



Alternatives for Commercializing a Medical Device

May 7, 2008

Emerging Enterprise Center at Foley Hoag

■ Program Description

This MDG Forum will address a dilemma that is faced by many medical device entrepreneurs – how to move from an interesting (patented) idea to a commercially viable product. The meeting will feature a panel of experienced practitioners, each of whom will advocate for a particular approach to furthering product development. The discussion will focus on a case, distributed by Harvard Business School, in order to make a consistent presentation of alternative approaches. The case is “Endius, Inc.: Alternatives for Developing a New Medical Device.” For those interested in ordering the case from HBS Publishing, the case number is DMI011.

Ken Toso, a seasoned product development leader from the Medical Device Industry, will advocate for in-house development. Ken Fine, CEO of Proven Process, a medical device design firm, will present his position on why outsourcing is the best choice. Carol Hempfling Pratt, a partner with Foley Hoag law firm, will present the case for licensing the patents owned by Endius to other companies.

■ Moderator

Michael Gram, Entrepreneur, Medical Device Industry

■ Panelists

Ken Toso, Seasoned Product Development Leader

Ken Fine, CEO, Proven Process

Carol Hempfling Pratt, Partner, Foley Hoag LLP

■ May Forum Co-Champions

Michael Gram

Lee Jones, Dekko Medical Devices

■ Agenda

5:30–6:15	Registration, informal networking, buffet dinner
6:15–6:25	MDG announcements
6:25–6:35	Moderator's introduction of topic and panelists
6:35–6:50	Ken Toso, advocating for in-house development
6:50–7:05	Ken Fine, advocating for outsourced development
7:05–7:20	Carol Hempfling Pratt, advocating for outlicensing
7:20–8:15	Q&A
8:15	Adjourn

■ MDG Mission

MDG's Mission is to contribute to the continuing development of medical devices and other medical technologies by enhancing the professional development of its members, fostering and supporting entrepreneurial thinking, serving as a forum for exploration of new business opportunities, and promoting best practices in enterprise management.

■ Biographies



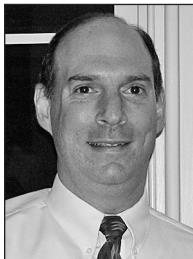
Michael Gram

Michael Gram has over 30 years of experience in managing technology-based businesses. His background includes design and manufacturing of medical telemetry systems as well as providing business and systems consulting to a variety of medical device and biotech companies. Mr. Gram's credentials include a B.S. in biomedical engineering from Northwestern University as well as an MBA from Northwestern's Kellogg School of Management.



Ken Toso

Ken Toso has 23 years of progressive experience in medical device technologies, product development and manufacturing. His innovative product experiences have been within the medical fields of general surgery, gynecology, cardiovascular, urology, interventional cardiology, oncology and blood hemostasis. Most recently, Mr. Toso served as vice president of research and development for the oncology division of Boston Scientific. Previously, he led the BSC Gynecology R&D group with responsibilities for products focused on stress urinary incontinence and endometrial ablation. He has been vice president of R&D for ACMI Circon (recently acquired by Olympus) and had responsibility for launching 22 new products within his three-year tenure, the most advanced being a full product line of digital electronic endoscopes. Previously, Mr. Toso was vice president of engineering at Xylum, a start up where he was responsible for the engineering and manufacturing of its diagnostic blood screening device. Mr. Toso started his career with US Surgical, where he served in a variety of technical and management roles ultimately as R&D director. Mr. Toso holds 21 U.S. patents and has another five pending. He received a bachelor's degree in mechanical engineering from SUNY at Stony Brook and an MBA from the University of Bridgeport.



Ken Fine

Ken Fine is president and co-founder of Proven Process Medical Devices, Inc., an ISO 13485:2003 certified and FDA registered full-service outsourcing partner that offers exceptional design, development, validation and contract manufacturing services exclusively for the medical device industry. Proven Process provides expertise in mechanical engineering, digital and analog electrical engineering, software engineering, and contract manufacturing to established and emerging companies marketing novel Class II and Class III therapeutic and in-vivo diagnostic medical products. Mr. Fine has over 25 years experience in the development and manufacture of medical therapeutic and in-vivo diagnostic devices, including active implantable devices. Before co-founding Proven Process, Mr. Fine was manager of electrical and software engineering for Pfizer's Infusaid division. Previously Mr. Fine held product development positions of increasing responsibility at Intermedics, Inc., a pioneering company in the cardiac rhythm management market. Mr. Fine earned a B.S. in biomedical engineering from Boston University and an M.S. in electrical engineering from Northeastern University.



Carol Hempfling Pratt

Carol Hempfling Pratt is a partner at Foley Hoag LLP, a Boston-based law firm with over 250 lawyers in Boston, Washington D.C. and at its Emerging Enterprise Center in Waltham. Ms. Pratt's early specialization was representing financial institutions in corporate and regulatory matters, and is recognized in both Chambers USA and The Best Lawyers in America for that practice. Much of her work for banking clients involves mergers and acquisitions, an expertise that has expanded into other business sectors, primarily the medical device industry. In particular, Ms. Pratt has substantial experience representing larger established medical device companies in acquiring important product lines from smaller companies. These transactions often involve field-specific intellectual property licenses of the smaller company's patents and know-how. Ms. Pratt also has close involvement with companies at the other end of the medical device industry spectrum, both through Foley Hoag's niche in Greater Boston's entrepreneur and venture communities, as well as through her role as counsel to, and service on the Board of Directors of, MedTech IGNITE. Ms. Pratt received a B.A. with distinction, Phi Beta Kappa, from Northwestern University in 1980, and a J.D. magna cum laude from Northwestern University School of Law in 1984.

■ **MDG Officers, 2007-2008**

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■ **MDG Volunteers, 2007-2008**

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Eric Peterson, Web Site Calendar
Mike Toomey, Publicity
John Wlassich, Outsourcing SIG

We are always looking for volunteers to help make our forums and networking successful. Please email the chairperson above if you would like to get involved with MDG.

■ **MDG Alliance Partners**

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