Florida Medical Manufacturers' Consortium, Inc.

Linking technologies that save lives

FMMC REPORT

October 2011

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In This Issue

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Chairman's Message

I am pleased to report that our September Executive Briefing was a resounding success with strong attendance and a very insightful presentation by Dr. Brain Jurbala on his experience starting a medical device company and commercializing a new product, from the physician's point of view. I hope you enjoy the recap below.

The FMMC's Regulatory Working Group was organized and took up its first task: providing public comment on the IOM report concerning the 510(k) process that was discussed in last month's newsletter. The FMMC is committed to staying actively involved in providing industry input on the raft of guidance documents issued and forthcoming from the FDA.

Our membership continues to grow. With it, members are finding new ways to benefit from our programs and from the networking opportunities where they have the chance to gain insights from their industry peers. We look

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forward to continuing to grow the organization, increase the benefits to our members, and to play an increasingly stronger advocacy role in shaping the legislative and regulatory underpinnings of our industry.

Our sincere appreciation goes out to all those of you that participate in our association and support the efforts to provide for the growing success enjoyed by our industry.

Geary A. Havran
Chairman

FMMC News

The Doctor's In: Starting a Device Company from a Physician's Perspective
Packed House at September Executive Briefing Welcomes Dr. Brian Jurbala

The FMMC's September Executive Briefing welcomed Brian M. Jurbala, M.D., to hear his insights on starting a medical device company from the perspective of a physician. Dr. Jurbala, a Lakeland-based orthopaedic surgeon, has launched SonicSurg Innovations, LLC, a development-stage company that is commercializing products for use in the orthopaedic surgical field, focusing on the upper-extremity market. The capacity crowd at the Feather Sound Country Club was treated to an illuminating and in-depth presentation of not only Dr. Jurbala's young company and technology, but of his observations of the many challenges and roadblocks new medical device entrepreneurs (particularly doctors) face in bringing an invention to market in Florida. Dr. Jurbala's talk concluded on a productive and optimistic note, as he outlined several innovative ideas and capacity features (including the presence of a robust industry association like the FMMC!) necessary to support and nurture medical device innovation in our state.

Thank You to Our Renewing Members!: ETI, Hill Ward Henderson, International Medical Industries, and Fortune Business Solutions.

Do you have any exciting and important company news. Please send to info@flamedmfg.org for inclusion in our next newsletter.

Regulatory Issues

FDA Guidance Documents Plan for 2012: On September 30, 2011 the FDA published its lists of

guidance documents it plans to work on during FY 2012. The list can be found here. It is highly unlikely that the FDA will complete the documents on the list based upon historical performance, but the list does give insight into the topics that are under discussion at the agency.

New FDA Transparency Report: On October 3, 2011 the FDA released 8 draft proposals (here) for public comment under the Food and Drug Administration Transparency Initiative.

FDA Draft Guidance on De Novo Classification Process: On September 30, 2011 the FDA released the "Draft Guidance for Industry and Food and Drug Administration Staff-De Novo Classification Process (Evaluation of Automatic Class III Designation)" for public comment. The document is available here. Additional discussion can be found in the FDA Law Blog section of this newsletter.

FDA Report on Regulatory Science Released: On October 3, 2011 the FDA released its report entitled "Regulatory Science in FDA's Center for Devices and Radiological Health: A Vital Framework for Protecting and Promoting Public Health". The report is available here.

FDA Commissioner Releases Blueprint to Spur Biomedical Innovation: Titled "Driving Biomedical Innovation: Initiatives for Improving Products for Patients," the blueprint addresses concerns about the sustainability of the medical product development pipeline, which is slowing down despite record investments in research and development. The report is available here and the announcement can be found here.

Capitol Notes

by John Ray
John Ray Consulting, LLC

Washington Update

The FMMC's Regulatory Working Group recently convened to develop and submit official comments to the FDA's Center for Devices and Radiological Health (CDRH) on the Institute of Medicine's (IOM's) recent report, "Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years." The consensus of the group was to support industry's (and FDA's) position not to scrap the 510(k) device approval pathway, as recommended by the IOM study. While there is clearly room for enhancements and improvements (and our letter highlights some key ones), the 510(k) review process works well and has a strong safety record. The Regulatory Working Group will now turn its attention to a series of draft FDA guidance documents, including 510(k) Device Modifications and the De Novo Classification Process, among others. FMMC members interested in participating in upcoming meetings of the Regulatory Working Group should contact me at jray@johnrayconsulting.com or 850.270.3158.

Tallahassee Update

The Florida Legislature returned to Tallahassee this week for their October Interim Committee Meetings which were again dominated by discussion of redistricting - the redrawing of Congressional and State legislative districts. Legislators also learned that Florida's recovering economy took a turn for the worse in August, highlighted by stagnating job creation and lower-than-expected tax revenues. Earlier this spring, State budget experts had optimitically predicted that Florida would enjoy a budget surplus next fiscal year. But these revenue projections were revised this week and it is now estimated that Florida will confront a $1B-$2.5B budget shortfall for the upcoming fiscal year. Here we go again.

FDA Law Blog

FDA Issues Draft Guidance Proposing to Streamline the *De Novo* Classification Process
By Jennifer D. Nerberger

On September 30, 2011, FDA announced the issuance of a Draft Guidance, *De Novo* Classification Process (Evaluation of Automatic Class III Designation), intended to update and streamline the *de novo* review process.

The *de novo* review process, formally known as Evaluation of Automatic Class III Designation, is established by section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), as amended. This process is a compromise between the 510(k) clearance process by which over 95% of medical devices come to market in the U.S., and the more rigorous premarket application ("PMA") approval process, generally reserved for higher risk devices. It was added to the FDC Act by the Food and Drug Administration Modernization Act of 1997 ("FDAMA") to address novel devices that lack a predicate device but pose only a low to moderate risk, making them ill-suited to the PMA process. (more...)

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Tax, Finance & Accounting

What may trigger an IRS audit?

The dreaded Internal Revenue Service audit is one of the universal concerns for companies everywhere. While there is no guaranteed method to avoid an audit, a variety of situations may increase the chance for examination.

IRS officials are naturally reluctant to share details of the audit selection process. But it makes sense to direct attention to the areas where the Service has focused attention with "Market Segmentation Specialization Program" (MSSP) efforts.

The IRS has developed literally dozens of industry guides to assist auditors in their pursuit of enforcement. These audit technique guides are highly detailed, and they reveal considerable investment by the IRS. The documents are public and available on the IRS website (www.IRS.gov).

While the Service won't provide a road map for avoiding an audit, there is certainly adequate information about "areas of interest" and therefore, seemingly, audit risk. The MSSP process aims to develop highly trained examiners in specific areas with the objective of ensuring taxpayer compliance. [Read Full Article]

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Calendar of Events

FMMC Executive Briefing
"Changes in the New Electrical Standards for Medical Devices"
Speaker: Paul D. Evers, Underwriters Laboratories, Inc.
Tuesday, November 15, 2011 - 8am
Feather Sound Country Club - Clearwater, FL