Post Sunshine Act: How Spine Surgeon Relationships With Industry Are Evolving

Written by Laura Devita | Tuesday, 10 June 2014 10:07

In August 2013, the Physician Payment Sunshine Act went into effect, meaning industry interactions with physicians were recorded and published online. The first set of interactions published on the Centers for Medicare and Medicaid Services website were in September 2014, leading some physicians to think twice about how they relate to device companies.

"I think surgeons don't want to deal with the fall out and don't want their data out there," says Frank M. Phillips, MD, Professor of Orthopaedic Surgery at Rush University Medical Center and co-director of the Minimally Invasive Spine Institute at Midwest Orthopaedics at Rush in Chicago. "There are innovative spinal surgeons who are avoiding working with industry because of the negative connotations that have been created by legislators and the media. Surgeon inventors have been vilified for receiving royalty payments from implant manufacturers for products they have developed."

There are few other funding sources beyond device companies for clinical trials. The federal government has limited grants for research and specialty organizations such as the Orthopaedic Research Education Foundation have some resources to doll out, but not enough to fund most of the projects in the field today.

"It's very rigorous to gain these limited government funds to conduct research. Government funds are limited and so are the research funds from the industry and it's becoming more expensive for industry to conduct clinical trials in the United States," says A. Nick Shamie, MD, chief of spine surgery at UCLA Health Systems.

Impact on relationships

There are some legitimate relationships that result in large payments for surgeons, and not all surgeons shy away from it. "There are some surgeons who are receiving huge amounts from the industry, and that's because they are making a significant contribution to the development of implants and teaching new procedures," says Michael Hisey, MD, of Texas Back Institute in Plano. "If you look at it as a bad thing, you're missing the boat. It's really a positive that surgeons are able to spend some of their time advancing the progress of medicine. I would be proud when it comes out that I'm a consultant to companies because I've put a lot of work into those products."
But has the legislation been effective?

"With increased scrutiny and transparency, questionable unethical surgeon consulting relationships have decreased which is a good thing. But at the same time, the wedge driven between surgeons and implant manufacturers has slowed opportunities for collaborative innovation to improve patient outcomes," says Dr. Phillips. "Interestingly, we've looked at how patients perceive surgeons participating in product development and receiving remuneration for this. Patients don't seem to mind these relationships as long as they are ethical. In fact, many patients think it's a plus to have innovative surgeons performing their procedures."

Even though some inappropriate relationships have ended, there will still likely be cases where surgeons don't follow the rules.

"The people who have unhealthy relationships and receive kickbacks are the last people who are disclosing that information," says Dr. Hisey. "Instead, we have a lot of people who are disclosing their relationships, but they aren't part of the problem. You aren't going to catch the bad actors with disclosures because they are already breaking the rules."

Relationship transparency

Co-director of the Minimally Invasive Spine Institute at Rush, Kern Singh, MD, likes the Sunshine Act because it has made the field more transparent. He always tells his patients disclosures upfront. "If I designed the implant I want to use, I go through that with my patients," he says. "Patients like it and they see me as innovative. They understand why I have relationships with the device company. I think the Sunshine Act is the right thing to do."

Transparency is a huge trend in healthcare and disclosures are routine for surgeons presenting research or discussing which devices they'll use with their patients.

"We've seen so much in the way of surgeon disclosures over the past decade, that we've become desensitized," says Dr. Phillips. "Generally most clinicians understand the need for surgeons to drive device innovation which may lead to conflicts of interest. When surgeon developers present their data, most surgeons take the conflict of interest with a grain of salt and assess the data based on its merits."
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Academic spine surgeons may be feeling the pinch more than most; they are often involved in research activities and publishing data on new products, and those studies take time and effort to complete, which must be compensated because of the additional staff required to run these trials.

"There are several people involved in the research projects, from the surgeons to the bookkeepers and staff who are working with patients to fill out their forms and collect information," says Dr. Shamie. "It's a very rigorous process. Who is going to pay for that process? If my staff are inundated with paperwork, do I just have them work for free or is there a fair remuneration? Some institutions have limited the remuneration so much that it makes being involved in clinical trials cost-prohibitive."

Some private practice surgeons are now becoming involved in research as well and may not face the same scrutiny from their institution. "We need to work through these challenges, and that will require a concerted effort to make the decision-makers aware of the importance of surgeon involvement from a wide spectrum of backgrounds; public and private sectors; academic and non-academic institutions," says Dr. Shamie. "If we limit the big institutions from getting involved, we are skewing the data, especially by limiting public institutions that are sometimes held to a higher standard."

Media controversy

The media frenzy around the most egregious inappropriate relationships has somewhat negatively impacted the perception of these relationships. "The media skews the conversation around the surgeon/company relationship, which is necessary in the field," says Dr. Singh. "The engineers don't have clinical sensibilities. You can come up with the best widget, but if you don't know how to employ it in a clinical setting, it won't make it to the hospital. I hope the perception never gets to the point where surgeons can't be involved in this development at all."

Many of the biggest innovations over the past quarter-century have come as a result of surgeons partnering with device companies. Since surgeons work in the field every day, they have a unique perspective on what designs and developments would make their job easier and improve patient outcomes.

"Most truly revolutionary medical device innovation has been conceptualized and driven by surgeons rather than device companies," says Dr. Phillips. "But now that surgeons are being alienated from the development process, we are seeing less game-changing and more incremental, marketing-driven device innovation. I think unfortunately meaningful device development is going to suffer as a result of the Sunshine Act."
Dr. Hisey sees the biggest changes with the little expenses, such as taking surgeons out to dinner, while the larger transaction relationships stay in place. Likely, these relationships will continue in some fashion going forward.

"I think the vast majority of these relationships are good," says Dr. Singh. "For most surgeons, I don't think the Sunshine Act has made much of a difference in their behavior. It's taken away some of the more shady relationships. It's going to clean up the system."

**Future impact**

Surgeons in the future may continue to develop intellectual property and make huge royalties as a result. "Sometimes in the process of working on projects with device companies, surgeons develop ideas that are patented and it's reasonable to collect royalties on those projects," says Dr. Hisey. "It's not a bad thing. I don't mind that we keep an eye on these relationships and make disclosures before presenting study results, but receiving money doesn't mean that someone is abusing the system."

However, the negative tone of this new legislation and media coverage has made an impression on young surgeons. When Dr. Phillips first began practicing, it was acceptable to form a relationship with device companies to enable surgeons to take their promising ideas to the next level; now those types of relationships are disincentivized and new ideas may never make it past the surgeon's imagination.

"I've noticed among my young spine colleagues, when they have innovative ideas and great concepts for devices, they don't have the same access to the device manufacturers that I did 20 years ago," says Dr. Phillips. "The relationship is more standoffish. It's definitely going to affect innovation because surgeons will be less likely to be able to commercialize their ideas and are more distrustful of device companies. The bottom line is that failure to innovate is a lost opportunity to progress spinal care."

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Steve • 20 hours ago

Excellent article. Dr. Hisey is dead on. I look at the Sunshine Act as merely a vehicle for the government to more fully scrutinize legitimate Surgeon/Industry relationships. The government is insulting Surgeons by thinking they can be "bought" by a steak dinner. I’ll disclose that dinner all day long. But with government watching these transactions, Surgeons are less likely to partner with us in the industry, creating a chasm in innovation in the device industry.

This administration has hit Spine Surgeons and Industry with a triple whammy; the ACA and Sunshine act (and Medical device Tax), the FDA slowing and halting the process of IDE’s and 510k approvals which slows innovation, and Medicare/Medicaid cuts in professional fees, effectively punishing the Surgeons who want to take care of older and poorer folks who often need care the most.