Sabit never mentioned his ownership stake in Apex.

Court records show Kaulback's case is one of 28 brought against Sabit for just 17 months of work at Ventura's Community Memorial Hospital. At least 10 of the suits involve Apex implants. Legal filings show in the 7 months before Sabit became an owner of the company, he did 115 spine surgeries. In the 7 months after, he did 154, a 34 percent increase. (Seven full months was the length of time from when Sabit began using the implants to when he left the hospital in December of 2010.)

Sabit chose not to give "CBS This Morning" an interview for this story, citing pending litigation. But in a deposition, he claimed he simply had more cases as he became more established. "As time went on I got more and more referrals," he said. "By June of 2010, the wait time to have surgery done by me was probably around 2½ to 3 months."

Physician-owned companies, also known as Physician-Owned Distributorships or PODs, have been around for a little over a decade, but already supply an estimated one-sixth of spinal implants nationwide. Most simply serve as middlemen, buying implants wholesale and selling them to hospitals, but some also design and manufacture their own products. In addition to spinal implants, they currently supply hip, knee, cardiac, and other devices.

Doctors are not required to disclose their ownership in these companies, so it's very difficult to get information about them. Often patients—and even hospitals—don't know their physicians are involved. But today, the Inspector General of the Department of Health and Human Services released a long awaited study on them.

The report found that in fiscal year 2012, hospitals served by physician-owned companies averaged 28 percent more spine surgeries. Their rate of spine fusions jumped 21 percent after they began purchasing from these companies (that compares to a 9 percent increase for hospitals overall, during the same period). The report also found that surgeries involving physician-owned companies used 13 percent fewer devices.

Dr. Scott Lederhaus and Dr. Charles Rosen are on the board of the Association for Medical Ethics. Both spine surgeons, they say they've seen many patients harmed by physician-owned companies, due to the strong financial incentive to perform unnecessary procedures. "The guys that are being egregious could make, just from putting in the implants . . . perhaps in excess of a half a million dollars each, per year," Lederhaus told "CBS This Morning."

"Doctors are not supposed to be salesmen," Rosen added.

Lederhaus and Rosen say physician-owned companies should be banned entirely. But Dr. John Steinmann says that would be a big mistake. His company is one of the few that discloses who its owners are. He says by cutting out the middle man and buying in bulk, he saves his hospital $1 million a year. "I can perform exactly the same effective surgeries at a 40 percent lower rate," he told "CBS This Morning."

Steinmann says these arrangements can greatly lower healthcare costs, they just need to be regulated, to weed out the "bad apples." To help do so, he founded the American Association of Surgeon Distributors, which certifies what it believes are legal and ethical physician-owned companies. It requires doctors to disclose their ownership stakes and show cost savings, and it monitors the number of surgeries they are performing.

But at least for now, it appears Steinmann is the exception rather than the rule. His association has fully certified just 14 of the more than 200 physician-owned companies operating across the country, according to the most recent estimates from the Centers for Medicare and Medicaid Services. And the inspector general report found that on average, physician-owned companies are charging no less than traditional suppliers. (You can read the association's response to the report here.)

The Justice Department is now investigating whether Sabit's ownership of Apex led him to do unnecessary procedures, according to the Office of Senator Orrin Hatch, R–Utah, and the Finance Committee. No one from Apex would give "CBS This Morning" an interview, but a spokesman claimed none of the suits involving the company's implants allege unnecessary procedures. In fact, at least 8 of the 10 plaintiffs we identified said they plan to argue just that, though no one has claimed the implants were defective.

In depositions, Sabit has denied the allegations. He charges that his former medical group, Ventura County Neurosurgical Associates, encouraged patients to sue, so it could fire him and avoid paying his bonuses. He claims he is owed millions and has sued for wrongful termination.

Sabit also blamed a non-sterile operating room for patient infections, and in a deposition, the chief executive officer of the hospital—which is also being sued—defended him, saying "the vast majority of cases that Dr. Sabit did were appropriate." Sabit has settled at least nine of the 28 cases, and at least one has been dismissed. He is no longer a part-owner of Apex.

Last month, the California Medical Board accused Sabit of committing dishonest, corrupt, and negligent acts in his care of five patients. It charged that he performed unnecessary procedures on three of them, and repeatedly documented procedures that he did not perform. The board will decide whether to revoke his state license after a hearing. For the time being he is still practicing, in Lapeer, MI.

From *Orthopedics This Week*

"FROM KABUL WITH LOVE"—DR. SABIT'S MISADVENTURES

By Walter Eisner

March 3, 2015

Spine surgeon Aria Sabit, M.D., is sitting in a Michigan jail awaiting trial on Federal healthcare fraud charges and trying to procure U.S. citizenship in an unlawful manner. He's sitting in jail because prosecutors convinced a Federal magistrate that Sabit would flee the country in a scheme worthy of an Ian Fleming novel.

The Federal Government says Aria surrendered his medical license in California, effective in 2014, and moved to Michigan, where he was licensed to practice medicine in March 2011. There he opened the Southfield-based Michigan Brain and Spine Physicians Group and began performing spine surgeries.

Or so he claimed. According to a Federal indictment, Sabit performed lumbar fusion surgery on a number of patients, but didn't actually install any hardware. Then he allegedly committed the worst sin—billing Medicare for work that wasn't done.

The U.S. Department of Justice (DOJ) charged him with false claims. After a detention hearing on December 4, 2014, the magistrate ordered Sabit held in jail. Prosecutors told the judge they fear he is a flight risk and would try to return to his native Afghanistan to start a hospital and drill for oil. They said he is a member of a politically prominent family.

After his detention, a Federal grand jury indicted him on 18 counts of fraud and 1 count of "unlawful procurement of naturalization" in a 20-page indictment. That happened on December 9, 2014.

Beginning in approximately 2011, and continuing through November 2014, Sabit, according to the indictment, convinced patients to undergo spinal fusion surgeries, "which were either medically unnecessary or never rendered and then billed public and private insurance programs for the fraudulent services."

According to the government's case against him, Sabit allegedly dictated surgical notes that he had performed various spine surgeries, which included laminectomies, discectomies or other procedures, with instrumentation—but which he never actually conducted.

The government is claiming that Sabit's operative reports and treatment records allegedly contained false statements about the diagnosis for the patient, the procedure performed, and the instrumentation used in the procedure. Sabit would also order spinal injections and simultaneously schedule the patient for surgery, "thus not waiting a sufficient amount of time to lapse to ascertain if the non-invasive treatment was successful."

Sabit claimed he used Zimmer Holdings, Inc.'s Transfacet Screw System. But postoperative X-ray and MRI examinations by other spine surgeons revealed that no medical device had been placed in or around the patient's spine.

"Subsequently, after continuing pain, all patients received second opinions from other doctors stating that no such spinal fusion had been performed and there was no evidence of any screw, or any medical device in the spinal column of the patient," Special Agent Peter Hayes of the FBI wrote in a court filing.

In all, Sabit billed almost $33 million and was paid more than $1.8 million, according to the criminal complaint. He performed surgery on almost everyone who walked through his office, an unnamed employee told an FBI agent.

"He had swagger off the charts," said Tonocca Scott, one of his former patients said of the 40-year-old Sabit in a published interview. "His hair was pulled back. He could have been a guy in a James Bond movie. Why would I go to anybody else?"

Sabit in California—PODS, Lawsuits and Kickback Charges

This isn't the first time the Justice Department had dealings with Sabit or the first time *OTW* has reported on his activities.

Between 2009 and 2010, Sabit was the subject of more than two dozen medical malpractice lawsuits in California. Special Agent Hayes testified at Sabit's detention hearing in Michigan that Sabit performed over 200 spinal fusion surgeries in California from June 2009 to December 2010 and that the DOJ had filed a Civil Complaint against him in September 2014.

Hayes also said that DOJ presently has an ongoing criminal investigation of Sabit in California.

Anti-POD Poster Child

During Sabit's detention hearing prosecutors also told the judge that the DOJ's California investigation of Sabit was focused on his participation in a physician-owned-distributorship (POD), which owned a particular device—an Apex pedicle screw made by Reliance Medical.

After buying into the POD, Hayes said Sabit began to use the Apex in 90 percent of his surgeries, and earned over $400,000. He added that Sabit had been subject to civil kickback charges in September 2014 based on California kickback allegations and that Federal California criminal kickback charges are likely coming.

A Flight Risk: From Dubai to Kabul to London

Accusations of unnecessary surgeries and false claims are not uncommon. But here is where Sabit is different and the story turns into an international thriller.

The government labeled Sabit a flight risk, noting that he was questioned in September in Atlanta while trying to fly to Dubai. There he allegedly told a customs officer that he owned a company involved in mining in Afghanistan. In his luggage, officers found a ruby and a 3.6-carat emerald, according to the complaint.

Dubai Informant

Special Agent Hayes testified that the FBI had information from an informant who was employed in Dubai, but had first met Sabit in Michigan in late 2013. The informant told the FBI that Sabit had asked him to help obtain a medical license in Dubai because he was considering practicing medicine there or in the United Arab Emirates.

The informant also told Hayes that Sabit went to Afghanistan in December 2013 to set up a hospital in Kabul. When the FBI searched Sabit's house they found plans dated October 2014, for Aria International Community Hospital in Kabul. They also found emails dated around the same time indicating he had invested $300,000 to $400,000 into the hospital with a profit hope of $30 million.

London's Newcastle Upon Tyne

Hayes testified that Sabit traveled to London in November 2013, and based upon papers seized in the home search, was in the process of applying for a position at a London area hospital: "Newcastle Upon Tyne," application dated November 11, 2013.

The application stated that Sabit was applying for the position of consultant spinal surgeon? "I am moving to the U.K., as most of my family resides in the U.K." Hayes testified, and Sabit's wife's subsequent testimony confirmed, that none of Sabit's family resides in the U.K.

Afghan Blue Bloods and Oil

The informant, according to Hayes, traveled to Afghanistan to meet Sabit and his relatives, and government officials—Sabit's father, who was the former Attorney General of Afghanistan; his uncle, the Speaker of the House, the Minister of Mines; Abdullah Abdullah, an individual then running for President of Afghanistan, who lost the final election, but who is now the Chief Executive Officer of Afghanistan.

The informant had an axe to grind. He claims that he had been "stiffed" out of money on a deal by Sabit.

Sabit, according to Hayes, incorporated the American Mineral and Oil Company in August 2014, to extract natural resources in Afghanistan. E-mails from Sabit to his business partner regarding their proposed venture, said that Sabit had secured the rights to survey and extract the 2 billion barrels of oil available for drilling in northern Afghanistan.

A Sabit August 4, 2014 email states:

> *Through connections and talks with the Government, including the President and incoming Prime Minister, I am able to secure these and any other mineral rights for our companies, and ideally partner with an American company.*
>
> *The rights to the grounds and all mineral content are secured. I met with the Minister of Mining and Petroleum, as well as the President of the country. My first cousin is the Minister of Finance. My other cousin is the head of the Central Bank. My uncle is the Speaker of the Lower House. My father is a very influential politician. My point is that we have very significant pull in the Government.*

Sabit's Defense

Sabit's wife, an RN, testified that she was willing to surrender her and her daughters' passports and offer the house as security. She also said that Sabit and his father are now estranged.

Dr. Khusraw Sabit is Sabit's younger brother, who lives in Montreal, Canada. He testified on December 8, 2014 that Afghanistan is not safe for Sabit because their father, who has not been speaking to Sabit, also has made many enemies and was kidnapped and released for ransom in 2011–2012.

The Money Flow

Hayes showed the court a flow chart showing some of Sabit's money movement of over $2 million from Michigan Brain and Spine into a joint account that he had with his wife at PNC Bank, and then over $1.7 million was transferred out to six accounts: two held by his wife, and two each held in the name of each of his then-two children, 8 and 6 years-old, respectively.

A home search of Sabit's house revealed a proposed complaint for divorce, seeking sole custody of the children. The home search also showed that Sabit had been living in the basement.

Hayes further testified that the informant said that Sabit had explained that the only reason he was still in the U.S. was because he had young children here, but that if he did leave, the U.S. "would never get him back."

Sabit's "Suspect" Character

After listening to the evidence, the detention hearing judge found that Sabit's character is "suspect given his past conduct of leaving his medical license behind in Cali-

fornia and not including that history in his curriculum vita in applying for future medical positions, and his transfer of a significant amount of funds to his wife and children as the investigations unfolded."

The judge noted that prosecutors offered proof that Sabit "has transferred significant sums of money to two of his young children (allegedly around $1,000,000 each), that he claimed to have spent $300,000 on the Kabul hospital project already, that the government has already frozen $750,000 in one of his bank accounts, and that it has not been able to identify accounts into which other transfers may have been made."

The judge ruled that Sabit would remain imprisoned until his trial.

Supplemental Statement for the Record, Submitted by Kevin Reynolds in Sentencing Proceedings for Dr. Aria Sabit in the U.S. District Court for the Eastern District of Michigan

To the Honorable Judge Paul D. Borman 8/17/15

I (Kevin Reynolds) am the son of victim in 2011 Lillian Kaulback. I'm writing to you about the Aria Sabit case.

The butcher Sabit operated on my mother in California she died of so many complications from surgery and the unbearable grief of never walking again at the hands of Sabit. She had to take 25–30 pills a day because of his greed and infections.

I am one of the few that have had him admit and settle a case of a wrongful death lawsuit against the evil Aria Sabit. I've spoken out against him in the local *Ventura County Star, The Wall Street Journal,* the CBS morning news broadcast and also the California Medical Board. In the last month I've spoken to Federal prosecutors representing California and Michigan.

Please, please, on behalf of all the victims in California and Michigan. We beg you to hand down the maximum sentence against this MONSTER.

There are hundreds of people mutilated, scarred and or DEAD because of Aria Sabit. Please make sure he receives the maximum prison sentence "YOU" can hand down and that he never leaves!

On behalf of my mother and the tortured souls,

Thank you for the Justice and your time.

Kevin Reynolds

PREPARED STATEMENT OF JOHN STEINMANN, D.O., BOARD ADVISOR, AMERICAN ASSOCIATION OF SURGICAL DISTRIBUTORS

Chairman Hatch, Ranking Member Wyden, Honorable members of the committee,

Thank you for this opportunity to offer testimony to the Senate Committee on Finance regarding physician ownership in medical device distribution.

I am a practicing orthopedic spine surgeon, in practice for 25 years, on faculty at two regional medical schools and residency training programs. I am a senior partner in one of California's largest orthopedic groups, Medical Director of the Spine and Joint Institute at Redlands Community Hospital and an elected Board member of the California Orthopedic Association. I am the proud father of six children and equally proud grandfather of nine.

Along with several colleagues, I helped develop a model for surgeon ownership in medical device distribution that mitigates conflicts of interest found in unregulated PODs.[1] The model I pursue is not aimed at unlimited personal financial benefit for physicians, but instead aligns with hospitals and restores market forces to an industry where costs were out of control—all while using tools such as transparency and accountability to ensure that patients are protected.

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[1] More information about these standards can be found on the website of the American Association of Surgeon Distributors, *http://aasdonline.org/*.

In our system today when it comes to choosing medical devices, the decisionmaker (surgeon) does not bear any of the financial burden of his or her decision, and hence has no incentive to create or support a competitive environment that could better control price in a sustainable manner. Furthermore, most orthopedic and spinal devices are standardized and multiple companies manufacture like, if not identical, quality products. Therefore, there is a missed opportunity to force these companies to compete on value.

This economic problem is not a small one. In the United States, we generally pay twice as much as Europe does for our own American-manufactured products. In theory, this could translate to as much as a $9 billion dollar overpayment.[2] In the U.S., 1.7 million Americans are affected by medically related bankruptcies every year with a few million more losing their life savings.[3] We will continue to create a substantial financial burden to American citizens and businesses until we address the fundamental flaws of our healthcare system that can cause it to cost twice what others' cost. One of those flaws can be fixed by addressing how we acquire medical devices.

The current system we have in the U.S. for acquiring medical devices is what is known as a **commissioned model,** whereby the manufacturers acquire and hold a full inventory and provide product one at a time in response to surgeon's request. Then, manufactures hire well-compensated sales and marketing staff to ensure that surgeons continue to request their product. This process, where we buy one item at a time, yoke the manufacturer with the inventory costs, and the sales and marketing costs, can double the price we have to pay. Instead, if we would simply derive a consensus among surgeons, purchase in volumes, and hire our own product specialists, we could see the cost of implants go nearly in half without affecting manufacturers profit or R&D budgets.

Instead of the commissioned model, I believe we are better served if we adopt and support a **stocking distribution model** where surgeons (along with their hospitals) prospectively derive a consensus on equal quality products, create a competitive environment, offer volume purchases consistent with historical use and employ product representatives so that we can drastically reduce sales and marketing expenses. This system should reduce the cost of these high quality products by 35–50 percent, thus providing the American public the value it deserves.

A properly structured POD represents a valuable alignment between the surgeons and the hospital. In a stocking distributorship, the owner of the inventory—and hence the distributorship—can be the hospital or the surgeon group. In some circumstances it is reasonable for the hospital to own the inventory, such as hospital systems with an employed (and hence, aligned) staff. However, in most circumstances where there is not an employment relationship, hospitals will be very reluctant to purchase inventory for fear the surgeons will not continue to support that inventory investment.

Furthermore, such as is the case in our distributorship, a surgeon-owned distributorship can support four hospitals with a single bank of inventory and a single representative. If these distributorships were hospital-owned, there would need to be four duplicative inventory expenses and four employed reps. Lastly, surgeons, who understand what supports product quality, control their schedules, and understand what is needed from the product rep, are far more suited to run the distributorship than the hospital. An alternate, very viable model is hospital ownership with surgeon management.

It is an unfortunate fact that throughout the medical profession there will always be a few "bad apples" who can do serious damage to peoples' lives. We simply must have mechanisms that force physicians to be held to the high standards patients deserve. That is what the American Association of Surgeon Distributors (AASD) standards I helped develop do.

The Standards published, audited and enforced by AASD ensure that a distributorship with surgeon ownership is structured in an ethical and legal manner. The Standards force AASD-compliant PODs to take many extra steps to ensure legitimacy and quality service, such as prohibiting the leveraging of referrals, submitting to monitoring, and disclosing to patients.

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[2] "$18 Billion Dollar Domestic Market," *Orthopedic Network News,* 2013. Subscription required.

[3] "Medical Bills are the Biggest Cause of U.S. Bankruptcies: Study," by Dan Mangan, CNBC, June 25, 2013, *http://www.cnbc.com/id/100840148.*

The 12 published Standards require the distributorship to demonstrate:

1. Compliance with Self-Referral and Anti-kickback statutes (legal opinion).
2. Merit by proving to be the lowest average cost provider.
3. Annual price increases below 3 percent above the CPI.
4. All functions of a free standing stocking distributorship.
5. Adherence to the AASD Product Evaluation Policy.
6. Adherence to the AASD Employee Training Policy.
7. Adherence to the AASD Disclosure Policy.
8. Adherence to the AASD Investment and Distribution Policy.
9. Adherence to the Appropriate Use Monitoring Policy.
10. Written contracts with hospitals.
11. No leverage of referrals.
12. No leverage or pressure to physician owners.

In addition, in order to ensure that physicians are appropriately involved in their distributorships, implementing a properly structured POD requires work and investment and specifically requires:

- Bringing together surgeons to derive a consensus on design features and like quality products and manufacturers.
- Critically evaluating these companies to ensure they meet all appropriate quality standards including testing results of the products being considered.
- Evaluating historical volumes and surgeon operative days to derive an understanding of implant and instrument volumes.
- Competitively negotiating with manufactures.
- Constructing the contractual relationship with the manufacturer.
- Obtaining healthcare legal opinions on the appropriate structure of relationship with the manufacturer and the hospital/surgery center.
- Developing an accepted vendor relationship with the hospital, inclusive of identifiable cost savings, disclosure of physician ownership, proof of appropriate legal structure and assurance of quality of good and services.
- Out of pocket investment to purchase inventory and often instruments.
- Hiring and training of a product rep and the identification and lease of a place of business.
- Procurement of a business license and insurance.

Moving from a commissioned model to a stocking model offers the American public the value it deserves. In our experience, creating a system of effective competition reduces cost by 35–50 percent—all while giving patients the information they need to make informed decisions, and using accountability tools to ensure patients are not exposed to unnecessary procedures.

Unfortunately, I believe the absence of clear, affirmative program guidance from the government has kept many honorable surgeons and their hospitals from sitting down to implement this very sensible model.

At the heart of the debate on physician's ownership in medical device distribution is the issue of conflicts of interest. As with other conflicts of interest, such as our fee for service payment system or DRG and bundled payments, the potential conflict that surgeon ownership in medical device distribution can create should be managed through enforced transparency, accepted quality and community standards, and appropriate use monitoring. The Standards of the AASD ensure that this conflict is managed in the best interest of patients, hospitals and society.

In summary, the healthcare industry is finally starting to innovate methods to increase value by finding means to enhance the patient experience and outcome at lower costs. It would be a shame for our country's leadership to not endorse in some manner a model that has proven to effectively produce these goals.

We have structured a model of surgeon ownership in medical device distribution in a manner that ensures substantial cost savings, while protecting patient safety and complying with all existing healthcare laws. Our model has been proven to reduce the cost of implants by at least 35 percent while ensuring patient disclosure, hospital and public transparency and maintenance of product quality and services.[4]

Conflicts of interest are a serious and valid concern. We have proven those real concerns can be countered—and patients can be protected—with high, clear, enforceable standards that bring accountability to Physician-Owned Distributorships.

[4] "Surgeon Ownership in Medical Device Distribution; Does it Actually Reduce Healthcare Costs?" Steinmann, et al. *Expert Rev. Pharmacoeconomics* 1–7 (2015).

We should ask the Office of the Inspector General to offer affirmative program guidance along the lines of those standards outlined by the AASD so that patients can be protected and the American public can start to see the benefits of effective well structured innovations in healthcare delivery that result in better value.

Expert Reviews

SURGEON OWNERSHIP IN MEDICAL DEVICE DISTRIBUTION: DOES IT ACTUALLY REDUCE HEALTHCARE COSTS?

Expert Rev. Pharmacoecon. Outcomes Res. Early online, 1–7 (2015)

John C. Steinmann,[i] CHARLES EDWARDS II,*[ii] THOMAS EICKMANN,[iii] ANGELA CARLSON,[iv] AND ALEXIS BLIGHT[ii]

Background: Surgeon ownership in medical device distribution is a new model that proposes to reduce the costs associated with surgical implants. In surgeon-owned distributorships (SDs), the surgeon becomes the purchaser through ownership and management of a distributorship. The purpose of this study is to determine whether significant cost savings can result from SDs. Methods: Five existing SDs were retrospectively reviewed, and their implant pricing was compared with non-SDs. The hospital pricing for implants supplied by the SDs was compared with 2010 pricing from the best contract/capitated rate for like implants from non-SDs. Results: The average first-year cost savings for the SDs was 36 percent, with U.S. $2,456,521 total savings in 2010. For distributorships in business for over 2 years, the average annual price from the SDs actually decreased by 1.41 percent. Conclusions: This study demonstrates that SDs are capable of providing substantial healthcare savings through lower implant costs and reduced annual price escalations.

KEYWORDS: cost-savings • healthcare costs • orthopedics • surgeon-owned distributorships • surgical implants

Healthcare costs in the USA continue to place an overwhelming burden on individuals, businesses and local and federal governments. In 2011, national health expenditures reached U.S.$2.7 trillion.[1] Although the rise in healthcare costs can be attributed to many factors, including technological advances and an aging population, significant costs are also attributable to fundamental flaws in the economics of healthcare delivery in the USA.[2] One prominent flaw results from separation between the decision maker (*e.g.,* a healthcare provider) and the purchaser (*e.g.,* a hospital, government or insurance company). This creates a "market failure," whereby typical market forces, such as competition and market equilibrium, are not available to control costs.[3] 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 needs. For the majority of patient conditions, however, several competitive products are available. When there are multiple appropriate product options, 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 purchasing hospital is given an order from the surgeon for a specific im-

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[1] National center for health statistics. Health, United States. 2013. Available from: *www.cdc.gov/nchs/data/hus/hus13.pdf#112* [last accessed 10 July 2014].

[2] Kuttner R. Market-based failure—A second opinion on U.S. health care costs. N Engl J Med 2008;358:549–51.

[3] Mirmirani S, Spivack R. Health care system collapse in the United States: Capitalist market failure. Economist 1993;141:419–31.

plant. The purchasing hospital is left with very little leverage in creating competition or in negotiating the price for a specific implant.

Hip implants were introduced in the 1960s, knee implants in the 1970s and pedicle screws in the 1980s. In their early days on the market, these implants were considered state of the art and were patent-protected. At that time, there were a few manufacturers for these implants. As hip, knee and spine implant development slowed, breakthrough implant designs gradually lost their patent-protection. Today, the intellectual property incorporated into contemporary implants is for the most part public domain. The implant marketplace has become well populated, with manufacturers providing nearly identical implants. While the implants used in a large majority of hip, knee and spine surgeries have common designs, the implant pricing levels remain surprisingly high.

The similarity of contemporary implant designs is highlighted by the process by which all current hip, knee and pedicle screw implants were submitted to the U.S. FDA for approval. Under the 510K approval process, a manufacturer must demonstrate to the satisfaction of the FDA that their proposed implant is substantially equivalent to a device currently marketed in the USA.

One solution to the market failure in surgical implants is to place the surgeon in a purchasing position. Restoring the roles of decision maker and purchaser to a single entity would reestablish normal market forces to, in theory, reduce surgical implant costs. The paradigm shift would align the 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. Orthopedic implants and procedures are considered a major cost contributor to the overall rise in healthcare costs.[4] By 2030, the demand is projected to increase by 173 percent for total hip arthroplasties and by 673 percent for total knee arthroplasties, representing over 4 million primary hip and knee replacements.[5] Implant costs account for the largest single expense in total hip and knee replacement operations.[6] Measurable implant cost savings, therefore, could 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 creates competition, and has the potential to result in substantial healthcare savings. The purpose of this study is to determine whether 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 is 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 hypothesize that the cost of implants sold by surgeon owned distributorships (SD) will increase each year.

Materials and Methods

To test this hypothesis, a study sample was 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 are deidentified 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 used 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

[4] Jain N. Joint replacement costs in the era of healthcare reform. J Bone Joint Surg Am 2012;94(18):e140(1–2).

[5] Kurtz S, Ong K, Lau E, et al. Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030. J Bone Joint Surg Am 2007;89:780–5.

[6] Scott WN, Booth RE Jr, Dalury DF, et al. Efficiency and economics in joint arthroplasty. J Bone Joint Surg Am 2009;91:33–6.

for the SD and the next lowest cost contracted provider of like implants to the hospital. On the basis of these criteria, we selected a sample population of five SD.

The hospital pricing for implants supplied by the SD was compared with 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.[7] The prices obtained were the price paid to the vendor, not the list price and not the price that was necessarily reimbursed by insurance carriers. This case versus control model represents an optimal apples to apples comparison due to the data coming from the same hospital, at the same time periods, for the same implant type.

For those distributorships that have been operational for 2 or more years, annual and cumulative data were 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.

Sources of Funding

The authors did not receive any outside funding or grants in support or preparation of this manuscript. One or more of the authors has an investment interest in a medical commercial entity (Inland Surgical Products, Specialty Spine Products, Mesa Surgical, Millennium Spine, Calvary Spine, Alliance Surgical Distributors, Renovis Surgical Technologies).

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. At the time of study data acquisition, the distributorships had been in continuous operation for an average of 2.3 years (range, 1.0–4.4 years).

Table 1. Five Distributorships Profiled

	Start of operation	Number of Surgeons—spine	Number of 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

SD: Surgeon-owned distributorship; TIA: Total joint arthroplasty.

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 minimum number of a specific procedure performed by a SD in the study sample was 20 (anterior cervical fusion by SD4). The maximum number of procedures was 189 (total knee replacement by SD5) (TABLE 2).

Table 2. Hospital Implant Prices Surgeon Versus Non-Surgeon Distributorships

	Procedures	SD cost	NSD cost	Average annual cost
Total knee replacement				
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

[7] 2010 Hip and Knee Implant Price Comparison. Orthopedic Network News 2010;21:9–12.

Table 2. Hospital Implant Prices Surgeon Versus Non-Surgeon Distributorships—Continued

	Procedures	SD cost	NSD cost	Average annual cost
Total hip replacement				
SD1	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				
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				
SD1	118	$6,410	$11,007	$542,446
SD2	83	$13,564	$14,628	$88,312
SD4	46	$4,892	$15,931	$507,795

NSD: Non-surgeon owned distributorship; SD: Surgeon-owned distributorships.

The types of 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 U.S.$1,814 (33 percent) less for the SD (U.S.$3,640 vs. $5,453). Hip replacement implant costs were U.S.$1,937 (30 percent) less on average for the SD compared with the NSD (U.S.$4,564 vs. $6,501). For anterior cervical fusion cases, the SD implant cost was U.S.$1,055 less for the SD (36 percent; U.S.$1,859 vs. $2,914). The lumbar fusion implant costs were U.S.$5,567 (40 percent) less on average for the SD (U.S.$8,289 vs. $13,855). Across each of the implant lines studies, the SD implant cost was on average U.S.$2,589 (32 percent) less than the NSD cost. Considering the 1,366 cases included in the sample population, the 1-year cost savings to hospitals/surgery centers and society was U.S.$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 SDs ranged from 11 to 69 percent, with a mean aggregate annual savings of U.S.$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: U.S.$558,109). The least cost savings came from a total joint arthroplasty distributorship serving seven general orthopedists (U.S.$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	Percent 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%	$490,304	$247,792

SD: Surgeon-owned distributorship.

For those distributorships with greater than 1 year of data, annual changes in implant pricing are reported in TABLE 4. Three distributorships (SD1, SD2 and SD3) have been in existence for 2 or more years and thus have multi-year pricing data available (5, 4, and 3 years, respectively). These three distributorships have carried a combined total of 10 product lines since inception. Over this 12-year combined experience, only one product line for one distributorship has seen a price increase (1 percent 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 was −1.41 percent.

Table 4. Average Annual Change in Implant Pricing

Distributorship	Total knee replacement	Total hip replacement	Anterior cervical fusion	Posterior lumbar fusion
SD1 (5 year average)	−0.6%	−2.4%	−1.6%	−1.0%
SD2 (4 year average)	1%	−2%	−4%	−3%
SD3 (3 year average)	0%	0%	n/a	n/a
Average price change	0.24%	−1.40%	−2.70%	−1.76%

SD: Surgeon-owned distributorship.

From July 2007 to July 2011, the average cost of goods in the USA rose by +8.34 percent.[8] On the basis of this index, the actual price of the implants sold by the SD decreased by 9.75 percent over the 4 years in constant dollars (8.34 percent to [−1.41 percent]).

Discussion

Market failure associated with the current model of medical device distribution is evidenced by the persistence of elevated implant prices despite increases in volume and increases in the number of companies producing nearly identical products. The current medical implant economy runs counter to the economic principal of commoditization. In a reactive economy, purchasers increasingly view similar products as commodities and become less willing to pay premium prices for what are viewed as generic products.[9]

In industries where market justice forces act, commoditization will result in dramatically reduced costs to society.[10] The medical device industry has been shielded from such reductions because of the unique circumstance, whereby separation exists between the individual selecting the implant and the party purchasing the implant. Surgeon ownership in medical device distribution proposes to remove such separation and establish more effective competition.

In 2009, there was an initial report from a single distributorship finding a 34 percent reduction in implant costs across three hospital systems.[11] No other studies have validated the cost savings associated with this model. This article represents the first study of multiple SD in multiple States, using 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 percent and totaling U.S.$2,456,521, with an average cost savings of 36 percent across all five SD, averaging U.S.$136,473 per surgeon. These savings are of importance for the years ahead when considering the anticipated increased demand for hip, knee and spine surgery and the annual cost increases that have been the norm for this industry.

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[8] Bureau of Labor Statistics. CPI detailed report—Data for July 2011. Available from: *www.bls.gov/cpi/tables.html* [last accessed 1 September 2011].

[9] Reimann M, Schilke O, Thomas J. Toward an understanding of industry commoditization: Its nature and role in evolving marketing competition. Int J Res Mark 2009;27:188–97.

[10] Budetti P. Market justice and U.S. health care. JAMA 2008;299:92–4.

[11] Steinmann J, Hopkins G, Burton P, Skubic J. Surgeon Ownership in Medical Device Distribution: Economic Analysis of an Existing Model. American Academy of Orthopedic Surgeons Annual Meeting; Feb 2009, Las Vegas, NV.

The 2010–2011 Orthopaedic Industry Annual Report cited total U.S. orthopedic product sales of $23.7 billion, with total joint reconstruction sales at $7.3 billion.[12] The escalation in total joint implant price over the 14-year period from 1994 to 2006 was reported to be 171 percent (average 13 percent).[13] In contrast, SD in this study have shown the ability to save 37 percent the first year and to keep annual escalations at or below 1.0 percent.

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 have the potential to profoundly affect healthcare costs associated with orthopedic implants. The magnitude of cost savings in total joint reconstruction is projected in FIGURE 1. Here, it is optimistically assumed that the 13 percent annual escalations [13] associated with NSD would decrease for the next 20 years to 7.5 percent. It is further assumed that the SD model, with a first-year reduction in cost of 36 percent, would demonstrate a 1.5 percent annual escalation in price as opposed to the 1.41 percent reduction currently demonstrated. FIGURE 2 uses the same assumptions but includes all orthopedic implants, to demonstrate the broader potential cost savings associated Reconstruction devices with the SD model.

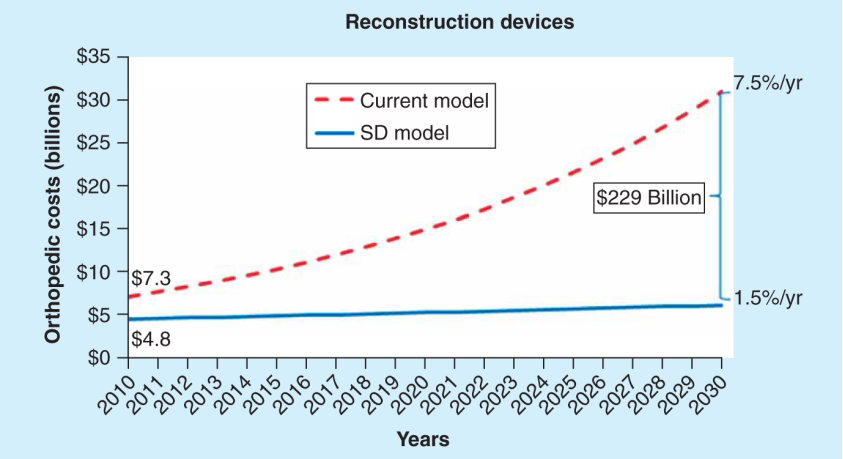


Figure 1. The potential economic benefit of SD on total joint reconstruction devices.
SD: Surgeon-owned distributorship.

[12] The 2010–2011 Orthopaedic Industry Annual Report. Chagrin Falls (OH): OrthoWorld 2011 July.
[13] Healy WL. Gainsharing: A primer for orthopaedic surgeons. J Bone Joint Surg Am 2006;88:1880–7.

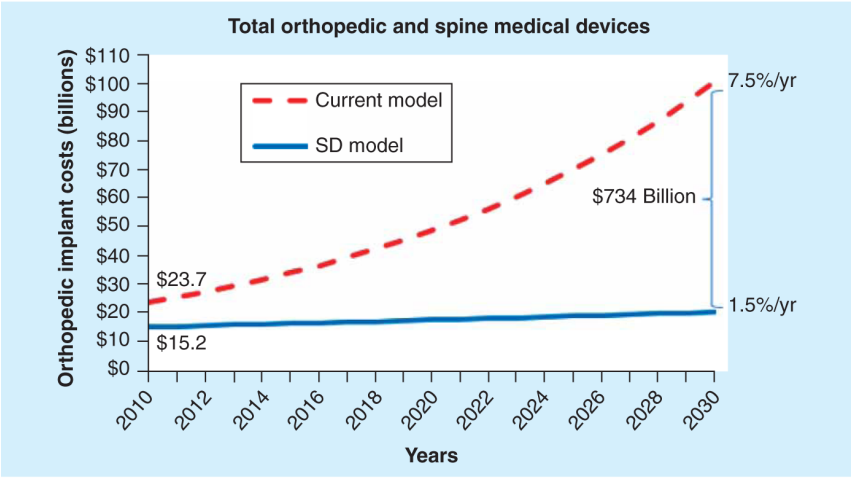


Figure 2. The potential economic benefit of SD on total medical devices.
SD: Surgeon-owned distributorship.

This calculation reveals that over the next 20 years, the SD model has the potential to save U.S.$229 billion in total joint reconstruction costs alone (FIGURE 1). This figure does not take into account the expected substantial increase in demand that was discussed previously, thus significantly understating the potential long-term savings associated with this model. In terms of the entire orthopedic medical device industry, the potential savings exceed U.S.$734 billion over 20 years (FIGURE 2). The present study's model may also be applied to other implant types and medical specialties. The SD model, thus, has the potential to be more broadly applied to the healthcare system, allowing for even more profound cost savings.

Concern exists for the financial feasibility of total joint procedures since the demand will increase by 673 percent for total knee replacements and by 174 percent for total hip replacements over the next 20 years,[5] and payments made to hospitals for total joint arthroplasties are not enough to keep up with inflation.[6] With fewer surgeons to provide total joint procedures[14] 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 the SD model. Critics question if the model will incentivize overutilization. Although not directly analyzed in this study, utilization in SDs is the focus of a separate ongoing study by the authors of this article. This other study looks at the utilization of orthopedic implants by seven different SD compared with each distributor's utilization for a 12-month period prior to the initiation of the distributorship, to analyze whether there is evidence to support that utilization is influenced by the SD model. This concern is also addressed by the AASD in its standards and procedures. Distributors accredited by the AASD are required to submit annual surgical volumes data for its surgeons, allowing for independent review and audit when indicated.

It is important to note the SD model does not introduce any new conflicts of interest. Financial conflicts of interest are already inherent to the fee-for-service healthcare system in the USA and are best managed through disclosure and transparency. Although physicians and surgeons may financially benefit by providing additional services, they are required to hold true to recommending and performing only what is truly best for the patient. It is unethical for healthcare providers to bias their decision-making process by opportunities for financial gain. The AASD, an organization strongly supported by the authors, has been very diligent in estab-

[14] Fehring TK, Odum SM, Troyer JL, et al. Joint replacement access in 2016: a supply side crisis. J Arthroplasty 2010;25:1175–81.

lishing standards that promote ethical and legal medical practice under the SD model. Membership in the AASD ensures this inherent conflict of interest is properly managed by requiring disclosure and transparency to patients, hospitals and colleagues.

Concerns have also been raised that SDs may use inferior materials and less quality control to reduce cost. Such concerns, although reasonable to raise, are mitigated by the fact that all implants used in the USA must be FDA approved and are subject to an FDA-approved quality program. Furthermore, the FDA 510K approval process used for all commonly used hip, knee and spine implants is based on the establishment of equivalency to other implants already in the marketplace.

A promising response to these concerns regarding the surgeon-owned distribution model has been the development of standards established by the AASD (BOX 1).[15] Although not all SD belong to the AASD and are subject to its standards, our findings show that the SD model can yield significant cost-savings in a regulated and ethical manner. The AASD's standards ensure an accredited SD demonstrates legal compliance, cost savings, transparency, product quality evaluations, appropriate employee training and utilization reporting. The present study only examined SD belonging to the AASD. Future studies should seek to eliminate this selection bias by including both AASD and non-AASD surgeon-owned distributorships.

Box. 1 Standards and Criteria for Membership: American Association of Surgeon Distributors

- Distributorship must maintain a business structure consistent with all Federal Stark and Anti-Kickback statutes, and report under the Physician Payment Sunshine Act.
- Distributorship must demonstrate merit by proving to be the lowest average cost vendor of like implants during a comparable contract period.
- Annual price increases must not exceed 3 percent above the consumer price index (CPI).
- Distributorship must demonstrate adherence to the AASD Product Evaluation Policy.
- Distributorship must demonstrate adherence to the AASD Employee Training Requirements.
- Distributorship must demonstrate adherence to the AASD Disclosure Policy.
- Distributorship must demonstrate investment risk and compliance with the AASD Investment and Distribution Policy.
- Distributorship must submit utilization data annually and is subject to audit.
- Distributorship must not leverage referrals to any hospital or surgery center.
- Distributorship must be a legitimate free standing stocking Distribution Company with employees, contracts, address, business license and insurance.
- Distributorship must have written contracts with hospitals and vendors for at least 1 year.
- Distributorship pricing must not vary between hospitals.

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. Although this is not the focus of our article, it is our hope hospitals, along with surgeons, will uphold their social duty to pass along these significant cost-savings to benefit their patients and society as a whole.

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. The present study obtained data on multiple implant types from multiple distributorships belonging to the AASD. The results reveal SD are capable of providing substantial healthcare savings through lower implant costs and reduced annual price escalations when compared with traditional implant distributor-ships. Safeguards, such as those established by the AASD, will serve to protect the best interest of patients and society on an ongoing basis.

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[15] American Association of Surgeon Distributors (AASD). Standards and Policies: Distributor Members. Available from: *www.aasdonline.org/MembershipandePODCertification/StandardsandPolicies.aspx* [last accessed 10 July 2014].

Financial and Competing Interests Disclosure

J.C. Steinmann is currently employed as a physician with Arrowhead Orthopedics. He owns stock in Alliance Surgical Distributors, Inland Surgical Products—companies related to those mentioned in this paper. C. Edwards has a minority interest in a surgical implant distribution company but was not one of those included in the present study. The results of this study in no way affect the profitability/prospects of this company. T. Eickmann is currently employed as an orthopedic surgeon with Cornerstone Orthopedics. He serves as a board member of the American Association of Surgeon Distributors. He works for Aesculap as a surgeon training consultant and receives compensation from Speciality Surgical for giving lectures on the "Quill" Suture. He also has a pending patent regarding the tibia and receives royalties from Innomed and Renovis. He owns stock/stock options in Renovis. He was a previous owner in Mesa Surgical, a Physician-Owned Distributorship. Currently, T. Eickmann is an owner in Alliance Surgical Distributors, LLC, which helps to start Physician-Owned Distributorships. A. Carlson has stock/stock options in Alliance Surgical Distributors, LLC and Renovis Surgical Technologies, Inc. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Key Issues

- Surgeon ownership in medical device distribution is a new model that may effectively reduce costs associated with surgical implants by establishing a legal framework for the surgeon to function as both the decision maker and purchaser.
- In the present study, involving 18 surgeons, the average first-year cost savings associated with the surgeon owned distributorships was 36 percent, totaling $2,456,521, with the average annual implant price decreasing by 1.41 percent for those distributorships in business for >2 years.
- This study demonstrates that surgeon ownership in medical device distribution has the potential to provide significant healthcare savings through substantial first-year reductions in implant prices and sustained downward pressure on annual price changes thereafter.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

When you walk into a doctor's office, you're putting an extraordinary level of trust—and maybe even your life—in your physician's hands. Today the Finance Committee will hear about one type of business called a Physician-Owned Distributorship that in some cases might violate that trust with dangerous and life-threatening consequences.

Here's how they work: a doctor sets up a distributorship company, which is often a middleman between a medical device manufacturer and a hospital or surgical center. The doctors then get an extra financial reward for every device used in treatment. That comes in addition to the payment they get from insurers or from taxpayers through Medicare or Medicaid. In theory, the more surgeries implanting devices into patients, the more money in the bank. That's what makes some of these arrangements so deeply concerning. In the worst cases, scam-artist doctors have left long trails of patients to recover from unnecessary or complicated procedures involving invasive and painful surgeries.

In fact, the Inspector General of the Department Health and Human Services issued a special fraud alert about these companies. Referencing the laws that are designed to protect against what seem to be serious conflicts of interest, the IG wrote that it, "views [distributorships] as inherently suspect under the anti-kickback statute."

This week, Dr. Aria Sabit is being sentenced for conducting unnecessary surgeries. Some resulted in direct harm to his patients. Dr. Sabit was an active participant in a Physician-Owned Distributorship that allowed him to profit directly from the spinal fusion surgeries he performed, and he is not the only one.

In 2013, Dr. Atiq Durrani, a surgeon in Ohio who was also reported to be a part of a distributorship, fled the country after being arrested for unnecessary surgeries. The hospital where he practiced just reached a $4.1 million settlement with the U.S. Department of Justice for unnecessary spine surgeries.

In my own State of Oregon, Dr. James Makker had his medical license revoked in 2012 after a long string of questionable surgeries and malpractice lawsuits. According to news reports, Dr. Makker was also affiliated with a Physician-Owned Distributorship. Before he lost his license, Dr. Makker had one of the highest number of spinal fusion surgeries of any surgeon in the country. He would sometimes operate six or seven times on the same patient.

A few bad apples don't mean the whole bushel is rotten. But the fact is, this type of business operates too often in the dark. Frequently, neither patients nor hospitals nor regulators know when a doctor is part of a distributorship.

Two years ago, the Health and Human Services Inspector General asked hospitals whether they did business with these distributorships. Only 60 percent of the hospitals buying from distributorships reported correctly. The IG found the rest by digging into invoice data. According the IG's report, less than two-thirds of the hospitals surveyed even had a policy requiring doctors to disclose ownership interests in a distributorship. Only 8 percent of the hospitals that purchased from distributorships required that patients be told about these potentially serious conflicts of interest.

One of the claims made in favor of these distributorships is they lower costs of treatment by reducing the price of devices that they sell. The IG found no such savings. And when hospitals don't even know they're dealing with distributorships, it's difficult to imagine how they can tally up any savings.

The Finance Committee has also received some extremely troubling information from industry sources. Under the Sunshine Act, distributorships are required to report doctors' ownership interests, as well as their own payments to doctors. But neither is happening when it comes to many distributorships. Furthermore, the committee has received one report of a device manufacturer offering to make payments to doctors through a third party to avoid disclosure. Senator Hatch and I will be referring information about this allegation and about possible Sunshine Act violations to the Inspector General, and I hope to work with Chairman Hatch and the committee on a bipartisan basis to shed a lot more light on this issue.

Transparency might not prevent every unnecessary surgery, but it's a good place to start. And right now, in my view, this part of our health care system is buried far too deep in the shadows. The bottom line is that patients should be getting care designed to help them—not to pad a physician's bank account.

COMMUNICATIONS

ADVAMED

AdvaMed Recommendations—Physician-Owned Distributors

AdvaMed supports the government's continuing commitment to addressing the issue of Physician-Owned Distributorships (PODs). PODs create inherent risks under the Anti-Kickback Statute and Stark Law, pose dangers to patients by incentivizing physicians to perform unnecessary procedures, drive overutilization of products and procedures, and cause inefficiencies and overpayments by Federal Health Care Programs. PODs are physician-owned supply-chain entities that sell or arrange for the sale of medical devices and allow physician owners to profit from the sale to hospitals and surgery centers of the devices they order and implant in their own patients. The U.S. Department of Health and Human Services Office of Inspector General (OIG) has investigated PODs and in 2013 issued a Special Fraud Alert (SFA) to the public, stating that PODs "pose dangers to patient safety," "produce substantial risk of fraud and abuse," and are "inherently suspect" under the Anti-Kickback Statute. In any of its efforts to address PODs, AdvaMed urges policymakers to distinguish between (i) PODs that serve no purpose other than to inappropriately incentivize physician owners and (ii) genuine innovator medical technology companies that may have an element of physician ownership.

1. **AdvaMed recommends that the Senate Finance Committee, the OIG, and other key policymakers reaffirm, strengthen, and enforce the policy that PODs are inherently incompatible with the Anti-Kickback Statute and Stark Law and distinguish illicit PODs from legitimate innovator companies.**

   - To stem the growing proliferation of illicit PODs, AdvaMed urges the Senate Finance Committee and OIG to issue a clear reaffirmation that PODs exhibiting the characteristics in the 2013 SFA pose a clear risk under the Anti-Kickback Statute and the Stark Law.
   - AdvaMed urges the Senate Finance Committee and OIG to distinguish between illicit PODs and legitimate innovator companies that might have some physician ownership. A majority of a suspect POD's revenue is derived from its physician owners, their referrals, and/or the procedures they perform using POD-distributed devices. This implicates the Anti-Kickback Statute and the Stark Law. Conversely, innovator medical device manufacturers, which are subject to FDA regulation and state distributor/wholesaler licensure, may also have an element of physician ownership (*e.g.,* as a result of a founding investment or a contribution of novel, significant, or innovative intellectual property, etc.). An innovator manufacturer's revenue, however, is not tied to physician owners, their referrals, or the procedures they perform using the manufacturer's products. Rather, these manufacturers (even with some physician ownership) market and sell (or expect to market and sell) products widely rather than primarily to health care facilities where the physician-owners refer patients or perform procedures. Physician ownership interests in these innovator manufacturers form an insignificant portion of the manufacturer's shareholders. Accordingly, unlike illicit PODs, innovator manufacturers do not implicate the Anti-Kickback Statute or Stark Law.

2. **AdvaMed urges the government to leverage the U.S. Physician Payments Sunshine Act (Sunshine Act) in its efforts to help ensure appropriate transparency regarding PODs.**
   - AdvaMed encourages the SFC to require CMS and OIG to conduct a detailed review and audit of the Sunshine Act data to determine whether PODs are reporting under the Sunshine Act and, if so, whether any payments disclosed by PODs implicate the Anti-Kickback Statute or Stark Law. The time is now for Congress to issue a stronger directive to CMS and OIG to take action on the 17 months' worth of Sunshine Act data available for review.
   - AdvaMed supports clarifying that the Sunshine Act requires all PODs to submit data regarding payments and transfers of value to physicians, including ownership information, regardless of the number of entities with which the POD does business. This does not create an implied acknowledgement that PODs are legally appropriate. Rather, clarifying the Sunshine Act's applicability simply makes explicit that PODs must file annual reports under the Sunshine Act. Whether the payments disclosed on these reports reflect illicit activity is a separate question. According to the OIG, a lack of transparency raises concerns about the OIG's ability to ensure that providers do not violate the Anti-Kickback Statute and the Stark Law as well as protecting patient safety and quality of care. Indeed, Senator Grassley (R–IA), author of the Sunshine Act, on numerous occasions has quoted Justice Louis D. Brandeis's line—"Sunshine is the best disinfectant"—in describing the purpose of the Sunshine Act. Transparency of PODs' relationships with physicians would enable providers and patients to identify more clearly unlawful PODs and conflicts of interest of their treating physicians.
3. **AdvaMed recommends enhancements to the OIG's Compliance Program Guidance (CPG).**
   - First, revised CPG should clearly state that POD arrangements pose a substantial risk to patient safety and a risk of causing health care providers to run afoul of fraud and abuse laws, and that an effective compliance program incorporates due diligence to determine whether a potential vendor/supplier is a POD.
   - Second, CPG documents should state that an effective compliance program should not be overly broad and should explicitly permit business with legitimate innovator medical technology companies that may have an element of physician ownership. Providers cannot simply prohibit doing business with *any* company with some physician ownership or legitimate risk sharing or other innovative arrangement. The mark of an effective compliance program is undertaking nuanced due diligence in engaging suppliers. As a baseline compliance control for providers, CPG documents should require a determination expressly based upon the SFA as to whether any physician-owned vendors/suppliers are potentially unlawful POD arrangements for the exclusive benefit of physician owners.
   - Third, revised CPG should explicitly instruct health care facilities to adopt policies that require physicians to disclose all ownership interests in any vendor/supplier with which the facility does business.
   - Finally, the OIG should update its CPG to require health care facilities' diligence of vendors and suppliers to include a review of compliance with all applicable FDA and state regulations.
4. **AdvaMed suggests that policymakers consider a longer-term solution to redefine the Stark Law to protect legitimate innovator companies while prohibiting inappropriate PODs.**
   - AdvaMed acknowledges that there may be room to draw clearer distinctions between minor or technical violations of the Stark Law (for example, missing signatures on documentation) and violations that pose a clear self-referral conflict of interest (for example, PODs) that the Stark Law was originally intended to prohibit. This longer-term approach is deliberate and

time-consuming and requires significant contemplation of the issues and a carefully crafted solution. The time is now, however, for the government to generate more immediate recommendations to prohibit POD arrangements.

AMERICAN ASSOCIATION OF SURGEON DISTRIBUTORS (AASD)

Honorable members of the Senate Finance Committee

Re: Physician-Owned Distributors

I have served as Chairman to the Board of the American Association of Surgeon Distributors (AASD) since its inception in 2010. This organization is a public benefit nonprofit association whose purpose is to provide recognized standards to ensure ethical and legal conduct for surgeon owned distributorships. The AASD's mission is to protect patients, promote healthcare savings, and develop, audit, and enforce standards for the operation of surgeon owned distributorships. The AASD's strict standards have demonstrated our member's commitment to transparency, full disclosure to hospitals and patients, documented cost savings, and strict legal compliance.

Applicants for membership must submit detailed practice and utilization data, obtain a legal opinion that will meet all state and federal statutes, and utilize only FDA approved quality products. Membership is granted only to those distributorships that demonstrate and maintain full compliance with standards and criteria that include the following:

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 being the lowest cost provider of like implants.
3. Distributorship annual price increases to customers do not exceed 3 percent above the CPI.
4. Distributorship is a legitimate free standing stocking distribution company with employees, contracts, an address, a business license and insurance.
5. Distributorship demonstrates strict adherence to policies on product evaluation, employee training, disclosure, investment and distribution and appropriate use and monitoring.
6. Distributorship has written contracts with hospitals, with consistent pricing and contract periods of at least one year.
7. Distributorship does not leverage referrals to any hospital or surgery center and does not require, pressure or otherwise leverage physician owners' use of the Distributorship devices.

The AASD disclosure policy requires that all in office patients receive written disclosure and ownership disclosure must be displayed in a visible area in the office. All contracted hospitals and all colleagues are informed that the distributorship has surgeon ownership.

The AASD has also established an Appropriate Use Monitoring Policy to closely monitor any inappropriate increase in utilization. As part of the initial application and certification and annual review, each distributorship has to submit a practice profile for each physician member, which consists of the previous years data elements including patients visits and commonly accepted procedure codes (CPT codes). The baseline profile and subsequent years are monitored and a net change of greater than 15 percent that is not proportionate to non-implant related practice predictors (*e.g.,* total patients visits) initiates a series of audits that may result in probation, denial of the application, or revocation of the distributorship's AASD certification.

The AASD has conferred membership to 11 Distributorships as members and all have demonstrated clear substantial cost savings, while operating in a legal, ethical and professional manor. The strict standards that the AASD has established and have enforced have demonstrated this model, when operated correctly, offers immense benefit to hospitals and the public through improved efficiency and competition and can help control spiraling healthcare costs.

Paul Burton, D.O.

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Statement for the Record for Senate Finance Committee Hearing:

Physician-Owned Distributors: Are They Harmful to Patients and Payers?

November 17, 2015

The Honorable Orrin Hatch
Chairman
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of more than 90,000 physical therapists, physical therapist assistants, and students of physical therapy, the American Physical Therapy Association (APTA) is pleased to provide this statement to the Senate Finance Committee for the hearing "Physician-Owned Distributors: Are they Harmful to Patients and Payers?"

APTA's vision is to transform society by optimizing movement to improve the human experience. Physical therapists (PTs) diagnose and manage individuals across the life span who have conditions that limit their ability to move or function in their daily lives. We are committed to protecting and preserving resources within the health care system, and continue to strive for the highest levels of ethics, professionalism, and evidence-based practices for its members. APTA's own Integrity in Practice campaign is aimed at educating not only current and future physical therapists on methods and reasons to prevent fraud, but also educating the public on questions they should ask to make wise decisions on care. APTA applauds the committee's interest in investigating different areas of the Medicare system for potential abuses of physician ownership. As the committee continues to root out fraud and abuse in the Medicare system, we strongly urge you to consider reform of the in-office ancillary services (IOAS) exception.

Physician-Owned Distributorships and the IOAS exception both exhibit true conflicts of interest to physicians. Opponents of PODs claim that many of these setups consist of physicians holding an ownership-interest in a medical device company, which could in turn generate financial benefits based on the devices used. The IOAS exception allows physicians to bill the Medicare program for several designated health services that are self-referred. The intent of the IOAS exception was to allow for the provision of certain non-complex ancillary services, such as x-rays or simple blood tests, deemed necessary by the clinician to help inform the diagnosis and treatment of a beneficiary during an initial office visit, primarily for beneficiary convenience. Over the years, however, abuse of the IOAS exception has substantially diluted the self-referral law and its policy objectives, allowing Medicare providers to avoid the law's prohibitions by structuring arrangements meeting the technical requirements, while violating the true intent of the exception. In most instances physical therapy services cannot be provided to beneficiaries during an office visit. Even MedPAC found, in 2008, that only 3 percent of outpatient therapy services were provided on the same day as an office visit. Although the self-referral law was designed to prevent clinicians from basing clinical decisions on financial gain, at this point in time, there is significant evidence that the IOAS exception is being regularly exploited, which costs the Medicare program millions each year, with no proof of improved outcomes for beneficiaries.

There is evidence that beneficiaries may actually receive higher-quality care—and therefore better outcomes—when self-referral is not involved. A recent study on low back pain episodes of care, published in the July 2015 issue of the *Forum for Health Economics and Policies* by Dr. Jean Mitchell of Georgetown University, found that non-self-referred episodes of care were far more likely, 52 percent as opposed to 36 percent for self-referrers, to provide "active," or hands-on, services. This, according to the study's authors, suggests the care delivered by physical therapists in non-self-referred episodes is more tailored to promote patient independence and a return

to performing routine activities without pain. It is important to note that "passive" treatments, which are more likely found in self-referring episodes, can be performed by a person who is not a licensed physical therapist (PT). The authors of this paper also cite evidence that these passive physical therapy modalities are "ineffective" in treating low back pain.

Also striking about the study is the difference in overall expenditures for episodes of care provided by self-referring or non-self-referring physicians. Dr. Mitchell was able to look at total insurer allowed amounts for low back pain episodes of care and parse out expenditures on physical therapy only. On average, spending for self-referring providers was $144 as opposed to only $73 for non-self-referring providers. This is a significant difference for a very common episode of care. Even more, when the expenditures for the entire episode of care is calculated—not just physical therapy, but all care for the episode—self-referral episodes averaged $889 compared with only $602 for non-self-referral episodes. So not only is this a problem for physical therapy, it has spread far beyond.

These are just a few reasons APTA recommends the removal of physical therapy, advanced diagnostic imaging, anatomic pathology, and radiation therapy from the list of designated health services permitted to be rendered to beneficiaries during an office visit. This change would narrow the IOAS exception, but not eliminate it completely. APTA would like to see the rural exception kept in place, and an exception for truly integrated care providers instituted. This would keep the true intent of the exception while helping to eliminate Medicare abuse. The Congressional Budget Office estimates that narrowing the IOAS exception in this way will reduce inappropriate utilization of these four health care services and save the Medicare program upwards of $3.5 billion.

We look forward to working with the Senate Finance Committee and the Subcommittee on Health in the coming months to help eliminate Medicare abuse and save the health system and taxpayers billions of dollars. APTA appreciates the opportunity to submit this statement and respectfully recommends that the committee consider holding additional hearings on Medicare fraud and abuse, specifically examining the IOAS exception to the Stark laws.

APTA would like to thank Chairman Hatch and Ranking Member Wyden for holding this important hearing, and for APTA to share its comments. We look forward to being a partner in rooting out Medicare fraud and abuse and establishing an efficient, patient-centered health care system.

LETTER SUBMITTED BY BRUCE LE'ROY GAINES II

Dear Mr. Reynolds,

First. My family and I would like to send a heartfelt deep sincere sympathy to you and your family regarding the ordeal with your beloved mother.

Second. Thank you for your fight for justice and for humanity. Through your hurt and pain, we as victims are grateful that God has allowed you to be a guiding light for those who have suffered this dishonesty.

My name is Bruce Le'Roy Gaines II, February 29, 2012, Pre/Post Operative Diagnosis: Lumbar Radiculopathy, Low back pain, Degenerative disc surgery, left me with an injury that has been devastating with traumatic consequences on my life, my family, and my financial situation. The ability to earn a living has been lost, as well as sky-high medical bills, which have accumulated day after day, from the surgeon at the time: Dr. Aria Sabit.

Henry Ford Health System imaging reports, display legitimate imaging reports: NO Expensive Metal Device is located in my spine, there is NO Bone Dowel either! I was cut open and literally sewed back together. I was 38 years old, when I had my surgery at Doctor's Hospital, February 29, 2012. I arrived at the hospital with 2 legs, now, hypothetically, I have 3—(with the walking cane I am dependent on at present.)

My situation has been egregious with pain and suffering, as well as my wife and family. The biggest and most hurtful ordeal is having on RECORD of BEING INSTITUTIONALIZED IN A PSYCHIATRIC MENTAL HOSPTIAL FOR TREATMENT! I was a hardworking man, with a wife and family that I was committed to. I was employed for 15 years, now I will never have the opportunity to work.

I am saddened by this incident, but a beautiful life, victims, infections, could have been avoided due to GREED! Doctors and all medical boards take oaths to hold superior ethical standards. I was unfortunate in choosing a medical team I STRONGLY BELIEVED IN.

Thank you very much for your fight for justice! Thank you for submitting our e-mails to be read to the Finance Committee in Washington, DC, before the Chairman and 26 senators.

Sincerely,

Bruce Le'Roy Gaines II

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Statement for the Record

"Physician-Owned Distributors: Are They Harmful to Patients and Payers?"

Senate Committee on Finance
November 17, 2015

David C. Paul, Chairman and CEO, Globus Medical, Inc.
and
Anthony L. Williams, President, Globus Medical, Inc.

Globus Medical, Inc. appreciates the opportunity to submit this written statement for the record of the Senate Finance Committee hearing on November 17, 2015. Globus strongly endorses additional transparency regarding Physician-Owned Distributorships (PODs) in order to protect the safety of patients—a proposition that was universally acknowledged during the hearing.

Globus Medical, Inc.

Globus Medical, Inc. is a spinal implant manufacturer based in Audubon, PA. The company was founded in 2003 by an experienced team of spine professionals with a shared vision to create products that enable spine surgeons to promote healing in patients with spinal disorders. Globus and its distributors employ over 1,400 people worldwide, including more than 1,200 employees in the United States. To date, Globus has launched over 150 products, with more than 30 products currently in our pipeline.

Finance Committee Involvement

We commend the Committee for its ongoing bipartisan efforts to tackle this critical patient safety issue head-on. Beginning with the Finance Committee minority staff investigation and report in 2011, followed by the June 2011 bipartisan letters to the Administrator of the Centers for Medicare and Medicaid Services (CMS) and the Health and Human Service Inspector General (HHS OIG), and culminating in the November 17, 2015 hearing, the consistent theme has been the need for strict legal scrutiny of the ownership structures of PODs and, in the wake of the Physician Payment Sunshine Act [Section 6002 of the Patient Protection and Affordable Care Act ("Sunshine Act")], to assure robust reporting by these entities of their ownership interests.

The comprehensive study by HHS OIG in response to the June 2011 congressional letter focused on patient safety/utilization and alleged cost savings associated with PODs. The data squarely debunked any notion of Medicare savings and found alarmingly higher than average utilization rates for PODs—confirming the notion that physician ownership fuels potentially unnecessary surgeries.

In the midst of the Finance Committee's efforts, HHS OIG issued a Special Fraud Alert in March 2013 labeling PODs as "inherently suspect under the anti-kickback statute" resulting in "corruption of medical judgment, overutilization, increased costs to Federal health care programs and beneficiaries, and unfair competition." The Alert identified core characteristics of "suspect" ownership structures, which

should have put PODs on notice that they faced legal exposure. These findings underscore the imperative to uncover the physician-ownership structures of PODs and shine sunlight on their activities.

Marketplace Experience

Over the past decade, Globus has witnessed firsthand both the explosive growth of PODs and the detrimental effects that PODs have had on patient safety, specifically with respect to spinal surgeries. Our salesforce personnel have observed multiple instances of surgeons whose medical judgment appears to have been compromised by the lure of "double dipping" on earnings from the use of a device sold by a POD in which they are an investor, and payments from Medicare or private insurers for the procedure in which they use the device. The structures of PODs perversely incentivize physicians to perform *more* surgeries than are medically necessary or even advisable. We have experienced pervasive exaction of hospitals and surgery centers wherein PODs demand exclusive arrangements under the threat of surgeons' desertion, an outcome that is especially harmful for rural and community healthcare centers.

Along with many in the device manufacturing industry, we welcomed the HHS OIG alert, and expected the strong and unambiguous notice to significantly modify the behavior of PODs. Although the growth rate may have slowed, the Alert clearly has not had the expected corrective impact. Nor has the clear obligation for PODs to disclose their ownership interests under the Sunshine Act served to "shine a light" on these operations to enable the enforcement authorities to target potential bad actors, and patients to make informed judgments about which surgeons they choose. As detailed below, notwithstanding the legal obligation to report, PODs have chosen to ignore this mandate and gamble that their relative anonymity leaves them safe from prosecution.

For these reasons, we applaud the Committee's continuing efforts to tackle this serious issue. To assist the Committee's efforts, we have identified three areas (discussed further, *infra*) that we believe will increase transparency into POD ownership arrangements and attendant potential conflicts of interest. The first is to encourage HHS OIG to use the resources at its disposal to investigate known PODs suspected of fraud and abuse, and, where applicable, refer them to the Department of Justice (DOJ) for prosecution. The second involves ensuring that PODs are properly reporting their ownership interests under the Sunshine Act. Finally, we recommend adjusting the de minimis threshold under the Sunshine Act from the current $10 to $20 in order to de-clutter the payment reporting system and focus on the payments from manufacturers to physicians that truly are potential conflicts of interest.

Increased Enforcement

In the 2013 Special Fraud Alert, HHS OIG stated that PODs by their structure pose "substantial fraud and abuse risk and pose dangers to patient safety." The egregious violations of the anti-kickback and healthcare fraud statutes that came to light in the recent prosecution of Dr. Aria Sabit underscore HHS OIG's findings and highlight the need for robust enforcement in this area. Although, as discussed below, the full universe of PODs is unknown due to the PODs' non-compliance with Sunshine Act reporting obligations, CMS has estimated that as of February 2013, there were approximately 260 PODs in the United States, with at least 160 additional non-POD GPOs that have some form of physician ownership or investment.[1] Information about the identity of at least some of these PODs is ascertainable from media reports, anecdotal information from hospitals and device manufacturers, state business registration websites, and other publicly available sources.

We encourage the Committee to prioritize enforcement of existing fraud and abuse laws against known PODs that display the "suspect characteristics" identified by HHS OIG. The prosecution of Dr. Sabit is a laudable first step, however there are many PODs across the country engaging in less extreme conduct, but conduct that was identified at the hearing as unethical, who feel as if they are immune to prosecution. Vigorous criminal prosecution and civil enforcement by HHS OIG and DOJ addressing the more commonplace PODs will improve patient safety and reduce healthcare costs in the near term, and ultimately incite a voluntary correction to the structures and practices of PODs that will bring the industry into compliance.

[1] *See* Final Rule, "Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests," 78 Fed. Reg. 9458, 9512 (February 8, 2013).

Ownership Interest Reporting

Under the statute and the final rule issued by CMS implementing the Sunshine Act, Physician-Owned Distributorships, which are a subset of GPO's, are required to report to CMS on an annual basis all ownership and investment interests that were held by a physician or immediate family member thereof in the preceding calendar year. This was an integral aspect of the statute and regulations, intended to capture important information regarding potential conflicts of interest and self-dealing by physicians with interests in manufacturers and GPO's. As discussed in the explanation to the final rule:

> [. . .] we also interpreted the statute to encompass not only the more traditional GPO's that negotiate contracts for their members, but also entities that purchase covered drugs, devices, biologicals and medical supplies for resale or distribution to groups of individuals or entities. These interpretations would include, for example, Physician-Owned Distributors (PODs) of covered drugs, devices, biologicals, and medical devices.[2]

Unfortunately, a review of the initial data set released by CMS on September 30, 2014 and the subsequent calendar year 2014 data set released in June 2015 reveals that GPOs, and specifically PODs, have willfully ignored this requirement and, with few exceptions, have failed to provide any ownership information vis-a-vis their physician owners.

We urge the Committee to encourage CMS to issue definitive guidance to physician-owners of PODs outlining their clear requirement to report their ownership interests in accordance with the statute. Although we believe this requirement is already explicit in the existing statutes and regulations, it is possible that not all PODs are aware of their reporting requirements. Unambiguous guidance from CMS coupled with an education campaign would clear any confusion in the industry and hopefully result in the robust reporting that Congress intended when it enacted the Sunshine Act. Transparency into these POD ownership structures will allow patients to better understand the incentives and potential conflicts of interest that may be driving their physicians' recommendations and will permit CMS, HHS OIG and DOJ to carry out their audit, enforcement and prosecutorial functions.

In the event such guidance is not forthcoming and/or does not yield increased reporting, CMS and OIG should be encouraged to exercise their audit and enforcement authority to identify PODs that are failing to report their ownership interest information. Because there is no other registry of PODs in existence against which to compare the Sunshine Act data, PODs are relying on their relative obscurity in hopes of evading enforcement authority. As a case in point, HHS OIG released a report in August 2015 focusing on overlaps between physician-owned hospitals and physician-owned PODs, HHS OIG was forced to rely on information gleaned from POD websites, state business registration websites and other publicly available information to determine the universe of ownership interests. In the executive summary to the report, HHS OIG states "[a]vailable information about ownership interests in limited and raises concerns about a lack of transparency."

To bolster the ability of CMS and HHS OIG to enforce the law, we propose statutory language that would add to the current definition of "Covered Recipient" an additional category of covered recipients, specifically, "An Applicable Group Purchasing Organization." The draft amendatory language is included below. This addition would close the existing loophole through which payments that are ultimately funneled to physicians are provided through third party Group Purchasing Organizations (GPO's).

This statutory change would expand the obligations of manufacturers of pharmaceutical products and medical devices to disclose payments and transfers of value they make to GPOs. Similar to the payments they are currently required to report with respect to physicians and teaching hospitals, manufacturers are in a good position to know and track which payments they have made to GPOs. By reporting such payments, it would create a dataset of existing GPO's, as well as payments made thereto that are effectively indirect payments to their physician owner-investors. This data set would provide a critical cross-reference point and ultimately an enforcement mechanism for CMS, HHS OIG and DOJ.

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[2] *See* Final Rule at 9493.

De Minimis Exclusion

The national disclosure program enacted under the Sunshine Act was intended, as is clear from a review of the legislative history, to provide transparency into certain payments made by "applicable manufacturers" of pharmaceutical products and medical devices to physicians and teaching hospitals in order to shine light on conflicts of interest that could ultimately affect treatment decisions. The statue as currently enacted sets forth a $10 exclusion, to be indexed annually for inflation, from the universe of reportable payments. This low exclusion threshold has the effect of not only unduly burdening manufacturers by requiring them to collect and report data regarding low-dollar payments that do not pose a realistic threat of impropriety, it also severely dilutes the dataset and makes it more much difficult to pinpoint more material payments that the statute was generally intended to expose. Accordingly, we propose an incremental increase of the $10 threshold to $20, while preserving the $100 annual aggregate limit. The draft amendatory language is included below.

At this point in time, the data from two reporting periods is available: the August 2013–December 2013 data, and data from all of calendar year 2014. A review of this data shows that for both periods, an astounding approximately 66 percent of the reported payments were under $20 (versus 21 percent between $20 and $100 and 13 percent over $100). The risk for potential conflicts of interest by physicians and teaching hospitals clearly lies with these larger payments; it is implausible to believe that a health provider would be swayed by an $18 sandwich or an $11 cab ride. There is strong precedent for a $20 de minimis standard—the Office of Government Ethics, in implementing the Ethics in Government Act, established a gift limit of $20 for all federal executive branch employees.

Raising the threshold from $10 to $20 would eliminate the burdensome reporting of these inconsequential payments while still preserving the original statutory intent.

The existing $100 annual aggregate in the Sunshine Act already serves to prevent exploiting the de minimis payment scheme in circumvention of the statute. Moreover, the $10 threshold imposes an enormous burden on the Centers for Medicare and Medicaid Services (CMS), which is responsible for collecting, reviewing and publishing the vast amounts of data currently required under the statute. The millions of entries between $10 and $20 are not material to the transparency goals of the Act, but instead detract and distract from spotlighting the truly concerning payments that may pose a legitimate potential conflict. The modest threshold increase would unclutter the database without undermining the integrity of the statute.

Finally, we would recommend amending the statute to require indexing every 3 years rather than every year. This would be less burdensome for CMS and will impose more consistency among regulated manufacturers.

Proposed Amendment Language

Part A of title XI of the Social Security Act:

Sec. 1128G(e)(6) COVERED RECIPIENT.—

(A) IN GENERAL.—Except as provided in subparagraph (8), the term "covered recipient" means the following:

(i) A physician.
(ii) A teaching hospital.
(iii) An applicable group purchasing organization.

Sec. 1128G(e)(10) PAYMENT OR OTHER TRANSFER OF VALUE.—

(B) EXCLUSIONS.—An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

(i) A transfer of value of anything the value of which is less than **[**$10**]** *$20,* unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. **[**For calendar years after 2012,**]** *On October 1, 2016, and at 3 year intervals thereafter,* the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers *rounded to the nearest $5* (all items; U.S. city aver-

age) for the [12-month period ending with June of the previous year.] *subsequent 3 calendar years.*

Conclusion

As discussed above, Globus is grateful to the Committee for its bipartisan efforts to resolve the very serious concerns raised by the POD model. If we can provide any additional information to assist the Committee, we would be pleased to do so.

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Statement for the Record, Mark Leahey, President and CEO

United States Senate Committee on Finance

December 1, 2015

Senate Committee on Finance
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Washington, DC 20510–6200

Re: Hearing on Physician-Owned Distributors: Are They Harmful to Patients and Payers?

On behalf of the Medical Device Manufacturers Association (MDMA), a national trade association representing hundreds of innovators in the field of medical technology, we welcome the opportunity to submit a statement for the record in response to your November 17, 2015 hearing entitled, "Physician-Owned Distributors: Are They Harmful to Patients and Payers?" MDMA's mission is to ensure that patients have timely access to safe and effective products. Our members, the majority of which are small to mid-sized, research-driven medical device companies, have a strong record of delivering innovative therapies to treat chronic disease and life-threatening conditions while lowering the cost of care.

MDMA appreciates the Senate Finance Committee and the Health and Human Services Office of Inspector General ("HHS IG") for your efforts to shine a light on the troubling concerns with Physician-Owned Distributors ("PODs"). It has been well documented that these PODs have placed profits in front of patient care, and additional steps are needed to protect patient care and competition in the healthcare marketplace. MDMA looks forward to working with the Committee, the IG and others on additional reforms to achieve these objectives.

While MDMA strongly supports the scrutiny given to PODs, we are very concerned that some in the healthcare ecosystem have incorrectly and inappropriately deemed *all* physician relationships with the medical device industry as problematic. For example, some hospitals and health systems appear to be taking the position that *any* physician ownership interest in a medical device company is reason to exclude companies from access to their hospitals. This is a very troubling development that is denying patient access to novel medical technologies.

Some hospitals and hospital systems reference the March 26, 2013 Health and Human Services Office of Inspector General ("HHS IG") "Special Fraud Alert" which "focuses on *certain* Physician-Owned Entities that derive revenue from selling, or arranging for the sale of, implantable medical devices."[1] It is important to note that the HHS IG does not identify *all* Physician-Owned Entities as problematic. Specifically, the March HHS IG Special Alert states, "This Special Fraud Alert focuses on the specific attributes and practices of PODs that we believe produce substantial fraud and abuse risk and pose dangers to patient safety."[2] The Special Alert includes eight "suspect characteristics" that the HHS IG indicates are particularly

[1] Prohibition on Purchasing Certain Products from Physician-Owned Businesses Policy, LL. 029.
[2] OIG Special Fraud Alert: Physician-Owned Entities (March 26, 2013).

concerning, none of which include simply a financial interest in a medical device company.[3] The fact that these characteristics are included in the Special Alert support the position that the HHS IG does not intend to limit *all* physician ownership in medical device companies, just those that exhibit certain "suspect characteristics" found with PODs.

The March HHS IG Special Fraud Alert was followed up by a comprehensive report issued in October 2013 entitled, "Spinal Devices Supplied by Physician-Owned Distributors: Overview and Prevalence of Use." As the title indicates, the sole focus of this report is on spinal devices sold through PODs. Nowhere in the report does the HHS IG raise any concerns with medical device companies who have physician ownership but are not structured as a POD. The fact that the HHS IG states *certain* physician-owned and not *all* physician-owned demonstrates that the HHS IG draws a distinction among different types of relationships and structures.

Some hospital policies permit physicians to have a large stake in a publicly traded company but not private companies. Beyond these inconsistencies, some policies fail to appreciate how the medical technology innovation ecosystem operates. The overwhelming majority of medical technology innovations are developed based upon experience at the bedside by physicians. Therefore, it is often reasonable and appropriate for the physicians who are involved with the development of the technology to have an ownership position in the company. As the company advances the technology and seeks venture capital, investors take equity in the company in exchange for financing, often reducing the ownership stake of the founding physician or physicians. By the time the company is ready to launch a commercial product, most companies have very little physician-ownership, certainly far below the 40 percent threshold with PODs that the HHS IG raised concerns about in their March 2013 Alert and subsequent October 2013 report.

Another complicating factor of these policies is that they impact companies that received angel or venture capital investment from firms in which some of the partners may include physicians. In these cases, the policy would preclude their hospitals from utilizing these devices. From a patient care standpoint, this would be devastating because most of the medical innovations are developed by smaller, privately held companies, which rely upon venture capital investment to fund the product development process.

The issue of disclosure is an area worthy of further clarification as well. Some hospitals require companies seeking to do business with them to disclose the financial relationships with any physicians who have an ownership position in a medical device company, regardless if that physician practices in their system. For the purposes of compliance, it is not reasonable for hospitals to seek disclosure of physician relationships outside of their system.

To further enhance transparency, MDMA recommends that greater scrutiny is placed on PODs to ensure compliance with the U.S. Physician Payment Sunshine Act. Currently, it is unclear if PODs are satisfying the requirements under the Sunshine Act.

In closing, we support efforts to address the troubling POD practices outlined by the HHS IG. It is clear that certain companies and physicians have abused their positions and compromised the trust with patients and their institutions. However, implementing a sweeping policy that prohibits *any* physician ownership in a medical technology company, regardless of circumstances surrounding the relationship or whether the physician is part of the hospital network, is unreasonable. It will also have a chilling effect on the valid and appropriate engagement of physicians to develop the medical breakthroughs of tomorrow. We strongly encourage the Committee to work with the HHS IG and all stakeholders in the healthcare ecosystem to ensure that the ongoing abusive practices of PODs are addressed while clarifying appropriate physician relationships that are permitted.

Sincerely,

Mark B. Leahey
President and CEO, MDMA

[3] Ibid.

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The Honorable Orrin G. Hatch
Chairman
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Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
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Dear Senators Hatch and Wyden:

As an active, Board certified neurosurgeon and lawyer with an M.B.A., I have observed the highly questionable behavior of Physician-Owned Distributorships (PODs) from multiple perspectives including medical, legal and business.

Troubling me most is what I see from the patient perspective—the physical, financial and emotional harm PODs cause, as documented by the Inspector General of the Department of Health and Human Services.

Profit-driven unnecessary surgeries have put patients' health at risk, directly cost families hard-earned dollars because of high deductibles and shatter the trust patients have that their physician will do the right thing for their patients and not their bank account.

The fact is PODs represent an unavoidable conflict-of-interest that can lead physicians to choose implants and/or surgeries based on profit instead of on their patients' best interests. They have already been associated with patient harm, do not save money, and lead to increased utilization. Moreover, POD ownership is not transparent and disclosure is not sufficient to protect patients and the healthcare system.

The manner in which PODs recruit, reward and remove investors reveals a POD's intended role in the spinal implant supply chain. I have seen PODs recruit investors because they are in a position to generate substantial business by selecting the POD's implants; they require investors who cease practicing in the service area to divest their ownership interests; and POD investors enjoy extraordinary returns on investment compared to the level risk incurred.

Specifically, I have observed that:

- Size of investment offered to each physician varies with expected or actual volume or value of devices used.
- Distributions are not made in proportion to ownership interest, or physician owners pay different prices for their ownership interests, because of expected or actual volume or value of devices used.
- Physician-owners condition referrals to hospitals or ambulatory surgery centers (ASC) on their purchase of the POD's devices thru coercion or promises.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for purchase of devices sold by PODs.
- The POD retains right to repurchase a physician-owner's interest for physician's failure to refer, recommend or arrange for purchase of the POD's devices.
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or contract with personnel necessary for operations.
- The POD does not maintain continuous oversight of all distribution functions.
- When hospital or ASC requires physicians to disclose conflicts of interest, the POD's physician-owners often fail to inform the hospital or ASC of, or actively conceal thru misrepresentations, their ownership in the POD.

Congress should pass legislation to eliminate PODs. Doing so will promote patient safety by eliminating the conflict of interest affecting physicians' choice of surgical procedures and spinal implants.

Sincerely,

Richard N.W. Wohns, M.D., JD, MBA

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Testimony for the Written Record
Senate Finance Committee Hearing entitled,
"Physician-Owned Distributorships: Are They Harmful to Patients and Payers?"
November 17, 2015

Chairman Hatch, Ranking Member Wyden, and Members of the Committee:

On behalf of the Orthotic and Prosthetic Alliance (the O&P Alliance), a coalition of the leading national organizations representing the orthotic and prosthetic profession, thank you for the opportunity to submit testimony for the written record with respect to the hearing entitled, "Physician-Owned Distributorships: Are They Harmful to Patients and Payers?", held by the Committee on November 17, 2015.

The five organizations listed on this letterhead comprise the O&P Alliance and represent the scientific, research, professional, business, and quality improvement aspects of the field. Collectively, the Alliance represents over 13,000 O&P professionals and 3,575 accredited O&P facilities. The O&P Alliance advocates for federal and state policies that improve the practice and quality of orthotic and prosthetic care and maximize access to these services provided to patients in need of artificial limbs and orthotic braces. The Alliance's priorities include ensuring patients receive services from appropriately trained, educated, and credentialed practitioners, and promoting fair and equitable coverage and reimbursement policies.

We are writing to echo the concerns that arose during the November 17, 2015 hearing on the risks surrounding Physician-Owned Distributorships (PODs). Although this hearing focused specifically on PODs involving surgical supplies and instrumentation, we are concerned that if the Office of Inspector General (OIG) issues additional guidance with respect to PODs, it is unlikely to draw a distinction between surgical supply PODs and any other medical devices, including O&P items and related services.

We maintain that Medicare and its beneficiaries are best served by licensed and/or certified orthotic and prosthetic clinicians acting on a referral from a physician or other healthcare provider who has no financial interest in the O&P practice. As we outline below, allowing for physician self-referral of O&P care and physician use of O&P items from PODs, whether it is through the in-office ancillary services (IOAS) exception to the Stark law or allowing for joint ventures, does not serve to improve beneficiary access or quality of care. With the exception of certain prefabricated off-the-shelf orthoses and supply items, allowing for the provision of most types of O&P care by referring physicians opens the door to overutilization, potentially compromised medical judgment, unfair competition, and increased costs to the Medicare program and its beneficiaries.

Background

Over the past few years, the O&P field has experienced an increase in Medicare-enrolled physicians and physician groups who have made arrangements with other enrolled suppliers in order to bill for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items, specifically custom O&P devices, from their own physician-owned laboratories. We are aware that the potential profitability of self-referring to physician-owned O&P laboratories is being presented at many medical business meetings. We also see entities marketing turnkey O&P laboratory services to physician groups.

We note that these arrangements are not specifically prohibited under current laws or regulations and, while custom O&P devices constitute a small subset of DMEPOS, these arrangements may dramatically and negatively affect the way care is provided to the beneficiary. We have previously encouraged both OIG and the Centers for Medicare and Medicaid Services (CMS) to become involved, analyzing the effect of physician-owned O&P laboratories, custom O&P services provided under the IOAS exception to the Stark law, and contractual joint ventures formed for the provision of custom O&P care. To shed additional light on these types of arrangements, we set forth our position on these types of arrangements below.

POD Special Fraud Alert—March 2013

As you are aware, on March 26, 2013, the OIG issued a Special Fraud Alert addressing Physician-Owned Entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs). The focus of these PODs tends to be in the surgical arena, with a particular emphasis on orthopedic implants (spine and joint prostheses) and cardiac implants (pacemakers and defibrillators).[1] However, within a footnote to this Fraud Alert, the OIG notes that ". . . Although this Special Fraud Alert focuses on PODs that derive revenue from selling, or arranging for the sale of, implantable medical devices, the same principles would apply when evaluating arrangements involving other types of Physician-Owned Entities."[2]

We contend that many of the concerns that the OIG delineated in the Special Fraud Alert regarding implantable prosthetics apply equally to external prostheses (in the form of artificial limbs) and to custom orthopedic bracing (orthoses). We believe that the fraud and abuse risks, as well as (and more importantly) the patient safety concerns related to PODs, are equally applicable to physician-owned O&P laboratories.

While it might not appear that there are significant opportunities for fraud or abuse when a physician either owns or joint ventures with an O&P laboratory that is not necessarily the case. Overutilization of O&P services may occur through ordering a replacement device when repairs to an existing orthosis or prosthesis are indicated; ordering a more expensive or complex device when a less expensive or complex orthosis or prosthesis is medically appropriate; or coding and billing for a more expensive device while providing a less expensive orthosis or prosthesis to the patient. These avenues to overutilization of O&P services are similar to those described by Senators Hatch and Wyden during the November 17 hearing, as they relate to medically unnecessary surgical procedures.

Further, the fact that physicians are exempt from the O&P accreditation requirement and related Medicare quality standards creates a circumstance that could result in the physician opting to replace devices that otherwise would be repaired by an O&P facility that has the necessary equipment and laboratory to effect such repairs. This is because an accredited O&P practice is required to offer repairs, while an unaccredited practice is not.[3] In addition to fraud, abuse, and overutilization, the Special Fraud Alert raises other concerns—corruption of medical judgment, increased costs to Federal healthcare programs, and unfair competition. Each of these concerns exists when discussing physician-owned O&P laboratories.

Due to the similarities that exist between the two entities, we maintain that the suspicion with which PODs are viewed should be applied equally to physician ownership of O&P laboratories. We further believe that insufficient attention has been paid to physician relationships with O&P laboratories that are essentially the equivalent of PODs, and we support the application of the same principles when considering the legality of physician-owned O&P laboratories going forward.

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[1] *See* Deyon TA, Mirza SK, Martin BI; et al. "Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults." JAMA 2010; 303 (13); 1259–1265 (noting a marked 15-fold increase in the number of spinal fusion surgeries from 2002 to 2007 and highlighting the significant financial incentive to both hospitals and surgeons to perform such complicated surgeries).

[2] OIG, "Special Fraud Alert: Physician-Owned Entities," March 2013, *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf.*

[3] *http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DMEPOSAccreditationStandardsCMB.pdf.*

IOAS Exception to the Stark Law

The IOAS exception set forth to the prohibition on physician self-referral (the Stark Law)[4] was implemented to provide patients the opportunity to receive designated health services (DHS), including O&P, during the time of their physician office visit and was intended to accommodate certain legitimate physician business arrangements. We believe that the IOAS exception and other loopholes in Medicare regulations related to O&P services are being exploited and foster physician business arrangements that do not conform to the IOAS exception's original intent.

Custom O&P services are rarely, if ever, completed at the time of an office visit and certainly do not meet the criteria for being provided "ancillary to physician services." The provision of such custom O&P care is rarely accomplished during a single office visit; rather, the patient assessment, casting, measurement, fabrication, fitting, adjustment, and follow-up care may take several weeks—or even months—to complete. We maintain that the current regulatory and legal exceptions, as they apply to all of DMEPOS, opens a door for prescribing physicians to over-order or upcode in the specific area of custom O&P devices and related services. Therefore, the loophole allowing physicians to refer services to O&P laboratories which they own or have a financial interest in should be eliminated.

We do acknowledge that it can be in the interest of improved patient access or quality of care to allow for the provision of off-the-shelf orthotic (prefabricated) items, some custom fit (prefabricated) orthotic devices or prosthetic supply items during a physician office visit. We will not argue that it can be convenient for the patient to obtain simple prefabricated orthotic items, supplies, or items such as a cane or a sling during the course of a physician visit; in fact, we believe such scenarios were the original intent of the IOAS exception.

However, to allow for the provision of custom fabricated and certain custom fit orthoses and prostheses under the IOAS exception simply serves as a mechanism to maximize physician profits, with no corresponding benefit to patients. In the design, manufacture, fitting, adjustment, and training on the use of a custom O&P device, the patient must return on multiple occasions. Unlike with a one-time dispensing or pick-up of an off-the-shelf prefabricated product associated with a physician visit, it is not more convenient for a patient to have to return to a physician's medical office than to go to a specialized, accredited O&P facility. However, when a physician has a financial interest in the O&P facility, that physician's patients surely will feel some obligation or possibly pressure to return to that physician's O&P laboratory—even if the services are not the most appropriate.

Although lawmakers have progressively tightened the IOAS loopholes in recent years, even a narrow loophole affords ordering physicians the opportunity to improperly self-refer. CMS acknowledged this in 2010, when it required physicians who self-refer under the IOAS exception to disclose when they were self-referring patients for advanced imaging services.[5] Simply put, allowing payment for custom O&P care under the IOAS exception could lead to overutilization and self-referral abuses, and does not contribute to patient access to appropriate and quality O&P care.

Contractual Joint Ventures

Contractual joint ventures have long been of concern to the OIG, dating back as far as August 1989 when it released its Special Fraud Alert on joint venture arrangements.[6] The OIG followed this Fraud Alert by a Special Advisory Bulletin addressing contractual joint ventures in April 2003.[7]

The 1989 Fraud Alert addressed arrangements between those in a position to refer business (*e.g.,* physicians) and those who provide items for which the Medicare and Medicaid programs make payment. The OIG contended that certain of those arrangements may violate the anti-kickback statutes. The April 2003 Advisory Bulletin focused more narrowly on arrangements where a health care provider in one line of business (referred to by the OIG as the "Owner") expands into a related health care business by contracting with an existing provider or supplier (referred

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[4] 42 U.S.C. § 1395nn.

[5] MLN Matters® Number: SE1023, "Provisions in the Affordable Care Act of 2010 (ACA)," (rev. Aug. 12, 2012), *available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1023.pdf.*

[6] OIG, "Special Fraud Alert: Joint Venture Arrangements," August 1989, *available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.*

[7] OIG, "Special Advisory Bulletin: Contractual Joint Ventures," April 2003, *available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/042303SABJointVentures.pdf.*

to as the "Manager/Supplier") of the related item or service in order to provide the new item or service to the Owner's existing patient base. In these arrangements, the Manager/Supplier would otherwise be a potential competitor in the provision of the Owner's new business line. The Manager/Supplier manages the new line of business on behalf of the Owner, and may go so far as to supply the Owner's new line of business with employees, inventory, space, and billing or other related services. The Owner receives the profits of the business as remuneration for his/her referrals. Many PODs are structured in this fashion.

These joint venture arrangements can contribute to self-referral abuses and overutilization. Some might attempt to make the argument that such arrangements improve patient access to service; however, these arrangements instead may limit access by removing the Manager/Supplier's ability to serve patients in its own right. We encourage increased enforcement activities and regulation as they relate to these often-abusive arrangements.

Documentation for Custom O&P Services

In recent years, O&P clinicians engaged in providing services to Medicare beneficiaries have seen an increase in the amount and type of documentation required to support the medical necessity for the services they provide. In addition to a detailed physician prescription, certain circumstances require that the ordering physician's contemporaneous clinical documentation support the patient's diagnosis and the medical necessity for the O&P services ordered.

This issue raises several important questions. When a medical doctor self-refers for O&P services under one of the above scenarios, he/she becomes the supplier of record when billing Medicare. When acting as the O&P supplier as well, will the medical doctor's own clinical documentation be considered sufficient to support the medical necessity for O&P services? If a licensed and/or certified O&P clinician's documentation must be additionally supported by a third-party in the form of the referring physician's prescription, clinical notes, and in some instances letters of medical necessity, will the same standard be applied when a medical doctor acts as a supplier of O&P services?

These questions illustrate one of the inherent problems in allowing for the self-referral of O&P services—under the typical model for providing O&P, the O&P clinician is financially independent of, but coordinates clinically with, the physicians from whom he/she receives referrals. The referring physicians act as "gatekeepers" of sorts, by providing the required prescriptions and documenting the need for any ordered O&P devices. Without this gatekeeper's prescription and clinical validation, the O&P clinician cannot be paid for the services provided to Medicare patients. In a self-referral situation, no gatekeeper exists; no one independent of the supplier of record (who is also the ordering physician) has responsibility for supporting the medical necessity of the O&P care provided. In these self-referral situations the checks and balances that are generally in place no longer exist.

Conclusion

In order to ensure that the interests of both the Medicare program and beneficiaries continue to be served, that access to quality O&P care is maintained, and to mitigate the potential for fraudulent and abusive activities, we believe:

- The suspicion with which PODs are viewed should be applied equally to physician ownership of O&P laboratories.
- Billing of custom fabricated and certain custom fit orthoses and prostheses should be eliminated from the IOAS exception. The IOAS exception, when applied to custom O&P, does not serve any ancillary care advantages and simply serves as a mechanism to maximize physician profits, with no corresponding benefit to patients. Allowing payment for custom O&P devices and related services under the IOAS exception can lead to overutilization and self-referral abuses, and does not contribute to patient access to appropriate O&P care.
- Enforcement activities should be increased as they relate to often-abusive contractual joint venture arrangements wherein a referring physician realizes the profits gained by referring his or her patients to an O&P laboratory in which he or she has ownership interest, with little or no professional or clinical oversight.
- The requirement should be maintained for all suppliers of O&P care, including physicians and physician practices, that a third-party referral source must

prescribe and support the medical necessity for custom O&P devices and related services provided to Medicare beneficiaries.

Thank you for the opportunity to submit this statement for the written record.

RETIRESAFE
Standing Up for America's Seniors!

November 13, 2015

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden,

All Americans deserve quality healthcare throughout their lives. Since 1991, RetireSafe has worked tirelessly to maintain the safety and personal freedoms of older Americans. RetireSafe works to preserve treatment choices and access for doctors and patients while maintaining their safety. We believe that a strong and trusting relationship between physician and patient is the foundation of good healthcare. We think that Physician-Owned Distributors of implantable medical devices (PODs) undermines this relationship by creating financial incentives for physicians who unduly influence medical decision-making, putting patient health at risk.

In 2011, the *Wall Street Journal* reported on the death of a patient during a spinal-fusion surgery performed by neurosurgeon Dr. Adam Lewis in Jackson, Mississippi; for the surgery, Dr. Lewis had chosen implants sold by a company he partially owned, Spinal USA, and he profited from the sale. According to the *Wall Street Journal,* two spine surgeons who later reviewed the patient's records said that the patient was a poor candidate for the surgery that Dr. Lewis performed.

RetireSafe was alarmed at the finding in the 2013 U.S. Department of Health and Human Services Office of Inspector General (HHS OIG) that *PODs may encourage unnecessary surgeries.* We implore the members of this Committee to not let this stand. Not only do PODs lead to unnecessary patient suffering but they also waste scarce Medicare dollars on unnecessary surgeries. The use of PODs and its negative influence on the physician's decision making process is indirect opposition to RetireSafe's mission to ensure that seniors are safe. It seems that any good physician would avoid even the appearance of an adverse influence that would exist by their participation in a POD.

We applaud the Senate Finance Committee for its continuing investigation into these inherently suspect entities and hope that serious, concrete measures will be taken to hold PODs to account and, ultimately, in our view, be eliminated. We urge the committee to take the necessary steps to ensure that Medicare remains a safe and secure healthcare system for our senior citizens.

Sincerely,

Thair Phillips
President/CEO, RetireSafe

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November 30, 2015

Re: Senate Finance Committee Hearing on "Physician-Owned Distributors: Are They Harmful to Patients and Payers?"

Dear Senate Finance Committee:

The Quality Implant Coalition ("QuIC") is a coalition of manufacturers of implantable medical devices that is concerned with the potential for harm to patients and the Medicare program that results when physicians have a financial interest in the devices they order for implantation in their own patients. QuIC appreciates the opportunity to provide a statement for the record for the Senate Finance Committee's November 17, 2015 hearing entitled "Physician-Owned Distributors: Are They Harmful to Patients and Payers?"

At this hearing, three of the four witnesses—Dr. Scott Lederhaus, MD, President of the Association for Medical Ethics; Ms. Suzie Draper, Vice President of Business Ethics and Compliance, Intermountain Healthcare; and Mr. Kevin Reynolds, son of Lillian Kaulback, who died as a result of surgery from a POD-involved surgeon—expressed the concern that PODs were harmful to patients and payers. The fourth witness, Dr. John Steinmann, DO, of the American Association of Surgical Distributors ("AASD"), conceded that PODs presented a conflict of interest, but argued that this conflict could be managed using AASD standards.

In this statement, we review the 12 standards set out by AASD, and conclude that the standards do not adequately address the harms created by PODs. These harms include the fact that the strong personal profit incentive created by PODs can lead to physician-owners performing more and/or unnecessary surgeries that use their own medical devices, raising serious patient safety and ethical questions. These unnecessary surgeries or revisions also add substantial costs to patients and payers. The AASD standards do not address these harms; rather, they either merely restate that compliance with law is required (without giving guidance as to how); are irrelevant to the harms; are insufficient; or are unrealistic.

Therefore, we urge the Committee to take further steps, beyond requiring disclosure, to prohibit PODs from causing further harm. While disclosure is important, it is insufficient to address the fundamental legal and ethical issues posed by PODs, and it is insufficient to protect patients, payers, and the public from PODs.

AASD Standards and QuIC Response:

As an initial matter, we note that the 12 AASD standards do not affect POD obligations for Physician Payment Sunshine Act reporting, do not affect analysis under the physician self-referral law (the "Stark Law"), and likely do not affect analysis under any state self-referral laws.

Below, we discuss the relevance of each of the standards to an anti-kickback statute analysis and to the conflict of interest:

Standard One: Distributorship maintains a business structure consistent with Federal Self-Referral and anti-kickback statutes, and reports in compliance with the Physician Payment Sunshine Act.

> Response: This states the obvious, that applicable laws must be complied with, but by itself it provides no guidance to such compliance. This is an apple pie statement, not a "standard."

Standard Two: Distributorship demonstrates merit by proving to be the lowest average cost vendor of like implants during a comparable contract period.

> Response: Lower cost is not relevant to whether the anti-kickback statute is violated, or whether a conflict of interest inappropriately influences a physician's choice of whether to perform a procedure, where to perform it, or what implant to use. Guidance by the Department of Health and Human Services Office of Inspector General ("OIG") has long made clear that where an investment interest is motivated by the intent to induce (or to be induced to make) referrals, the anti-kickback statute is violated. We also note that OIG's own report concluded that purchasing from PODs does not have a lower cost, and in some cases a measurably higher cost.

Standard Three: Distributorship annual price increases to customers do not exceed 3 percent above the consumer price index (CPI).

Response: Like Standard Two, this is another cost element, not relevant to whether the anti-kickback statute is violated or whether a conflict of interest exists.

Standard Four: Distributorship is a legitimate, free-standing stocking distribution company with employees, contracts, an address, a business license, and insurance.

Response: The absence of these factors—a business that is a "shell" outsourcing all of its operations, placing no financial risk on the investor-physicians—obviously would present a greater risk of fraud and abuse under even the oldest OIG investment guidance.[1] However, being a "shell" entity has never been a necessary component of an unlawful investment relationship. The conflict of interest still exists with a stocking distributor.

Standard Five: Distributorship demonstrates adherence to the AASD Product Evaluation Policy (*e.g.,* vendors maintain insurance, meet FDA requirements, not debarred; products cleared by FDA, selected by surgeons based on comparison to other products).

Response: This also is not relevant to the anti-kickback statute legal analysis, or to the corrupting effects of the conflict of interest.

Standard Six: Distributorship demonstrates adherence to the AASD Employee Training Policy (*e.g.,* product rep trained in sterile techniques and sterilization, HIPAA, compliance, and the products s/he reps).

Response: Again, this is not relevant to anti-kickback statute legal analysis or the existence of the conflict of interest.

Standard Seven: Distributorship demonstrates adherence to the AASD Disclosure Policy (*e.g.,* hospitals, patients, colleagues all receive notice of physician-ownership).

Response: This is not relevant to the anti-kickback statute legal analysis and has specifically been noted by OIG not to be a sufficient protection.[2] Disclosure is only effective if patients can adequately assess this information; we note that there is sound social science evidence that disclosure to patients of a physician conflict of interest is apt to be perceived as an endorsement rather than a warning.[3] Furthermore, patients ought to be able to trust that their physicians act in their patients' best interests. Stating that physicians should tell their patients they have other interests (*i.e.,* a personal profit motive) is far from actually resolving the conflict of interest.

Standard Eight: Distributorship demonstrates adherence to the AASD Investment and Distribution Policy (*e.g.,* ownership based on investment interest, return not vary based on referrals, no mandatory terminations based on failure to use).

Response: Like Standard 4, this standard sounds good without meaning anything. As noted above, the test for whether an investment interest violates the anti-kickback statute is whether it is motivated by the intent to induce (or to be induced to make) referrals. Even a proportional return on investment will violate that standard where, as here, the obvious and primary purpose of a POD is to give the ordering physician a financial reward for using certain products at facilities that agree to buy them in order to obtain the physician's referrals. Moreover, because most PODs represent a small number of doctors, and because in most PODs most of the users are the owners, even a proportional investment will correlate closely to the owners' own referrals, and/or to their collective referrals.

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[1] OIG, Special Fraud Alert: Joint Venture Arrangements (August 1989), reprinted at 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

[2] As we noted in the preamble to the final regulation for the safe harbor relating to ASCs: ". . . disclosure in and of itself does not provide sufficient assurance against fraud and abuse . . . [because] disclosure of financial interest is often part of a testimonial, *i.e.,* a reason why the patient should patronize that facility. Thus, often patients are not put on guard against the potential conflict of interest, *i.e.,* the possible effect of financial considerations on the physician's medical judgment." See 64 Fed. Reg. 63,518, 63,536 (Nov. 19, 1999). Although these statements were made with respect to ASCs, the same principles apply in the POD context. OIG, Special Fraud Alert on Physician-Owned Entities (March 2013).

[3] See, *e.g.,* Jason Dana and George Lowenstein, A Social Science Perspective on Gifts to Physicians from Industry, 290 JAMA 252, 254 (July 9, 2003).

Standard Nine: Distributorship submits utilization data annually and demonstrates adherence to the AASD Appropriate Use Monitoring Policy (*e.g.,* surgical procedure volume and implant usage base-lined and tracked, with more than 15 percent change requiring independent audit that will re-set baseline or result in disciplinary action).

> Response: While not relevant to an anti-kickback statute legal analysis or to the conflict of interest, utilization review and management is of course an important tool, and one that hospitals should have physicians engaged in through hospital committees. But putting doctors with a financial interest in the outcome in charge of such reviews makes little sense. Moreover, this standard does not appear to subject a change in choice of implant to this tracking, which is of course a key indicator in the POD conflict of interest.

Standard Ten: Distributorship has written contracts with hospitals, with pricing that is consistent among hospitals, and contract periods of at least 1 year.

> Response: This is not relevant to the anti-kickback statute legal analysis or to the conflict of interest.

Standard Eleven: Distributorship does not leverage referrals to any hospital or surgery center.

> Response: While clearly relevant to the anti-kickback statute legal analysis and to the conflict of interest, it is a fanciful standard. It is impossible to think that POD owners will not leverage their ability to make referrals to hospitals to require those hospitals to purchase from their POD.

Standard Twelve: Distributorship does not require, pressure, or otherwise leverage physician owners' use of the Distributorship devices.

> Response: Again, this is probably fanciful: it is hard to believe that the owners of a POD would not pressure the other owners to use the POD's implants. But in any event, the existence of pressure on the owners is secondary to the conflict of interest that already creates all the incentive necessary to influence the choice of whether to perform a procedure, what implants to use, and where to perform the procedure.

In sum, AASD's standards fail to resolve the legal and ethical issues presented by PODs. None of the standards are sufficient to resolve the conflict of interest or to ensure that PODs do not violate the anti-kickback statute. The standards are also irrelevant to Stark Law analysis; to state self-referral laws; and to reporting obligations under the Physician Payment Sunshine Act.

Therefore, we urge the committee to take decisive steps, beyond transparency, to protect patients, payers and the public from the well-documented harms created by PODs.

Respectfully submitted,

Thomas N. Bulleit

Lisa Q. Guo

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