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Physician-Owned Distributorships Under Scrutiny at Senate Finance Committee Hearing

On November 17, 2015, the Senate Finance Committee (“SFC”) held a hearing on physician-owned distributors of implantable medical devices (“PODs”). The hearing was the latest bit of increasingly unfavorable federal government scrutiny devoted to PODs dating back almost a decade. Although the Minority Staff of the SFC issued a [report](#) in 2011 raising questions about the abuses that result when physicians are permitted to profit from the sale of the implants they order for their own patients through ownership in a POD—a report that led to the HHS Office of Inspector General’s (“OIG’s”) 2013 [Special Fraud Alert](#) calling PODs “inherently suspect under the anti-kickback statute”—this is the first congressional hearing on the subject. The hearing was notable for the bipartisan consensus of Chairman Hatch and Ranking Member Wyden that PODs represent a conflict of interest that can cause and has caused harm to patients and payers, and that further action to curb these abuses is warranted. This Alert summarizes key takeaways from the hearing, including thoughts about the likely nature of future action that might result from the hearing.

Attorneys
[Thomas N. Bulleit](#)
[Lisa Q. Guo](#)

What clearly emerged from the SFC hearing is a consensus that POD ownership is not sufficiently transparent to give hospitals and patients warning of the potentially harmful effects on patient care of the physician-owners’ financial interest. For example, Chairman Hatch stated that the Committee intended to refer such a matter to the Department of Justice and OIG for potential criminal prosecution. Although the Chairman made reference to a pending criminal proceeding against a physician for multiple offenses related to his ownership of a POD, there was no clear indication of how much additional Federal enforcement or additional legislative action may be in the offing. It is telling, however, that the Chairman reacted favorably to the testimony of one witness—the Vice President of Business Ethics and Compliance of Intermountain Health—who described how her hospital system had responded to the OIG’s Special Fraud Alert by banning all purchases from PODs (with only limited exceptions in order to protect truly innovative technologies). This may suggest at a minimum that such hospital policies will come to be regarded as an industry “best practice.” We anticipate that the Committee will issue a report, likely in the first quarter of 2016, which will articulate more fully the Committee’s concerns and recommendations for PODs.

1. Statements by Senators Hatch and Wyden

The hearing was notable for its bipartisan agreement, with both SFC [Chairman Orrin Hatch](#) (R-Utah) and [Ranking Member Ron Wyden](#) (D-Ore.) making strong statements regarding the harms created by PODs. In his opening statement, Senator Hatch stated that “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.”

Senator Wyden echoed this sentiment, noting that PODs receive a “double dip,” stating that: “in addition to the payment they get from insurers or from taxpayers through Medicare or Medicaid” for a surgery, doctors “get an extra financial reward for every device used in treatment.” Using somewhat inflammatory language, he continued by saying that “[i]n the worst cases, scam-artist doctors have left long trails of patients to recover from unnecessary or complicated procedures involving invasive and painful surgeries.”

2. Witness Statements

Three of the four witnesses at the hearing—[Mr. Kevin Reynolds](#), the son of a deceased patient ; [Ms. Suzie Draper](#), Vice President of Business Ethics and Compliance, Intermountain Healthcare; and [Scott Lederhaus](#), MD, President of the Association for Medical Ethics—expressed 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.

- **Mr. Reynolds’** testimony related to his experiences with his mother. Mr. Reynolds testified that his mother had passed away from complications related to a spinal fusion surgery performed by a doctor who had an ownership interest in the POD supplying the implants used in the surgery, but had never disclosed the ownership interest to Mr. Reynolds or his mother. He urged the Committee to “do whatever is necessary to ensure that doctors make decisions based on what is best for the patient, not the doctor’s wallet.” His final statement in the hearing was “PODs no more.”
- **Ms. Draper** provided a perspective on how Intermountain Healthcare has acted to resolve the conflict of interest presented by PODs while allowing for continued technological innovation. Intermountain has developed a [policy](#) banning its hospitals from purchasing from PODs except in two situations: PODs that cannot generate business for Intermountain (because the owner-physicians do not practice in the service area of an Intermountain hospital); and PODs that sell a product that represents a truly innovative technology.
- **Dr. Lederhaus** further underscored the ethical and other issues presented by PODs, noting that “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,” and that, “[i]n addition to the severe ethical problems posed by PODs, they adversely affect competition and distort the true price of healthcare services.”
- **Dr. Steinmann**, whose organization supports PODs, conceded that PODs presented a conflict of interest, but argued that the standards promulgated by the AASD for “ethical” PODs are sufficient to manage the conflict. AASD’s standards do incorporate a few favorable features identified in the OIG’s Special Fraud Alert, such as transparency of ownership to hospitals and patients and proportional return on investment. However, the standards do not address other key concerns of the Special Fraud Alert, such as:
 - the physician-owners are the POD’s primary customers;
 - the physician-owners may change their product allegiance as a result of their investment;
 - the physician-owners may condition their hospital referrals on the hospital’s buying the POD’s implants; and
 - investment return is high or correlates closely to referrals.

Dr. Steinmann also said that his organization has found that PODs save money, which is contrary to OIG’s findings in its [2013 report](#).

3. Committee Follow-Up Actions

Chairman Hatch noted that the Committee intended to submit information to OIG and to the Centers for Medicare & Medicaid Services (“CMS”) with respect to the rate at which PODs report their ownership interests, noting that he believed “these findings will say quite a bit about the lack of accountability for these types of business arrangements.” He and Ranking Member Wyden are also making a formal referral to OIG and the Department of Justice of at least one POD case that, in Hatch’s words, “deserves review for potential criminal action.” Wyden noted that this referral is in connection with an assertion that “a device manufacturer offering to make payments to doctors” “through a third party to avoid disclosure.” At a minimum, this appears to indicate that the Committee is pushing for increased transparency around POD reporting.

The Washington, DC grapevine also indicates that the Committee intends to release another report on PODs, which is anticipated in mid-January.

4. Implications

The weight of evidence against and in opposition to PODs clearly continues to grow. The [SFC Minority Staff’s 2011 Report on PODs](#) cited some concerns, but on the whole took a fairly neutral approach to whether PODs were inherently problematic, or if there were just a few bad apples, raising the question as to whether it is possible “to structure a POD that does not raise [conflict of interest] issues” noting further that “there appear to be some PODs

that try to appropriately balance these competing interests.” OIG’s Special Fraud Alert cited as “inherently suspect” several features that are part and parcel of the POD business model (including those noted in Section 3 above), and [OIG’s report on PODs](#) from later that year confirmed that, based upon its findings, the one favorable feature touted by PODs—cost savings—was not supported by the evidence. The private sector has taken these concerns seriously, with a number of larger hospital systems having adopted policies banning PODs. And, in contrast to the more inquisitive statements of the 2011 SFC Minority Staff Report, the language used by Chairman Hatch and Ranking Member Wyden in this hearing—asserting that “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,” and that “patients should be getting care designed to help them—not to pad a physician’s bank account”—demonstrates that it will be increasingly difficult to do business with a POD and not be at significant risk of governmental scrutiny and challenge.

For more information regarding the hearing, or to discuss PODs generally, please feel free to contact [Tom Bulleit](#), [Lisa Guo](#), or your usual Ropes & Gray attorney.