



Developing Medical Devices For Children: Opportunities & Challenges

Wednesday, October 9, 2013 • 5:30 – 8 p.m.
Judah Folkman Auditorium,
Boston Children's Hospital

■ **Program Description**

The development of medical devices for children has greatly lagged behind the development of devices for adults. The label "child" covers such diverse periods of human growth — from newborn to age 17 — that it creates a segmented and tiny market for device makers. Technical barriers challenge engineers to develop products for rapidly changing bodies. Implanted rigid devices do not grow with the child. And unless devices are designed with exquisite consciousness of child behavior, safety and patient compliance may be extremely difficult to attain.

Despite these challenges, some companies have succeeded in small, niche markets. There also are opportunities for incredible engineering accomplishments in solving health care needs. While the FDA has set up incentives for developing child age-specific pharmaceuticals, there is no similar program for medical devices.

Our October program will feature a panel of experts discussing the economic gaps, will examine some of the unique engineering hurdles and will look at one model for addressing some of these challenges.

■ **Moderator & Panelist**

Don Lombardi, *CEO*, Institute for Pediatric Innovation

■ **Panelists**

Aaron Sandoski, *Managing Director*, Norwich Ventures

George B. Kenney, ScD, *President*, EntraTympanic

■ **October Event Champion**

Edward Dolan, *Organizational Learning & Development Professional*

■ **Agenda**

5:30 Registration, informal networking, buffet dinner

6:15 MDG announcements

6:20 Moderator introduction of panelists

6:30 Panelist presentations

7:30 Audience Q&A

8:00 Continued networking

■ **About MDG**

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.

■ Speaker Biographies



Donald Lombardi

Donald Lombardi is founder and CEO of the Institute for Pediatric Innovation, a collaborative nonprofit organization dedicated to the medical needs of pediatric patients. Under Mr. Lombardi's leadership, the institute has formed partnerships with key leaders in the pharmaceutical industry, hospitals, universities and pediatric advocacy leaders to create medical devices and drugs specifically for children. Mr. Lombardi uses his extensive experience in higher education, intellectual property, and biomedical business to overcome the barriers to making medical innovations commercially available for treating children. Mr. Lombardi is also Coordinator of the Global Alliance for Pediatric Therapeutics, serves as consultant in intellectual property management to healthcare and research organizations worldwide, and is adjunct assistant professor of pediatrics at Tufts University School of Medicine. He earned an M.S. in life sciences from MIT and a B.A. from Amherst College.



George Kenney

George B. Kenney, ScD, president of EntraTympanic, participated in his first start-up before graduating from MIT and has been involved in numerous startups since as a co-founder, officer, advisor or director. Most recently, Dr. Kenney has focused on the innovative application of technology to unmet medical needs, especially in underserved areas such as pediatrics. His current focus is pediatric middle ear infections which are second only to the common cold in occurrence. This technology eliminates the use of systemic antibiotics which represent nearly half of all pediatric antibiotics, thereby mitigating both the drug resistance issue and disruption of the child's developing microbiome, which regulates their autoimmune and digestive system. Dr. Kenney has been president and co-founder of Tympanix; president, CEO and co-founder of LumenZ; associate director of MIT's Microphotonics Center; director of MIT's Materials Processing Center Industry Collegium; and associate director of MIT's Materials Processing Center. He earned bachelor's, master's and doctor of science degrees from MIT.



Aaron Sandoski

Aaron Sandoski, co-founder and managing director of Norwich Ventures, is involved in all facets of the investment process and draws from a broad background in healthcare and start-up operations to advise and support companies throughout their growth. He serves on the board of directors for Daktari Diagnostics, Pelvalon, Podimetrics and Vaxess Technologies. Previously, he served on the board of Intelligent Bio-systems (acquired by Qiagen) and was actively involved in Rhythmia Medical (acquired by Boston Scientific). Prior to co-founding Norwich Ventures, Mr. Sandoski worked for DEKA, the engineering think tank of Dean Kamen, where he helped develop partnerships and formulate business plans for emerging technologies. He has also worked in start-up operations where he helped launch a subsidiary of Express Scripts and helped launch a venture-backed payments company. He has an MBA from Harvard Business School and graduated summa cum laude from Dartmouth College with a double A.B. in chemistry and economics.

■ Upcoming Events

October 29 Networking

Experience the Incubation and Successful Launch of Life Science Companies and Medical Devices

(At Massachusetts Biomedical Initiatives office, Worcester)

Observe first-hand the incubation of life science companies. Learn of the commercialization of medical device products from concept to manufacturing to sale. This process will be examined from the perspectives of small start-up firms. There are many challenges encountered to successfully bring a new idea from concept to prototype and then to production and finally to market. The considerations are particularly daunting in the highly litigious and tightly regulated medical device market. Small startups often show a pattern towards breakthrough products or disruptive/paradigm shift type devices. Visionary leadership tends to be at the helm of the successful start-up navigating through the many technical, business and regulatory risks.

November 6 Forum

Dentistry: The Rodney Dangerfield of Medical Devices

(At Constant Contact, Waltham)

Dentistry often "gets no respect" (to borrow the words of Rodney Dangerfield) within the medical device industry, even though dental devices, equipment and lab and clinical services produce \$80 billion revenue annually in North America and \$300 billion worldwide. In this program, we'll talk about why dental is a diamond in the rough, give a brief overview of some dental basics. We also will introduce several new technologies and innovations that are already forever changing the world of dentistry, providing huge productivity gains, better fitting and functioning prosthetics, greater patient convenience and better esthetics. Many of these innovations involve the intersection of new imaging technologies (optical, X-ray, and CT), CAD/CAM software, materials, diagnostic tools and fabrication (milling and 3D rapid manufacturing). Although dental is often viewed as a separate island, many similar technologies can be found across dental and orthopedics, and other medical devices.

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MDG Member News

News You Can Use

■ New Members

MedDev welcomes new members who have joined since the Septembert Forum:

Daniel T. Brown
James Ellsworth
Pierre J. Levasseur

Douglas MacDonald
Brooke McCarthy
Aaron Muncey

Rene Myers
Allison Salke
Rudi Scheiber-Kurtz

Alexis Turjman

In addition, we welcome back those who have renewed their MDG membership:

Mario Castañeda

Anthony Colasin

Sean Phillips

Sandy von Stackelberg

■ Stay Connected with MDG



- ▶ Medical Development Group
- ▶ MDG – Product Development & Manufacturing Outsource – SIG
- ▶ MDG Marketing & Sales Special Interest Group



- ▶ twitter.com/MedDevGroup

Medical Development Group 2013-2014 Program Calendar

■ **Forum Panels** (Location: Constant Contact Headquarters, Waltham, unless noted otherwise)

- Sep 11 Boston's Emergency Medicine Response to the Marathon Attacks:
The Inside Story of Saving Lives by Advance Planning & Rapid Deployment
- Oct 9 Developing Medical Devices For Children: Opportunities & Challenges (At Children's Hospital, Boston)
- Nov 6 Dentistry: The Rodney Dangerfield of Medical Devices
- Dec 4 New Product Launch in Asia-Pacific: How to Attack an Unmet Need
- Jan 8 Challenges Within Internal Culture, Communication & Collaboration Processes
- Feb 5 Advances in Human-Robotic Interaction: Present and Future Impact on the Medical Field
- Mar 5 Commercialization of Implantable and Innovative Devices: Development of Testing Standards to Minimize Risk and Maximize Safety
- Apr 2 Cardiac Disease: From Algorithms to Products
- May 7 Medical Device Innovation Under the Affordable Care Act: Where are the Biggest Opportunities for Growth?
- June 4 Tissue Regeneration: Regenerative Medicine & Materials

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