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FDA Extends Date for Public Comment on IVDMIA Guidance

The FDA has extended the public comment period on the IVDMIA to March 5, 2007. Research Advocacy Network has conducted two informational webconferences to update advocates about the issues surrounding this draft guidance in preparation for comments.

The speakers on the webconferences were:

- Steven I. Gutman, MD, Director, Office of In Vitro Diagnostic (OIVD) Device Evaluation and Safety, Center for Devices and Radiological Health
- Paul Radensky, MD, JD, Partner, McDermott, Will and Emery
- Bob Erwin, Patient Advocate, Founder and President, Marti Nelson Cancer Foundation

The links to the replays are:

October 30th Briefing Playback <http://playback.claripoint.com/play/30013525>

November 2nd Briefing Playback: <http://playback.claripoint.com/play/30014417>

Other information that may be helpful as you consider your response:

- The draft guidance document: <http://www.fda.gov/cdrh/oivd/guidance/1610.html>
- The Research Advocacy Network document -Patient Considerations Click here to download [>Patient Considerations](#).
- Also, an example of the public comment made by Research Advocacy Network on this issue is available to download: [RAN Public Comment IVDMIA](#)

Nanotechnology in Cancer Research

The NCI Alliance for Nanotechnology in Cancer is a comprehensive, systematized initiative encompassing the public and private sectors, designed to accelerate the application of the best capabilities of nanotechnology to cancer.

Currently, scientists are limited in their ability to turn promising molecular discoveries into benefits for cancer patients. Nanotechnology can provide the technical power and tools that will enable those developing new diagnostics, therapeutics, and preventives to keep pace with today's explosion in knowledge.

Nanotechnology is making major inroads in advancing cancer research. For more information about the latest announcements go to <http://nano.cancer.gov/>. Topics from *Nanotech News*, November 20th include:

- [Nanotechnology Continues to Advance Anticancer Gene Therapy](#)
- [Improving Blood Stem Cell Transplants, Bioseparations Using Magnetic Nanoparticles](#)
- [Watching a Tumor Cell Migrate](#)

Issues and concerns about the technology was a recent topic of a publication in the journal, *Nature*. In the article, Chief Science Officer, Project on Emerging Nanotechnology Woodrow Wilson Center, Dr Andrew D. Maynard and his co-authors discuss the pursuit of responsible nanotechnologies.

To link to the full article or to review a webcast of the public event to discuss these issues please go to: <http://www.nanotechproject.org/95/111606-scientists-set-five-grand-challenges-for-nanotechnology-risk-research>

FDA Approves Silicone Gel-Filled Breast Implants After In-Depth Evaluation

After rigorous scientific review, the U.S. Food and Drug Administration (FDA) has approved the marketing of silicone gel-filled breast implants for breast reconstruction in women of all ages and breast augmentation in women ages 22 and older. The products are manufactured by Allergan Corp. (formerly Inamed Corp.), Irvine, Calif., and Mentor Corp., Santa Barbara, Calif.

"FDA has reviewed an extensive amount of data from clinical trials of women studied for up to four years, as well as a wealth of other information to determine the benefits and risks of these products," said Daniel Schultz, M.D., Director, Center for Devices and Radiological Health, FDA. "The extensive body of scientific evidence provides reasonable assurance of the benefits and risks of these devices. This information is available in the product labeling and will enable women and their physicians to make informed decisions."

In the past decade, a number of independent studies have examined whether silicone gel-filled breast implants are associated with connective tissue disease or cancer. The studies, including a report by the Institute of Medicine, have concluded there is no convincing evidence that breast implants are associated with either of these diseases. However, these issues will be addressed further in the postapproval studies conducted by the companies.

FDA approved the silicone gel-filled breast implants with a number of conditions, including requiring each company to: conduct a large postapproval study; continue its core study through 10 years; conduct a focus group study of the patient labeling; continue laboratory studies to further characterize types of device failure; and track each implant in the event, for example, that health professionals and patients need to be notified of updated product information.

The postapproval studies will continue to gather information about the safety and effectiveness of the implants. Information will be collected about rates of local complications, rates of connective tissue disease and its signs and symptoms, rates of neurological disease and its signs and symptoms, potential effects on offspring of women with breast implants, potential effects on reproduction and lactation, rates of cancer, rates of suicide, potential interference of breast implants with

mammography, and MRI compliance and rupture rates.

The postapproval studies will be closely monitored by FDA. FDA anticipates that data from the studies will provide important information for patients and physicians, and may lead to improvements in device labeling.

From the FDA website <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01512.html>.

RAN Co-Founder Changes Role

Judy Perotti Semi-Retires

We wish to express our sincere gratitude to Judy Perotti as she leaves Research Advocacy Network board and leadership. Judy was one of the original co-founders of Research Advocacy Network. She is a talented writer and a strong advocacy voice. She hopes to continue her advocacy work as she "semi" retires with her husband, Bob. For more information about her plans please see her at the San Antonio Breast Cancer Symposium or contact her via email at japero@ameritech.net. Our best wishes to Judy!

Alamo Breast Cancer Foundation Hot Topics 2006

Each year the Alamo Breast Cancer Foundation sponsors a mentor program at the San Antonio Breast Cancer Symposium. Following the symposium (after approximately 3 months) they publish a Hot Topics publication/CD from the year's symposium. For more information go to <http://www.m3login.com/Content/E99FDD09-0391-4793-B2A2-A227AE1DD322/>.

Research Advocacy Network Activities

- Nov 7 -8 Summit on Cancer Clinical Trials
- Nov 14 PRIM&R Community Member Training
- Nov 15- 17 PRIM&R Annual Meeting
- Nov 28 - 29 caBIG Data Sharing and Intellectual Capital Meeting
- Dec 14-17 San Antonio Breast Cancer Symposium

We need your help! Your Donation Makes a Difference! If you believe in the hope of research and the power of advocacy, you can help the Research Advocacy Network (RAN) by sending a donation. RAN is an exempt 501 c 3 organization and dependent on your support to keep going.

PLEASE NOTE our new mailing address is: 6505 W. Park Blvd, Suite 306, PMB 200, Plano, TX 75093.
Thanks!

Research Advocacy Network Welcomes New Members!!! Thanks to all of you who have recently joined the Network. For those that have not yet please go to <http://www.researchadvocacy.org/> and click on "Join" There are no dues for Network membership and this will assure that you receive all notices and have access to Network programs.

Editor: Elda Railey

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