

In this issue...

- NCI Announces Results of ACRIN Study Comparing Digital and Film Mammography for Breast Cancer Screening
- Saving Research from the Forces of Nature
- New Leadership at the FDA is Announced
- New Fact Sheets Available
- Research Advocacy Network Website
- Research Advocacy Network Activities
- Your Two Cents Make a Difference!

NCI Announces Results of ACRIN Study Comparing Digital and Film Mammography for Breast Cancer Screening

The National Cancer Institute (NCI) recently announced results of the Digital Mammographic Imaging Screening Trial (DMIST), which evaluated digital versus film – also known as traditional – mammography in detecting breast cancer in the general population of women in the trial. The study was conducted by the American College of Radiology Imaging Network (ACRIN), and determined that the diagnostic accuracy of digital and film mammography was very similar in the overall population. However, digital mammography was found to be significantly more accurate in three subsets of patients: women under 50 years of age, women with heterogeneously or extremely dense breasts, and pre- and peri-menopausal women.

Beginning in October 2001, the trial enrolled 49,528 women who had no signs of breast cancer at 33 sites in the United States and Canada. Patients in the study were given both digital and film mammograms, which were interpreted independently by two different radiologists. The breast cancer status of each patient was determined through a breast biopsy done within 15 months of entering the study or through a follow-up mammogram at least ten months after study entry.

The study also had two secondary goals: measuring the relative cost-effectiveness of both digital and film technologies, as digital mammography costs 1.5 to 4 times more than film mammography; and evaluating the effect on participants' quality of life due to the expected reduction of false positives. Data on these secondary goals is still under analysis and will be available at a later date, according to the NCI.

In spite of learning that three subsets of patients benefit significantly from digital mammography, these trial results leave many questions unanswered for women and their physicians. Since neither technology demonstrated superiority in screening the overall population, which tool should women ask for when receiving a mammogram? Or should women ask to be screened with both film and digital mammograms, since each test sometimes caught tumors that the other test missed?

Even more importantly, it would be helpful to understand whether either of these screening techniques can actually result in saving women's lives. Or whether breast cancer patients benefit specifically from undergoing either digital or film mammograms. But the DMIST protocol was not designed to answer questions about mortality, and the subset of breast cancer patients studied in the trial was too small to make any clear determinations about which test might be more effective for that population.

In thinking about the limitations of this study – as well as the limitations of many clinical studies – it is important to consider how we can positively effect change. As advocates who frequently have a seat at the table when studies are being designed, we have an opportunity to voice these questions early in the process, so that we can help ensure that clinical trials will answer the most relevant and pressing questions that patients face.

For more information on the DMIST study, the abstract is currently available online at the New England Journal of Medicine's web site at <http://content.nejm.org/cgi/content/abstract/NEJMoa052911>. The full study will be published in the October 27th issue of the NEJM.

Saving Research from the Forces of Nature

You may have read the recent *MedPage Today* article about Dr. Tyler Curiel, a Tulane Medical School cancer immunologist, who returned to a flood- and hurricane-ravaged New Orleans in order to save decades worth of medical research samples. He and his colleagues broke into their laboratory, armed with tanks of liquid nitrogen, to rescue as many tissue samples as possible.

And while Dr. Curiel's efforts are courageous, there have been many similar stories emerging in the wake of both hurricane Katrina and Rita, as the research community has come together to preserve and protect medical research materials that survived the storms.

Unfortunately, it is estimated that Tulane and Louisiana State universities' medical schools lost thousands of laboratory animals to flood waters and starvation, while tissue samples thawed after the electricity was cut and labs were abandoned. According to an initial survey by the National Institutes of Health (NIH), about 300 federally-funded projects at New Orleans colleges and universities worth more than \$150 million were affected in some way by hurricane Katrina. And the National Cancer Institute (NCI) has reported that approximately 7,500 patients participating in clinical trials in the Gulf Coast area were affected by the hurricane.

In the aftermath of all this damage, several organizations have established help-lines and resources for the researchers and patients affected by the hurricanes. We have included this information for you below, in the hope that together we can assist those who have lost vital research, tissue samples, and lab equipment, so that perhaps all of our investment in critical research won't be lost.

Resources for Researchers and Patients

- **National Cancer Institute (NCI)**

For patients who are on NCI-sponsored clinical trials – and doctors who are asked to treat cancer patients who have been on an NCI-sponsored trial – NCI has established a phone number to call for information: 301-496-5725. This line will be answered from 8:30 a.m. to 5:00 p.m. Eastern Time. After hours and on weekends, callers can leave a message and an NCI employee will respond within an hour. During the emergency, NCI will send cancer investigational drugs for displaced patients to sites that had not previously participated in the trials; assist with sharing of cancer drug supplies; assist with regulatory issues; and provide protocols to physicians caring for cancer trial patients in emergency situations. Additional details are available through the NCI

number listed above. More information is available on NCI's web site at <http://www.cancer.gov/newscenter/pressreleases/Katrina-and-Rita>, including key NCI program contacts to help research grantees with their inquiries and concerns.

- **American Society of Clinical Oncology (ASCO)**
ASCO has established a Hurricane Message Board to help re-connect patients with their healthcare providers. Additionally, ASCO has a list of oncology care providers who can treat displaced patients. For more resources, go to http://www.asco.org/ac/1,1003,12-002144-00_18-0041924,00.asp, including information on financial assistance for displaced patients.
- **American Association of Clinical Research (AACR)**
AACR has launched "Saving the Science," a series of services available for members, as well as for students, fellows, clinicians, and researchers in the Gulf Coast. Specific services include a registry for displaced scientists to locate and re-connect with colleagues, a list of resources and equipment being offered by other institutions for displaced scientists, and travel grants for researchers to temporarily relocate to host institutions to continue their research. Detailed information on "Saving the Science" is available at <http://www.aacr.org/default.aspx?p=4468>.

Other Resources

Many other organizations and cooperative groups have also established resources for those affected by the hurricanes. For that information, please go to these web sites:

- National Institutes of Health (NIH) www.nih.gov
- Radiation Therapy Oncology Group (RTOG)
http://www.rtog.org/HKatrina_Trials_Participant.html
- American Society of Therapeutic and Radiation Oncologists (ASTRO) www.astro.org

New Leadership at the Food & Drug Administration is Announced

As many of you may be aware, there have been major changes in the leadership at the Food & Drug Administration (FDA) recently. Dr. Lester M. Crawford resigned as FDA Commissioner on September 23rd, surprising many within the advocate community since Dr. Crawford had recently been confirmed as FDA Commissioner after serving as Acting Commissioner for three years. With the departure of Dr. Crawford, President Bush has appointed Dr. Andrew C. von Eschenbach, the current Director of the National Cancer Institute (NCI), to assume the position of Acting FDA Commissioner.

Dr. von Eschenbach has accepted the President's appointment, and he will now oversee the activities of both the FDA and the NCI. Although Dr. von Eschenbach's role at the FDA is currently designed to be an interim position, it is unclear whether he will eventually be confirmed as FDA Commissioner. It is also unclear whether Dr. von Eschenbach will remain in both leadership positions on a long-term basis, or whether he will eventually stay with just one of the agencies.

Dr. von Eschenbach's appointment to the FDA raises many questions for the patient advocate community. There may be conflicts of interest in combining the responsibilities and roles of the FDA Commissioner and NCI Director. While the NCI is charged with funding and conducting cancer research, the FDA is responsible for rigorously reviewing, approving and regulating that research. Additionally, the FDA is responsible for overseeing more than just cancer research. Will Dr. von Eschenbach's expertise in cancer limit his ability to fairly review therapeutics and research in other disease areas, or will new cancer therapies be prioritized ahead of rare and infectious diseases and chronic conditions?

There are also concerns about the logistics of one person serving in a dual role. How will Dr. von Eschenbach be able to effectively manage both agencies, given that FDA and NCI are each unique and complex organizations? It raises the question of whether each organization deserves its own director, who can remain focused and dedicated to its organization's mission and vision.

While there are many questions and concerns about how Dr. von Eschenbach navigates this new role, it is important to consider the possible benefits that could result from this consolidation of leadership. In a letter to the advocate community that Dr. von Eschenbach sent on September 26th, he stated that "I've made it one of my top priorities for NCI to collaborate with the FDA to develop a series of joint initiatives. The two organizations are now working together on translational research, a critical aspect of the continuum of scientific discovery, development of new interventions, and delivery of treatments. Among other projects, NCI and FDA have announced a joint program to train a key group of young scientists – at both institutions – to understand both bench research and the process of drug approval." This is an optimistic message from Dr. von Eschenbach, and we will wait to see if he will find a way to increase understanding and communication between the two agencies while reducing bureaucracy and waste.

Hopefully Dr. von Eschenbach will take his experience with the evolution of cancer research and the development of targeted therapies and apply that knowledge to many disease areas, to advance new treatments for all patients – not just cancer patients. As advocates, we have a role in helping both Dr. von Eschenbach and the patient community by working to ensure that it is science – not politics – that is driving the important work at both the NCI and the FDA forward.

New Fact Sheets Available

Two new fact sheets have been added to the "What it Means for Me" Fact Sheet Series. The new topics are on the results of the Avastin and Herceptin studies in breast cancer. These are available for download on the [Research Advocacy Network Publications](#) area of the website.

- [Avastin Studies: What It Means For Me](#)
- [Herceptin Studies: What It Means For Me](#)

Research Advocacy Network Website www.researchadvocacy.org

Check out the first version of our new website at www.researchadvocacy.org. New areas have been added and more will come soon. Be sure to join Research Advocacy Network with the "Join" link. There is no charge for Network membership and this will assure that you receive all notices and have access to Network programs.

Research Advocacy Network Activities:

Sept 16-18 NSABP (National Surgical Adjuvant Breast and Bowel Project)
Sept 19-23 NCCTG (North Central Cancer Treatment Group)
Sept 26-27 Summit on Cancer Clinical Trials
Oct 1 Presentation at Colon Cancer Alliance Conference
Oct 5 Indiana Cancer Consortium
Oct 5 IRB Community Member Training, Rush University Medical Center
Oct 6-9 Lynn Sage Breast Cancer Conference
Nov 18-21 ECOG (Eastern Cooperative Oncology Group)
Dec 3 PRIM&R / ARENA Pre-Conference Workshop for IRB Community Members
Dec 3-6 PRIM&R / ARENA Annual Conference
Dec 8-11 San Antonio Breast Cancer Conference

Do you know of conferences/meetings/ activities that you would like posted to the calendar? Let us know at info@researchadvocacy.org.

Your Two Cents Make a Difference!

If you believe in the hope of research and the power of advocacy, you can help the Research Advocacy Network just by shopping! Your two cents can make a difference – how do you make that happen? Just by buying your office supplies, books, sporting gear, CDs and everyday items at through the iGive Mall at www.iGive.com/ResearchAdvocacyNetwork. You can shop at 500+ stores and without even knowing it, you'll be helping Research Advocacy Network at the same time.

Of course, if you'd rather just send a check we would greatly appreciate that!!! We are an exempt 501 c 3 organization and dependent on your support to keep going. Our mailing address is 309 East Rand Road, Suite 175, Arlington Heights, IL 60004. THANKS!!!!

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