

Statement of
Dr. John Steinmann, D.O.,
before the
Committee on Finance
United States Senate
Hearing on
Physician Owned Distributorships

November 17, 2015

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 6 children and equally proud grandfather of 9.

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.

In our system today when it comes to choosing medical devices, the decision maker (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.

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

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 savings³. 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, manufacturers 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%, 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

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

³ "Medical Bills are the Biggest Cause of US Bankruptcies: Study," by Dan Mangan, CNBC, June 25, 2013, <http://www.cnbc.com/id/100840148>.

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.

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% 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% -- 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% 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.

Respectfully Submitted,

John Steinmann, DO

Biography:



John C. Steinmann, DO

Dr. Steinmann is a practicing orthopedic spine surgeon, and partner in one of California's largest private orthopedic surgery groups. After completing his residency in Orthopedic Surgery at Botsford Hospital (Michigan State affiliate) he went on to complete a spine surgery fellowship at the University of Washington.

Since joining Arrowhead Orthopedics in 1992, Dr. Steinmann has attended at Arrowhead Regional Medical Center (County Hospital) as the Director of Spine Trauma. In addition, Dr. Steinmann is on active staff at four other regional medical centers.

Dr. Steinmann has played an active role in building Arrowhead Orthopedics into one of California's largest private Orthopedic Groups. In addition, he has engineered the development of many important business entities dedicated to enhancing the patient's experience and improving value in healthcare. In 2004 Dr. Steinmann designed and led the development of 7-Oaks Medical Center where, in one location, patients can receive orthopedic care, physical and occupational therapy, orthotics and prosthetics, state of the art imaging including CT and MRI and outpatient surgery. Dr. Steinmann remained for 10 years the managing member of the highly successful surgery center at 7-Oaks.

In 2006 Dr. Steinmann founded Inland Surgical Products to offer hospitals better leverage in the acquisition of medical devices. In 2009, Dr. Steinmann founded Renovis Surgical Technologies, to bring high quality orthopedic and spine products to market and to meet a growing demand for value. In 2012, Dr. Steinmann developed the Spine and Joint Institute at Redlands Community Hospital and as medical director has taken this hospital from average to first in patient satisfaction

(HCAHPS ratings) while reducing the hospital spend by \$7 million annually. In 2013, Dr. Steinmann was elected to the Board of the California Orthopedic Association.

When asked how he manages to maintain an active practice, a medical directorship and run a rapidly growing medical device company, he is quick to point to the outstanding individuals he surrounds himself with.

EXPERT
REVIEWS

Surgeon ownership in medical device distribution: does it actually reduce healthcare costs?

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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%, with US\$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%. **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 US\$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 implant. 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 US 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 re-establish 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% for total hip arthroplasties and by 673% 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 & 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 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).

The study sample represents 1366 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).

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 US\$1814 (33%) less for the SD (US\$3640 vs. 5453). Hip replacement implant costs were US\$1937 (30%) less on average for the SD compared with the NSD (US\$4564 vs. 6501). For anterior cervical fusion cases, the SD implant cost was US\$1055 less for the SD (36%; US\$1859 vs. 2914). The lumbar fusion implant costs were US\$5567 (40%) less on average for the SD (US\$8289 vs. 13,855). Across each of the implant lines studied, the SD implant cost was on average US\$2589 (32%) less than the NSD cost. Considering the 1366 cases included in the sample population, the 1-year cost savings to hospitals/surgery centers and society was US\$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%, with a mean aggregate annual savings of US\$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: US\$558,109). The least cost savings came from a total joint arthroplasty distributorship serving seven general orthopedists (US\$17,453 per surgeon over 12 months). While not specifically studied, the variation may be explained at

Table 1. Five distributorships profiled.

	Start of operation	No. of surgeons-spine	No. 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; TJA: Total joint arthroplasty.

least in part by differences in practice emphasis (general orthopedics vs. spine), geographic market price differences (four states represented), and distributorship scale (TABLE 3).

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% increase in total knee

Table 2. Hospital implant prices surgeon versus non-surgeon distributorships.

Total knee replacement	Procedures	SD cost	NSD cost	Average annual savings
SD1	90	\$3588	\$5385	\$161,730
SD2	116	\$3889	\$6573	\$311,344
SD3	92	\$3285	\$5568	\$210,036
SD5	189	\$3817	\$4288	\$92,799
Total hip replacement		SD cost	NSD cost	Average annual savings
SD1	35	\$5128	\$7295	\$75,845
SD2	78	\$4630	\$7117	\$193,986
SD3	52	\$4250	\$6900	\$137,800
SD5	66	\$4288	\$4694	\$29,370
Anterior cervical fusion		SD cost	NSD cost	Average annual savings
SD1	91	\$2092	\$2651	\$50,869
SD2	43	\$2140	\$2230	\$3870
SD4	20	\$1345	\$3861	\$50,320
Posterior lumbar fusion		SD cost	NSD cost	Average annual savings
SD1	118	\$6410	\$11,007	\$542,446
SD2	83	\$13,564	\$14,628	\$88,312
SD4	46	\$4892	\$15,931	\$507,795

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

Table 3. Aggregate annual savings for all procedures and percentage cost reduction.

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

SD: Surgeon owned distributorship.

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%.

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

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].

Table 4. Average annual change in implant pricing.

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

SD: Surgeon owned distributorship.

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% reduction in implant costs across three hospital systems [11]. No other studies have validated the cost savings associ-

ated 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% and totaling US\$2,456,521, with an average cost savings of 36% across all five SD, averaging US\$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.

The 2010–2011 Orthopaedic Industry Annual Report cited total US 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% (average 13%) [13]. In contrast, SD in this study have shown the ability to save 37% the first year and to keep annual escalations at or below 1.0%.

The substantial first-year reductions in implant prices and sustained downward pressure on annual price changes that result from surgeon ownership in medical device distribution 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% annual escalations [13] associated with NSD would decrease for the next 20 years to 7.5%. It is further assumed that the SD model, with a first-year reduction in cost of 36%, would demonstrate a 1.5% annual escalation in price as opposed to the 1.41% reduction currently demonstrated. FIGURE 2 uses the same assumptions but includes all orthopedic implants, to demonstrate the

broader potential cost savings associated with the SD model.

This calculation reveals that over the next 20 years, the SD model has the potential to save US\$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 US\$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% for total knee replacements and by 174% 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 establishing 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

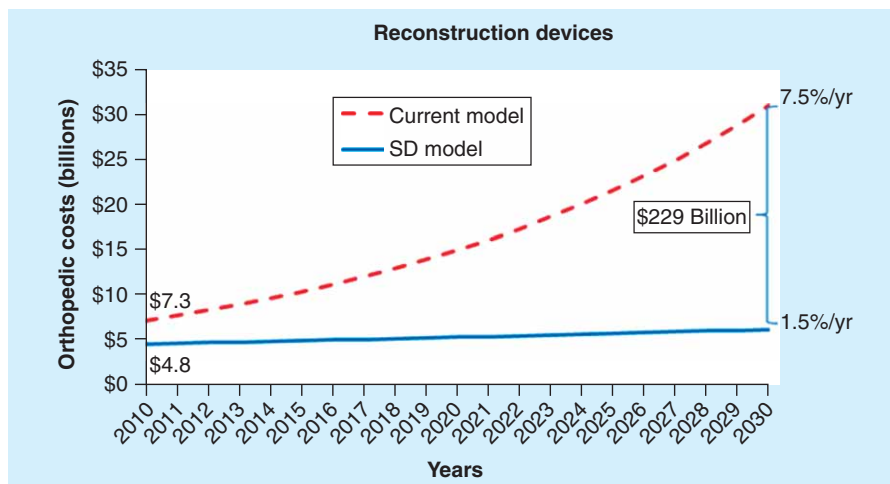


Figure 1. The potential economic benefit of SD on total joint reconstruction devices.

SD: Surgeon-owned distributorship.

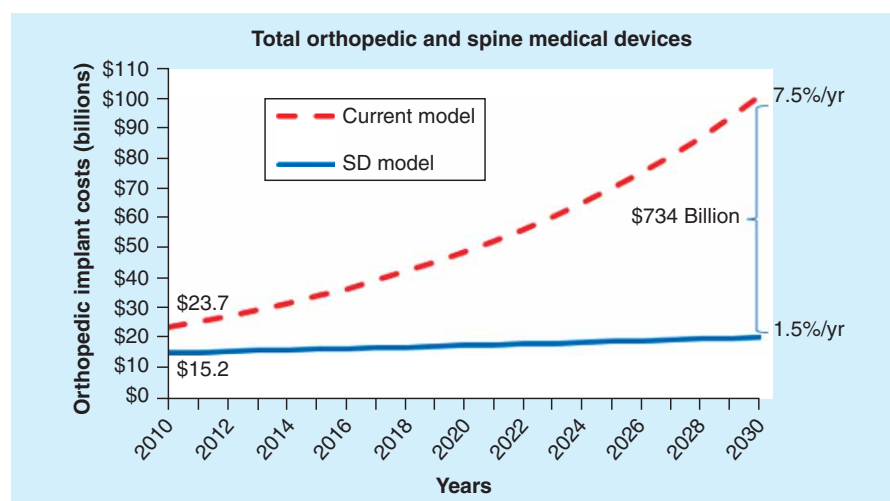


Figure 2. The potential economic benefit of SD on total medical devices.

SD: Surgeon-owned distributorship.

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% 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

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.

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 distributorships. Safeguards, such as those established by the AASD, will serve to protect the best interest of patients and society on an ongoing basis.

Financial & competing interests disclosure

JC 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%, totaling \$2,456,521, with the average annual implant price decreasing by 1.41% 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.

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