

**Department of Health Professions
Board of Health Professions
REGULATORY RESEARCH COMMITTEE
Public Hearing - HB1235 Implantable Medical Devices
May 20, 2014**

TIME AND PLACE: The meeting was called to order at 10:00 a.m. on Tuesday, May 20, 2014, Department of Health Professions, 9960 Mayland Drive, 2nd Floor, Board Room 4, Henrico, VA, 23233.

PRESIDING OFFICER: Irene V. Farquhar, Chair

MEMBERS PRESENT: Irene V. Farquhar
Yvonne Haynes
Charlotte Markva

MEMBERS NOT PRESENT: Allison Gregory
Maureen Clancy

STAFF PRESENT: Elizabeth A. Carter, Ph.D., Executive Director for the Board
David E. Brown, D.C., Director DHP
Laura Jackson, Operations Manager

OTHERS PRESENT: John Steinmann, Orthopedic Surgeon
Charles Edwards, Orthopedic Spine Surgeon
Kathleen McDermott, Morgan, Lewis & Bockius LLP
Senator Steve Martin
Thomas Tremble, VP Advanced Medical Technology Association
Cal Whitehead, Whitehead Consulting, LLC
W. Scott Johnson, Hancock, Daniel, Johnson & Nagle PC
James Pickral, Pickral Consulting LLC
Jacob Harper, Morgan, Lewis & Bockius LLP
Ralston King, Lobbyist
Mike Jurgensen, Medical Society of Virginia

QUORUM: A quorum was established with three members in attendance.

EMERGENCY EGRESS PROCEDURES: Dr. Carter provided the emergency egress procedures.

AGENDA: There were not edits made to the agenda.

APPROVAL OF MINUTES: A motion was made by Ms. Haynes and properly seconded to approve the minutes of the February 25, 2014 meeting. All committee members were in favor, none opposed.

PUBLIC COMMENT – PUBLIC HEARING: **John Steinmann, Orthopedic Surgeon**
Mr. Steinmann took two days out of his practice to travel across the country to inform the Committee of his concern about the anticompetitive aspect of HB1235. He stated that there has

been a great deal of honorable work performed by many outstanding individuals representing outstanding companies that have demonstrated a dedication to bringing change that is vital to our national healthcare system. He stated that we cannot allow the interests of those profiting from this overly expensive system to suppress the innovation and competition that our system so badly needs. He offered himself as a resource to address issues surrounding physician ownership in medical device manufacturing and distribution.

Charles Edwards, Orthopedic Spine Surgeon

Mr. Edwards stated that he established a distribution company for spine implants five years ago. He indicated that the company purchases FDA approved spinal implants from a respected domestic manufacturer, and then sells the implants to the hospital at 40% of the discount price of implants sold by major manufacturers. If the legislation proposed in early 2014 were successful, it would limit competition and strengthen the power of a few large surgical implant companies or trusts. Legislation would hurt small business, reduce competition from the marketplace, and result in higher prices. He stated that the only ones that will benefit from HB1235 are a handful of large public companies.

Kathleen McDermott, Morgan, Lew & Bockius, LLP

Ms. McDermott stated that she has spent the last 14 years in the private sector focusing on fraud and abuse issues. Ms. McDermott urges regulation or prohibition and indicated that this issue is not about good or bad, small or big, but about regulation corruption. She posed the question, “Do we care if it’s cheap if it’s unethical?” Ms. McDermott cited three literature sources that she will be providing in further public comment prior to the June 20, 2014 deadline.

Senator Steve Martin, 11th Senate District

Senator Martin reported that he has served the Commonwealth for 27 years with a focus in healthcare. He stated that PODS are a conflict of interest simply because they exist, causing harm to credibility and integrity. He stated that our laws are designed to prevent victims and that PODS practice should not be permitted in the Commonwealth of Virginia.

Thomas Tremble, VP, State Government Affairs, Advance Medical Technology Association

Mr. Tremble stated that AdvaMed is the national trade association of medical technology manufacturers, comprised of 400 member companies, including manufacturers of implantable orthopedic devices that allow patients to regain mobility. He stated the following points. 1) PODS are “inherently suspect” as the HHS Office of Inspector General cited. 2) PODS have an inherent conflict of interest because their success is based on referrals by

their investors. 3) HHS studies have shown that PODS can threaten patient safety by performing a higher rate of surgeries and increase healthcare costs. 4) As the OIG has advised, it is not possible to create a good POD where the purpose of the investment is to induce or reward referrals. Mr. Tremble stated that he does not mean to question the integrity of the many Virginia physicians acting in the best interest of their patients. The perception, and reality in some cases, is that health care decisions are being made for economic reasons as opposed to what is in the best interest of the patient. Mr. Tremble urges the Board to carefully consider the finding of the HHS office of Inspector General's Special Fraud Alert and its strong admonition that "PODs are inherently suspect under the anti-kickback statute" and that they are concerned about their proliferation.

PUBLIC COMMENT DUE DATE:

The deadline for public comment on HB1235 is June 20, 2014 at 5:00 p.m.

ADJOURNMENT:

The public hearing adjourned at 11:30 a.m.

Irene V. Farquhar
Chair

Elizabeth A. Carter, Ph.D.
Executive Director for the Board