

PHYSICIAN-OWNED DISTRIBUTORSHIPS (PODS):

QUICK PROFIT OR LEGAL HAZARD?

Bill Kolter
Corporate Vice-President
Government Affairs, Public Affairs, and Corporate Communication

Disclosure

- Employee and shareholder of Biomet, Inc.
- Manufacturer of medical devices
- Registered lobbyist
- I am not a lawyer

Biomet's position on Physician-owned distributorships (PODs)

- Have passed on opportunities to work with PODs
- Concerns with business model
- Potential pitfalls for surgeons, hospitals, manufacturers

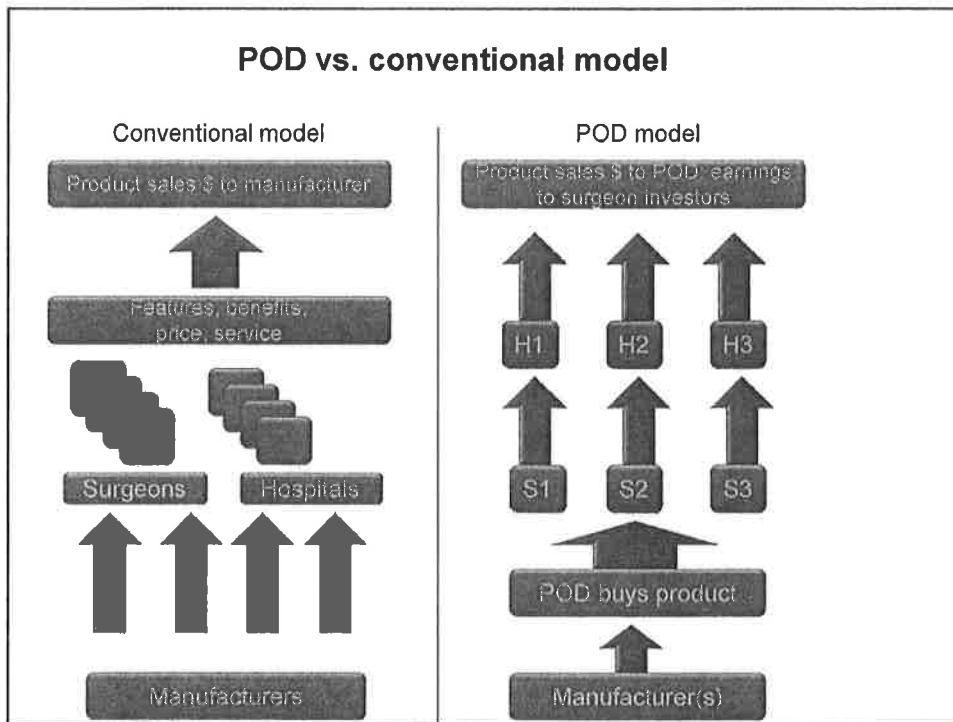
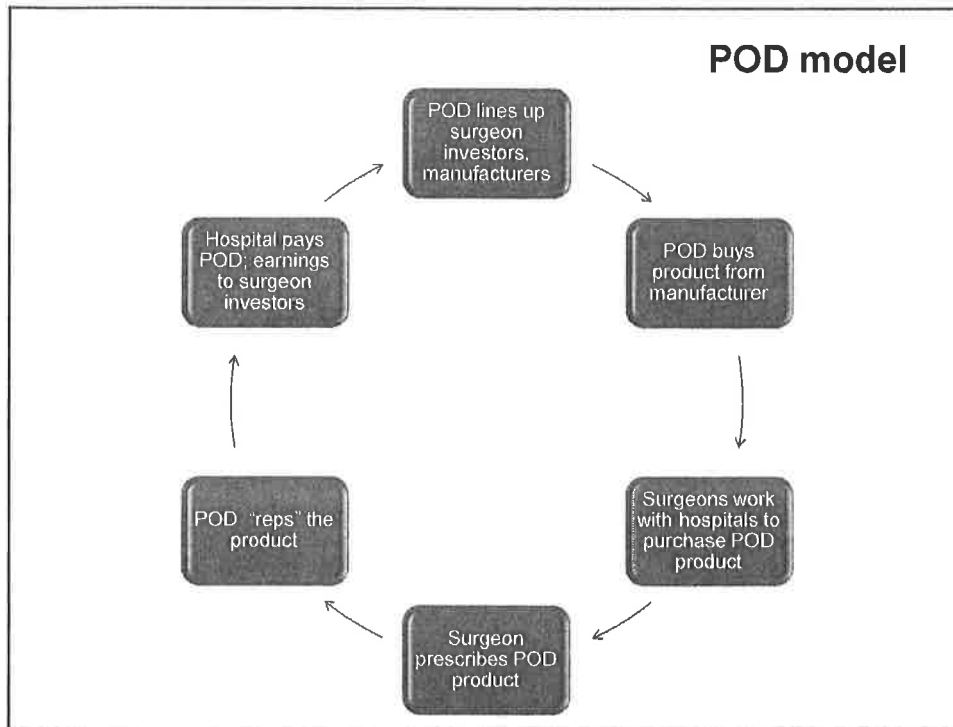
Healthcare climate

- Manufacturers, hospitals, insurance companies –all doing well
 - Although facing a changing reimbursement climate
- Surgeons are, and have been, rightfully frustrated
 - Inadequate, unpredictable compensation

Why PODs?

- PODs offer a tempting source of new revenue.
- But PODs are a trap.
- Reliance on surgeon-investor product usage
- Gov't: "substantial concerns" that PODs induce changes to purchasing and prescribing
- Inherently violative of Federal Anti-Kickback Statute

POD STRUCTURE

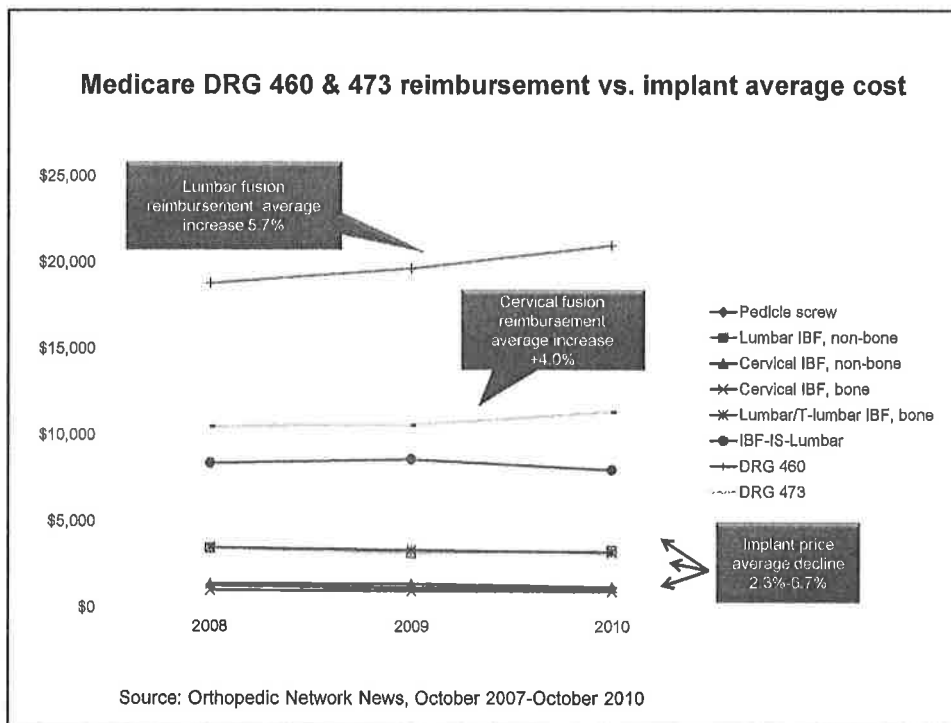
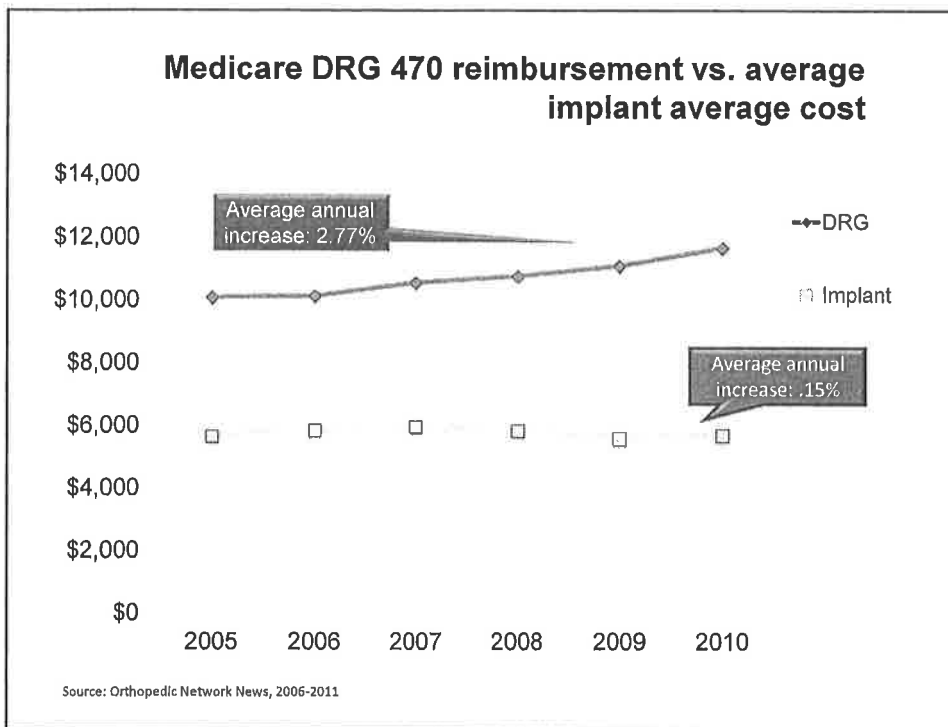


Justification for PODs

- Eliminating sales and marketing costs allows better pricing
- But how can PODs eliminate these costs?
 - Only by eliminating the *need to market*
 - i.e., captive customers

Justification for PODs: myths and facts

- **Myth:** “The costs of orthopedic implants continue to rise, over 13% annually...”
 - Steinmann, *et al.*, Scientific Exhibit SE48: 2009 Annual AAOS Meeting
- **Fact:** implant pricing is flat/declining
 - Orthopedic Network News, 2006-2011
 - Analyst reports, 2010-2011
- **Myth:** Hospital profits are declining
 - Steinmann, *et al.*, Scientific Exhibit SE48: 2009 Annual AAOS Meeting
- **Fact:** Orthopaedics is most profitable hospital service
 - UBS Hospital Survey, September, 2011



Profit as % of revenue (2008 data)

Payor	Knee	Hip	Lumbar fusion	Cervical fusion
Medicare	5.6%	2.6%	2.7%	9.3%
Private insurance	47.0%	47.4%	48.2%	44.9%

Source: Robinson, Health Affairs, 30, no. 7 (2011): 1265-1271

PODs are an anti-kickback trap

- The justification diverts attention from the danger
- Saving money, even if anecdotally true, doesn't change the legal landscape

THE LEGAL LANDSCAPE

Legal landscape

- “One purpose” test
- “If one purpose of the payment was to induce future referrals, the Medicare statute has been violated.”
 - United States v. Greber, 760 F.2d 68 (3d Cir. Pa. 1985)

The “red-face” test

- **Manufacturers must argue:**
 - Inducing business of surgeon investors is NOT one purpose
 - Yet the business always switches
- **Surgeons must argue:**
 - Financial upside is NOT one purpose
 - Yet surgeon-investors are paid based on collective use of POD product
- **Hospitals must argue:**
 - Preserving referrals from surgeon investors is NOT one purpose
 - Yet surgeons' PODs invariably win the contract

Legal landscape

- **Pro: ok if properly structured**
 - Hooper, Lundy & Bookman:
- **Pro: *If* PODs don't violate Anti-Kickback statute, they don't violate California statutes**
 - Lockyer, California Attorney General, Feb. 27, 2006
 - But: State has no standing to opine on Federal law
- **Con: they're not properly structured, and likely cannot be**
 - Hogan Lovells
 - What structure turns an inducement into “not a kickback?”
- **Con: “...substantial risk of violating the law.”**
 - Akin Gump
- **Con: “You can't possibly think this is ok...they're racing toward a cliff. This can't possibly hold up.”**
 - Tom Scully, former head of Medicare, Senior Counselor, Alston & Bird

Senators request OIG investigation

- "...there are far more [PODs] which are operating in a manner that appears to be unethical and illegal."
- "Previous guidance on this topic is not sufficient."
- "Until there is clarity, inappropriate versions of these entities could continue to proliferate."

Letter from Senators Kohl, Hatch, Grassley, Baucus, and Corker to Daniel R. Levinson, Inspector General, June 9, 2011

Office of Inspector General (OIG), Dept. of Health and Human Services

- Con: "These business ventures raise substantial concerns that a physician's return on investment from the venture may influence the physician's choice of device."
 - Demske, GE, Feb. 27, 2008
- Con: "Given the strong potential for improper inducements... these ventures should be closely scrutinized under the fraud and abuse laws."
 - Robinson, VL, Oct. 6, 2006
- Con: "...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 under the Federal Anti-Kickback Statute."
 - Letter to Senators Kohl, Hatch, Grassley, Baucus, Corker, Sept. 13, 2011

But OIG has not provided sufficient guidance

- OIG response does not address the most pressing questions
- Dangerous situation:
- Proliferation of controversial models
- Plus inadequate guidance
- Plus perceived OIG indifference
- Equals creeping non-compliance
- The next high-profile healthcare scandal

Irony: POD proliferation despite rising concern of conflict-of-interest

- Calls to avoid "even the appearance of impropriety"
- But:
- It's ok for surgeons to profit from prescribing certain implants?
- It's ok for hospitals to protect referrals by sourcing through PODs?
- It's ok for manufacturers to distribute through customer-owned companies?
- Hard to imagine a more conflicted scenario

Breaking down the firewall

- As PODs proliferate, issues related to conflict and impropriety will grow
- OIG will not be able to ignore indefinitely
- When the leash snaps, it will snap hard
- Reputations, patient trust will be damaged