

Issue 19, Fall/Winter 2011



THE VOICE

for Women & Families

Cancer Screening: When Does It Save Lives?

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National Research Center for Women & Families

www.center4research.org

We are dedicated to improving the health and safety of adults and children by using research to develop more effective treatments and policies.

Cancer Prevention and Treatment Fund

www.stopcancerfund.org

Our Cancer Prevention and Treatment Fund helps adults and children reduce their risk of getting cancer and helps everyone get the best possible treatment.

CFC # 11967

For some cancers, regular screening seems to really pay off, allowing doctors to catch and treat cancer early on, before it has spread elsewhere in the body. But screening is not the same thing as prevention, and experts are wondering if we haven't put too many dollars into some types of screening that add costs to health care and do not necessarily save lives.

Prostate Cancer: Screening Risks Outweigh Benefits

Prostate cancer screening has been a hot topic in the news. Until recently, experts from the U.S. Preventive Services Task Force advised that screening was not recommended for men over 75 and that there was insufficient evidence to recommend **for or against** screening men under 75 for prostate cancer – whether by the PSA blood test or by digital rectal exam (DRE).

In October 2011, the Task Force revised its position and **now recommends against screening healthy men of any age for prostate cancer.** They determined that the PSA test, with or without DRE, doesn't save lives and too often results in needless tests and treatment with life-altering consequences. For example, between 1986 and 2005, a million men in the U.S. were treated for prostate cancer with surgery, radiation therapy, or both. According to the Task Force, 5,000 of those men died following the surgery, as many as 70,000 had serious complications, and 200,000 to 300,000 suffered incontinence, impotence, or both.

PSA tests measure a protein in the blood that can indicate cancer causing cells in the prostate. However, an infection or other minor health problem can also elevate PSA levels, which tend to rise with age. In fact, 60% to 75% of men with high PSA levels that undergo biopsies do not have cancer. Unfortunately, the biopsy itself can cause infections and more serious problems.

On the other hand, there are patients who say that their lives were spared by PSA screening. Are they right? The Task Force concluded that men with possible symptoms, such as blood in the urine, should be screened (or biopsied), but that screening does more harm than good for the general population of men over 50. In contrast, patients at higher risk—those who are overweight, African-American, or have a family history of prostate cancer—will want to ask their doctors about screening.

Some of the opposition to the Task Force recommendations comes from those who have a financial incentive to treat prostate cancer. Treatment with radioactive seed implants (IMRT), for instance, is very expensive for patients but profitable for those who have invested in the multimillion dollar technology.

Autopsies show that one-third of men 40 to 59 years-old have prostate cancer that was undiagnosed and unrelated to their death. Does that mean it's better not to know? Once a man knows a cancer is inside him,

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FOREMOTHERS

Inspiring Women: Our 2011 Honorees

Every year, our Foremothers Award Luncheon achieves the impossible: it's even better than the year before. At the event, we celebrate remarkable women and men whose accomplishments have touched millions of lives.

Cathy Merrill Williams, publisher of *Washingtonian* magazine, gave opening remarks and spoke of being the fortunate product of "strong, smart, and resourceful" women. Her grandmother came to the U.S. at the age of 16, with no family other than her brother. She was soon on her own, when her brother died in the 1918 flu epidemic days after she reached Ellis Island. Cathy shared her mother's observation that "the most talented among us work the hardest, stay the longest, and don't forget where they came from." Cathy's mother worked with Ethel Merman when the famous singer was starring on Broadway. When she wasn't rehearsing, Miss Merman would sit and take steno notes of what others were saying. When asked why, Miss Merman responded, "I started out as a secretary and I never forget that if this thing doesn't work out..."

Foremother Honorees

We honored **Vicki Sant**, a visionary philanthropist who co-founded the Summit Foundation and the Summit Fund of Washington. The Summit Foundation provides support for international adolescent leadership training, reproductive health initiatives, and the conservation of the Mesoamerican Reef ecosystem. The Summit Fund of Washington focuses its efforts on improving the health and sustainability of the Anacostia River and preventing teen pregnancy in the District of Columbia.

We asked all the honorees to talk about a personal experience showing how times have changed or not changed for women. Mrs. Sant spoke with warmth and humor about her undergraduate years at Stanford, which had a quota of 30% women, which was "fine for dates," but noted that the quota was not officially voted out until 1973. Her desire to go to law school was squelched by her college adviser, who told her, "We only admit 2 or 3 women each year, so don't even apply." Although more than half the law students at Stanford today are women, Mrs. Sant observed that even now "the glass ceiling is cracked, not broken."

Mrs. Viorst spoke eloquently and candidly about growing up in the 1940s and 1950s, when it did not matter what talents a woman possessed as "we were nothing unless we had a husband and kids.... So we went to college to find a good provider and become a good listener." Once you were married, her mother told her, "then you can talk." Fortunately, her husband was the "wind beneath my wings" and supportive of her writing. Mrs. Viorst concluded that despite the challenges women still face, "The world is a hugely different and a better place for women today."



Photo by Gwen Lewis
Foremothers, past and present. From left to right: Connie Morella, Elaine Newman, Vicki Sant, Ruth Nadel, Omega Logan Silva, Fann Harding, and Judith Viorst.

Mrs. Sant thanked the National Research Center for Women & Families, saying "The work that you do for women and families is just remarkable and so important" noting that, "It's just extraordinary what you accomplish."

We also honored **Judith Viorst**, the award-winning author of much-loved children's books such as *Alexander and the Terrible, Horrible, No Good, Very Bad Day*, as well as nonfiction favorites for adults such as *When Did I Stop Being 20 & Other Injustices*.

Another Foremother honoree was **Congresswoman Eleanor Holmes Norton**, the sole Congressional representative of Washington, D.C. for the last 20 years. Ms. Norton is especially respected for fighting discrimination and standing up for the rights of women, minorities, and D.C. residents. She was the first woman to chair the U.S. Equal Employment Opportunity Commission. Unfortunately, she arrived too late to make her remarks.

FOREMOTHERS

Health Policy Hero

Dr. Margaret Hamburg, the FDA Commissioner, was selected as our Health Policy Hero for her devotion to the agency's mission to protect all Americans from unsafe food, drugs, and devices, as well as make it possible for life-saving medical products to get to patients who need them. Commissioner Hamburg proudly attributed her accomplishments to the inspiration provided by her mother, Dr. Betty Hamburg, who also attended the luncheon. As the first African American woman to be admitted to both Barnard College and Yale Medical School, Dr. Betty Hamburg set an example for not just her daughter but all women, showing what they can achieve, although "she made it look too easy."

Commissioner Hamburg expressed her pride in being part of a team with "dedicated professionals that make a difference from the food you eat to the sun screen you put on." Admitting that she didn't consider herself a "health policy hero or a hero of any kind," she quoted Eleanor Roosevelt, saying, "We do not have to become heroes overnight. Just a step at a time, meeting each thing that comes up, seeing it as not as dreadful as it appears, discovering that we have the strength to stare it down."

In receiving her award, Dr. Hamburg praised NRC for Women & Families and its dedicated staff for its work that "holds us accountable and advocates for the critical issues FDA must stand for." She



Photo by Gwen Lewis

Drs. Margaret and Betty Hamburg thanked the organization for its devotion to ensuring the well-being of our nation by demanding a strong and intelligent regulatory agency.

Closing remarks were made by NRC board member **Judith Harris**, who thanked everyone for coming and humorously reminded the audience that although asking for donations is not allowed at the Cosmos Club, the Center's budget took a hit because of the economy and that its dedicated and amazing staff was possibly "the worst paid in Washington."

This year's luncheon was held at the historic Cosmos Club of Washington, D.C., and was supported by many nonprofit organizations including the **American Association for Justice, the American Medical Women's Association, National Consumers League, National Business Group on Health, National Organization for Women, National Women's Health Network, Population Action International, Sierra Club, TMJ Association, Truth in Medicine, Union of Concerned Scientists, and Woody Matters.**

Generous corporate sponsors included **Morgan Stanley Smith Barney LLC, Walmart, Kaiser Permanente, Net-Centric Enterprise Solutions (NES), Akin Gump Strauss Hauer & Feld LLP, and the Cooley & Darley Insurance Agency.**

To see and hear the speakers' remarks in their entirety, visit the NRC for Women & Families' YouTube channel at: <http://www.youtube.com/user/nrc4wf>

Leaving a Legacy

Friends and loved ones are helping us honor **Lenora Moody, Marcy Gross, Ros Brannigan, Joy Simonson, and Omega Logan Silva** by naming internships in their honor.

Is there someone you would like to honor? Internships and fellowships provide training that can result in a lifetime of good works. Honor a friend or family member through a donation of cash or stock, a distribution from a retirement plan or life insurance policy, or a will.

For more information, call Brandel at (202) 223-4000 or e-mail her at bfb@center4research.org.

We have a Facebook page! Click the "Like" button to follow us at www.facebook.com/nationalresearchcenter. You can also follow us on Twitter @NRC4WandF for regular health news and event updates.

POLICY MATTERS

Is It Safe? Institute of Medicine Report Says We Don't Know

Reading the new Institute of Medicine (IOM) report on medical devices will make your heart race and your knees weak, even if you don't have a defective heart device or a defective artificial knee.

In a surprisingly blunt report, the well-respected IOM said the FDA's most frequently used process to determine if medical devices can be sold in the U.S. "was not designed to determine whether a new device provides a reasonable assurance of safety and effectiveness or whether it promotes innovation."

Most medical devices, including artificial hips, knees, and ankles; glucose test strips for diabetics; contact lenses; and many cardiac devices, are allowed to be sold after what is called a 510(k) review by the FDA. Unlike the review for prescription medications, the 510(k) process allows thousands of new medical devices on the market without testing them in clinical trials if the devices are somewhat similar to ones already on the market. Unfortunately, most of these previous devices were also never proven safe or effective.

"You've heard about this in the media," points out NRC president Dr. Diana Zuckerman. "Hips and heart implants and many other devices were sold to thousands of people before anyone realized that they were not safe or did not last very long. They never would have been sold to anyone if they had been carefully tested on humans first."

In a study that NRC staff conducted with Dr. Steven Nissen of the Cleveland Clinic, published in the prestigious *Archives of Internal Medicine*, we found that three out of

four medical devices that were later recalled because they posed life-threatening or very serious hazards, had been cleared by the 510(k) process. As the IOM report points out, the companies were not required to prove their products were safe or even that they worked.

The FDA had acknowledged problems and asked the IOM for advice on how to improve their approval process for devices. Instead, the IOM recommended scrapping the entire 510(k) program.

Unfortunately, that is not possible until the FDA has more staff to review medical devices more carefully. Meanwhile, NRC recommends incremental changes such as:

- Inspections of manufacturing facilities where devices are made, to make sure they are made correctly (and under sterile conditions if necessary);
- Scientific proof of safety and effectiveness in clinical trials for all high-risk devices, including all implanted devices and important diagnostic tests; and
- Follow-up studies required as a condition of approval if more safety information is needed.

The IOM tried to reassure the public not to worry about devices unless there is evidence of problems. NRC's Government Relations Manager Paul Brown disagrees. "That same argument could have been used about the levees around New Orleans before hurricane Katrina struck. We hope that FDA will improve the medical device clearance process now — before disaster strikes."

One of the Recalls: Metal-On-Metal Hip Implants



Image Courtesy of www.fda.gov

We don't accept funding from drug companies or device manufacturers, so we rely on the generosity of individual donors.

We welcome donations to the National Research Center for Women & Families by check or online (www.center4research.org).

*You can donate to our Cancer Prevention & Treatment Fund by check, online (www.stop-cancerfund.org), or federal employees can designate **Combined Federal Campaign # 11967**.*

*Checks can be mailed to:
1001 Connecticut Ave. NW,
Suite 1100,
Washington, DC 20036.*

Cancer Screening

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he may find it hard to ignore. Meanwhile, doctors at Johns Hopkins and elsewhere are experimenting with an active surveillance program where men are observed and biopsied over their lifetime to see if their low-risk cancer progresses. This form of “watchful waiting” may be the best approach for many men with early-stage prostate cancer.

Breast Cancer: Are Mammograms Saving Lives?

When the same Preventive Services Task Force announced in 2009 that most women should **begin mammography screening at age 50 (instead of age 40) and continue to get mammograms every other year (instead of every year) until age 74**, there was an uproar. Some assumed that the recommendation was a cost-saving measure rather than an evidence-based decision to promote public health.

In fact, the Task Force encouraged women at increased risk—due to family history, genetic mutations such as BRCA1 and BRCA2, or other factors—to consult with their doctors and possibly begin mammography screening at 40 or even earlier. The Task Force made an important point that screening does not always save lives, and that there are risks to screening too early and too often, which include excessive exposure to radiation, unnecessary biopsies, and anxiety from false positives (results that seem to indicate cancer when there isn't any).

Two years later, two new studies further support those mammography guidelines. In 2011, Dr. Rebecca Hubbard and her colleagues from the National Cancer Institute found that annual mammograms increase the rate of false positives, compared to mammograms every other year. After 10 years of annual screening, 61% of women will be called back

for further evaluation due to a false positive. And, a new study by Dr. H. Gilbert Welch from Dartmouth concludes that although screening mammography saves lives, most women with breast cancer would survive even if they did not undergo mammography screening.

How can this be? Many of the cancers detected through screening mammography were slow-growing and could have been successfully treated after a breast lump was found either by a health professional or by the patient herself. And, many of the cancers diagnosed through mammography and then treated would never have become dangerous. For example, one in five “cancers” diagnosed with mammograms are DCIS, a type of abnormal breast cells that might never develop into an invasive breast cancer but will always be treated by surgery and often radiation. Over-treatment can mean unnecessary surgery, radiation, chemotherapy, and years of taking hormone-blocking pills to prevent recurrence. Out of the 39 million women in the U.S. who were screened each year at a cost of \$5 billion, only between 4,000 and 18,000 women can truly say, “Mammography saved my life.”

Given the evidence from these studies, mammography appears to save fewer lives than expected. However, for individual women, it is still an important and effective screening tool, especially for women who want the option of undergoing a lumpectomy to remove an early breast cancer instead of a mastectomy to try to remove a larger cancer.

Lung Cancer: Catching the #1 Killer Before It Turns Deadly

Lung cancer is the second most commonly diagnosed cancer in the U.S. However, lung cancer causes more deaths each year than breast, prostate, colon, and cervical cancer combined.

Lung cancer is deadly because there are no approved screening tests. A new form of screening, however, is showing promising results. The National Lung Screening Trial (NLST) found that **screening current and former heavy smokers with low-dose computerized tomography (LDCT or “low-dose CT scans”) reduced lung cancer deaths by 20% compared to chest x-rays**. Chest x-rays have not been found to save lives, because by the time they diagnose lung cancer, it is advanced and often deadly.

Supporters of low-dose CT screening predict it could potentially increase the 5-year survival rate from 15% to 70%, because it detects small lung tumors at an earlier stage. However, at a cost of \$300 to \$700, CT scans are much more expensive than most other screening tools, and can also result in false positives, unnecessary radiation exposure, and overdiagnosis. When the men and women who had abnormal findings on either low-dose CT scans or x-rays underwent further tests, approximately 95% did not have lung cancer. These “false positives” result in expensive testing, and invasive diagnostic tests can cause complications for patients. Almost one in four smokers undergoing CT scans had abnormal results, but only 1% of all those screened were found to have lung cancer. Those with lung cancer would benefit from early diagnosis, which increases their chance of survival. In contrast, the one in four people screened who had false positive results would need to undergo additional tests. About 1 in 2,000 of these would have very serious complications from the testing, some of which would be fatal.

It's too early to tell if low-dose CT scans will become the basis for lung cancer screening guidelines or if testing can be improved to reduce false positives. But, most agree that this is the most promising lung cancer screening research in years.

NRC NEWS

Meet New Board Members Areta Kupchyk and Stephen Bozzo

Two very well-respected attorneys have joined NRC's Board of Directors: Areta Kupchyk, from Nixon Peabody, and Stephen Bozzo, who recently retired as a V.P. at Verizon and is now in private practice.

Areta Kupchyk joined the Board because of her strong interest in health care, particularly for women, and looks forward to her Board participation as "another good way to contribute." She joined the Nixon Peabody law firm in 2011 to lead



their FDA practice, after heading up the FDA practice in the Life

Sciences Health Industry Group at Reed Smith since 2003. She previously

was at the FDA for "ten fabulous years" and before that she was involved in health care litigation at the Maryland Attorney General's office.

Her proudest accomplishment at FDA was helping to develop a new regulatory framework for human tissue and cellular-based products, which include tissue donations and grafts. "The framework I helped develop allowed tissue products that had been used for many years to stay on the market. It reduced regulatory burden and focused on the real safety issue, which was the transmission of communicable disease by bringing some kind of standardization and oversight that was very much needed in that sector."

At Nixon Peabody and formerly at Reed Smith (where board member Judy Harris also works), Ms. Kupchyk helps companies "understand how FDA works, how to negotiate the agency, what FDA expects in terms of compliance, and

how to demonstrate compliance. I feel like that serves the public's health and safety. So, I feel very good about the work I do."

As NRC Board members, Ms. Kupchyk and Stephen Bozzo have recruited other Board members and set up a pro bono legal committee that will explore legal pathways to support NRC's mission. For example, they will help NRC advocate for better access to the safest and most effective medical treatments. Ms. Kupchyk says, "there are such terrific people on the board and I know I'll learn things and hope that I can contribute."

Stephen Bozzo found NRC through Boardnet.org, a service that matches executives interested in nonprofit work with organizations in need of their services. "I am the product of a single mother household. I grew



up in a house full of women: my mother, my sister, my aunt, and my grandmother — all of them were feisty. I saw a lot growing up that encouraged me to want to do what I could to help families." Mr. Bozzo recently retired after 26 years with Verizon, most recently as Vice President and Deputy General Counsel for Network Services. He has also served as an adjunct professor at George Washington University Law School.

For several years, Mr. Bozzo has volunteered for Streetlaw.org where he teaches high school and college kids about constitutional law and other legal subjects. Their mission is to introduce disadvantaged kids to the law and motivate them to pursue higher education, and in doing so, encourage diversity in the practice of law.

Mr. Bozzo isn't really retired -- in addition to his private practice, he continues his pro bono legal work for many clients, board duties, and volunteer work. On top of all this, he's also starting a vineyard. "I have the land in Virginia and I just got certified in viticulture. Being a city dweller and then a suburbanite, and now becoming a farmer is a big switch. On the other hand, I have winemakers in my ancestry." He expects to plant his first vines in the spring of 2012.

Mr. Bozzo will be very involved in NRC's new pro bono legal committee, and he's already introduced NRC's president and staff to the Verizon Foundation's leadership. As a result, NRC is helping the foundation evaluate one of their most innovative projects, Training Camp for Life. This program, which features NFL players at kickoff events, aims to educate high school boys about healthy, respectful relationships and thereby reduce domestic and sexual violence.

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Fall 5K Run/Walk for the Cancer Prevention & Treatment Fund

Our third 5K run/walk for the Cancer Prevention and Treatment Fund was held on September 17, on the beautiful Washington & Old Dominion Trail in Arlington, Virginia. The race raised money for our online cancer hotline, which provides free information to anyone who contacts us at info@stopcancerfund.org.

More than 200 runners and walkers between the ages of 7 and 66 gathered at Bluemont Park to race (or stroll) for a good cause.

It took just 18 minutes and 55 seconds for first-place finisher Anna Bernal of Quantico, Virginia to cross the finish line. With a time of 19 minutes and 21 seconds, Owen Lourie took first prize among men. These winners as well as the first place winners in each age group received gift certificates from **Pacers**, **Potomac River Running**, and **Casual Adventures**. For all finish times and rankings, see our 5K web site at www.cancer5k.com.

Individuals and groups raised money for the race. **Bev's Bosom Buddies** and **DC 101 DJ Ty Bailey** were our top fundraisers, each winning the \$1,000 challenge.

We had terrific support from community businesses, including our

Silver Sponsor **Net-Centric Enterprise Solutions (NES)** and our Bronze Sponsor **Medifast Weight Control Center of Arlington and Body Dynamics**. Friends of the Race Sponsors included **American Service Center for Mercedes-Benz**, **Mom's Organic Market**, and **The Teal Center**. We also had some great volunteers, such as GMU's Alpha Phi Omega. Thanks to the generosity of **Giant**, **Whole Foods**, **Brueggers Bagels**, **Bethesda Bagels**, and **The Bake Shop**, participants and their family members enjoyed bagels and fresh fruit after the race. **Body Dynamics** staff were there to provide free massages.



Ready, Set, Run! 5K Participants on Arlington's W & OD Trail

Our Outreach Coordinator Judith Faucette coordinated the race. "We were blown away by the incredible generosity of our supporters this year."

Fighting Lung Cancer: Our Lenora Moody Fellow

Tiffanie Hammond is the Lenora Moody Fellow at our Cancer Prevention and Treatment Fund. She is in charge of analyzing medical recommendations and health policy issues pertaining to lung cancer. Her focus is on how to improve prevention, screening, treatment, and quality of life for women diagnosed with lung cancer.

In addition, Ms. Hammond also serves as the Research and

Operations Coordinator for the National Lung Screening Trial and the Prostate, Lung, Colorectal, and the Ovarian Cancer Screening Trial at Georgetown University. In this capacity, she manages and ensures the quality of clinical data along with study compliance and retention of participants. She is currently completing her Master's degree in Health Promotion at The George Washington University.

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Tiffanie says, "I am very excited about this fellowship, as it offers the unique opportunity to educate and inform women about current and prospective lung cancer issues and translate research into sound public health policy."



NRC FOR WOMEN & FAMILIES

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Did you hear what NRC President Dr. Diana Zuckerman said about the new tattooed Barbie on Good Morning America? Tweet us what you think @NRC4WandF

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