

In this issue...

(click on the title to jump to the story)

- [**Report from the National Cancer Advisory Board Meeting**](#)
- [**Controversy and Questions Surround the CIRB and Its Utility**](#)
- [**Followup: New Leadership at the FDA is Announced**](#)
- [**Colon Cancer Alliance Annual Conference**](#)
- [**New Fact Sheets Available**](#)
- [**Research Advocacy Network Website**](#)
- [**Research Advocacy Network Activities**](#)
- [**Your Two Cents Make a Difference!**](#)

Report from the National Cancer Advisory Board Meeting

The National Cancer Advisory Board (NCAB) recently convened its quarterly meeting in Bethesda, Maryland on September 20-21, 2005. The NCAB functions as an advisory board to the Secretary of the Department of Health and Human Services (DHHS) and the Director of the National Cancer Institute (NCI). Members of the NCAB are appointed by the President of the United States, and the board is comprised of researchers, academicians, physicians, and advocates with expertise in cancer research. Of specific interest at the recent NCAB meeting were the reports from three working groups which are focused on: translational research; increasing the efficiency of NCI's biorepositories; and ensuring the recruitment of under-represented populations in clinical trials.

Dr. Ernest Hawk, Director of the Office of Centers, Training and Resources for NCI, presented the report from the Translational Research working group, which supports the role of translational research in evolving medicine from treating cancer at the time of diagnosis to predicting and preventing cancer before it begins. As part of this, the Translational Research working group tracks the support grants going to cancer centers, and works to promote collaboration and coordination between those centers and the community. This working group also monitors the SPORE (Special Programs of Research Excellence) program, which focuses on developmental research and transforming novel ideas into clinical interventions. Dr. Hawk's report emphasized the role of the working group in evaluating the current status of NCI's investment in translational research – such as cancer center grants and SPORE funding – while also providing vision to ensure that these programs are aligned with NCI's 2015 goal of eradicating death and suffering due to cancer. Currently, his working group is embarking on the research and strategic planning necessary to create the recommendations that will ultimately provide this vision for NCI's translational research efforts.

A report on NCI's efforts to streamline its biorepositories was presented by Dr. Anna Barker, Deputy Director of Advanced Technologies and Strategic Partnerships at NCI. This working group is charged with developing policies and procedures for NCI's biorepositories to use, in an effort to promote the utilization of patients' tissue samples to help advance crucial research. Dr. Barker's report centered on two meetings that the working group held this past summer, to gather researcher and advocate input on key issues surrounding biorepositories. The first meeting focused on the policies and procedures needed to ensure that biorepositories work efficiently, and the second meeting discussed the ethical and legal implications of storing and using patients' tissue samples. The Research Advocacy Network – along with other advocates – attended both these meetings to provide input from the community's perspective. This input was then used by Dr. Barker and the working group as the basis for their recommendations, which included implementing consistent "best practices" for each biorepository to use; developing quality assurance standards including stringent staff training and standard operating procedures for labs; creating a standard consent document for patients; and developing guidelines for disclosing research results to patients.

Another report of interest was given by Dr. Robert Croyle, Director of the Division of Cancer Control and Population Sciences at NCI, sharing the compiled findings from 45 different studies examining barriers and opportunities to trial enrollment in varying populations and age groups. The working group confirmed that some of the most common barriers to trial participation include a mistrust of research and the medical system, lack of education about clinical trials, logistical constraints, and perceived harms. Based on its analysis of these studies, the working group developed recommendations such as: requiring each clinical trial to report its recruitment goals and results; training investigators to be sensitive to the varying needs of patient populations; evaluating the role of under-represented healthcare professionals in clinical trial recruitment; and studying targeted recruitment interventions to identify effective methods for outreach.

These working group reports – as well as the other presentations at the NCAB meeting – give us a glimpse of the direction that cancer research and collaboration is heading. Because this meeting touched on several areas of interest and concern to advocates, the community should stay attuned to NCAB's progress to help ensure that patients' interests remain central to its efforts.

[Back to "In this issue...."](#)

Controversy and Questions Surround the CIRB and Its Utility

Follow-up The Coalition of Cancer Cooperative Groups convened a meeting of its Patient Advisory Board (PAB) on September 27th to discuss issues central to encouraging progress in cancer research and increasing patient participation in clinical trials.

A key agenda item discussed at this meeting was the controversial role of the Central Institutional Review Board (CIRB) in approving protocols and amendments to Phase III clinical studies. The concept of the CIRB emerged as a solution to provide independent review of approved protocols, in an effort to help expedite the review process at local Institutional Review Boards (IRBs). Launched in 1998, the intent behind the development of the CIRB – which is a National Cancer Institute (NCI)-sponsored organization – was to streamline the approval process for all Phase III multi-center trials conducted by the cooperative groups, by eliminating the work of protocol review at the local IRB level.

When the CIRB was implemented seven years ago, it was done so as a pilot initiative with just a handful of local IRBs participating, and with plans to evaluate its effectiveness prior to expanding the program. However, shortly after the program was introduced, the Cancer Therapy Evaluation Program (CTEP) – an arm of NCI – decided that the CIRB's decisions should apply to all local IRBs, regardless of whether or not they were part of the pilot program. Local IRBs that prefer to review protocols

according to their own procedures – rather than accepting the CIRB’s process – cannot begin enrolling a study before the CIRB has approved it. Some advocates believe that this type of bureaucracy can delay a study from opening for up to two months, ultimately hurting cancer patients who may be dying while they wait for a clinical trial to begin enrollment.

And this effort to make local IRBs conform to the CIRB doesn’t make sense when you look at the numbers. Advocates close to the program estimate that currently only 10-20% of local IRBs have opted for representation by the CIRB, so it is concerning to them that CTEP wants the CIRB to retain influence over all IRBs.

To help remedy the situation, the PAB conducted in-depth interviews with 39 stakeholders and compiled a thorough report of recommendations for the Director of NCI in August of 2002. Unfortunately, advocates involved with the development of that report believe that NCI has yet to respond to or implement those recommendations. Members of the PAB have also offered to help the CIRB with problems related to ensuring consistency among informed consent forms, but have had no support or response from the CIRB’s leadership on that.

With so much controversy and concern swirling around the CIRB, observers have asked NCI to evaluate the body so the community can quantify whether it has been effective in streamlining protocol review or whether it has just added another layer of complication to the process. After several years of requests from the advocate community, NCI has agreed to an evaluation which is just now being implemented. But because the CIRB is contracting out the audit, there is some hesitation that it may not be truly objective because it is not an independent review.

In spite of this ongoing debate, the PAB did have possible solutions for some of the issues that the CIRB faces. Perhaps most crucial, some advocates on the Patient Advisory Board recommend that the CIRB remove the constraint that local IRBs – which are not affiliated with the CIRB – must still wait for the body’s approval on trial protocols and amendments. Advocates believe that this change would positively impact patients by reducing the delays caused by the CIRB.

Some advocates wonder how the CIRB has continued to exist without any formal evaluation being completed, and without any pre-determined metrics on what constitutes success. These are accountability issues that come up with any new program or initiative. So we as advocates must learn from the CIRB’s challenges in order to ask tough questions of other pilot programs that we are involved with, helping to ensure that science and patients do not suffer as a result of disorganization.

[Back to "In this issue...."](#)

New Leadership at the FDA is Announced

*The following is a follow up to an article in last month’s Network News available at:
http://www.researchadvocacy.org/publications/html/networkNews_v3-09.htm*

On Friday, September 30th Andrew von Eschenbach, the director of the National Cancer Institute and newly appointed acting commissioner of the FDA, announced he will give up his daily duties at the NCI to focus on his new position at the FDA. John Niederhuber, former director of the University of Wisconsin Comprehensive Cancer Center, will manage day-to-day operations at the NCI.

The announcement was in response to criticism from Congress and some watchdog groups that Von Eschenbach could not perform both jobs well and that he would face conflicts of interest. Von Eschenbach stated that while at the FDA he would “not participate in FDA reviews of drugs researched

by the NCI, FDA oversight of potential side effects seen in NCI-sponsored studies or other matters involving NCI as a party in which FDA is exercising its regulatory authority." Critics are calling for both agencies to have permanent, competent, full-time leaders.

*Source: Reuters News, Friday Sep 30, US FDA head gives up cancer duties after criticism.
http://news.yahoo.com/s/nm/20051001/hl_nm/fda_dc&printer=1*

[Back to "In this issue....."](#)

Colon Cancer Alliance's Colorectal Cancer Conference

The Colon Cancer Alliance (CCA) held their 5th Annual Conference, Finding Hope, in Newark, NJ, September 30 to October 2. This year's successful conference was attended by about 200 colorectal cancer (CRC) patients, survivors, caregivers, and family members. The program covered advances in the treatment of CRC, including radiation, surgery, oncology and integrative medicine.

A unique feature of the conference was separate survivor's and caregiver's forums, followed by the forum "Roots of Support: Bridging Support for Survivors and Caregivers". Each of these panel sessions provided an opportunity for attendees to ask questions of healthcare professionals and their peers, which generated discussion among the audience. The sessions were marked by the openness of participants to share their experiences.

There were also breakout sessions that addressed Hope and Quality of Life, Managing Metastatic Disease, Pain Management and Palliative Care, and Making Your Voice Count in Your Community. Making Your Voice Count was co-lead by Angela Brown, manager of CCA's Voices project, and Judy Perotti, co-founder of RAN. Judy presented an overview of patient advocacy and clinical trials, while Angela presented an over view of the CCA's Voices project. Voices campaign will introduce colorectal cancer (CRC) to local communities, as well as uniting CCA volunteers across the country. Each Voice's Chapter is encouraged to participate in advocacy and event functions. A list of current Voice's Local Chapters can be found at <https://www.ccalliance.org/what/voiceschapters/chapter.html>

For more information about CRC advocate groups visit:

- Colon Cancer Alliance at <https://www.ccalliance.org/>
- Colon Cancer Coalition at <http://www.c-three.org/>
- Association of Cancer Online Resources (ACOR) for online support group at <http://www.acor.org/>
- Colorectal Cancer Network at <http://www.colorectal-cancer.net/>
- United Ostomy Association at <http://www.uoa.org/>
- Hereditary Colon Cancer Association at <http://www.hereditarycc.org/>
- Bowel Cancer UK (United Kingdom) at <http://www.bowelcanceruk.org.uk/>
- National Colorectal Cancer Research Alliance (Katie Couric's group) at <http://www.eifoundation.org/national/nccra/splash/index.html>

[Back to "In this issue....."](#)

Correction:

The reference to AACR was incorrect in the last issue of Network News. It should be the American Association for Cancer Research. More information about AACR can be found at: www.aacr.org. Our apologies to AACR for any confusion.

[Back to "In this issue....."](#)

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](#)

[Back to "In this issue....."](#)

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.

[Back to "In this issue....."](#)

Research Advocacy Network Activities:

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

Oct 31.....NCCN/ RAN Advocate Lecture Series Webconference 1: Research Into Practice

Nov 7.....NCCN/ RAN Advocate Lecture Series Webconference 2: Research Into Practice

Nov 14.....NCCN/ RAN Advocate Lecture Series Webconference 3: Research Into Practice

*For more information about this Lecture Series, please email info@researchadvocacy.org

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 Symposium

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

[Back to "In this issue....."](#)

Your Two Cents Make a Difference!

We need your help! If you believe in the hope of research and the power of advocacy, you can help the Research Advocacy Network by sending a donation. RAN is 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!!!

Another way to donate is just by shopping! Just by buying your office supplies, books, sporting gear, CDs and everyday items at 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. A check was just received from this program and we want to say thank you for supporting Research Advocacy Network in this way!

[Back to "In this issue....."](#)

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[Back to "In this issue....."](#)

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