

THE VOICE

for Women & Families

When Cancer Screening Does More Harm Than Good

The news has been shocking: is it possible that Americans get too many mammograms and prostate cancer screening tests? The question seems crazy: isn't early detection the next best thing to a cure?

The answer is: not always. On average, annual mammograms and annual PSA tests are not helpful. And, there are other ways to help prevent these cancers. The trick is for each person to figure out what is the best strategy for them and the people they care about.

Breast cancer and prostate cancer seem completely different, but they actually have much in common. Both are cancers of the reproductive system, both are the #1 cancers (for women and men, respectively) and the #2 cause of cancer deaths, and both have treatments that can harm a person's sexual self-image. Most importantly, both have relatively easy, widely used screening methods that result in frightening many patients with "false alarms" - results that look bad, but are really nothing.

Breast Cancer in the News

The latest news from the U.S. Preventive Services Task Force is that the **average** woman does not need to start getting screening mammograms until she is 50, not 40, and that she only needs mammograms every two years, not every year. This would save billions of dollars and result in fewer

unnecessary medical tests, surgery, and anxiety. And, it would greatly reduce the amount of radiation that women are exposed to from mammography. That radiation can increase the risk of cancer, so there are clear benefits to having fewer mammograms.

The new guidelines are not intended to discourage women at high risk of breast cancer from starting mammograms at 40, or even earlier if necessary. But it recognizes that there are real risks as well as benefits to mammography and that the risks outweigh the benefits for most women under 50.

The Task Force also said that there is no discernible benefit to teaching women to do breast self-exams. Although these exams are free (except in terms of time to teach and do them), there is no benefit to outweigh even that small cost, especially because they also result in false alarms and unnecessary, expensive testing for women who do not have cancer.

Prostate Cancer News

Screening tests don't need to be 100% accurate to be useful, but prostate tests are even less accurate than most, with many false positives (scaring patients who have no disease) and false negatives (falsely reassuring patients that they are O.K. when they actually have cancer). The PSA and DRE screening

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National Research Center for Women & Families

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

Cancer Prevention and Treatment Fund

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

CFC # 11967

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methods are often used together in order to miss fewer cancers, but they also increase the number of false positives.

Benefits of Screening

For both breast cancer and prostate cancer, the diseases are about 90% curable when caught very early. On the other hand, both tend to be slow-growing cancers. Prostate cancer is mostly diagnosed in older men and, since it usually grows very slowly, experts estimate that **18% to 85%** of screen-detected prostate cancers may never become clinically significant, which means they would not need to be treated. This wide range of uncertainty, however—is it less than 1 out of 5 (18%) or more than 4 out of 5 (85%)?—just adds to the confusion. Unnecessary treatment is a serious problem because life-changing side effects are common, such as impotence and incontinence.

Major research studies such as the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial and the European Randomized Trial of Screening for Prostate Cancer (ERSPC) have tried to shed light on the risks and benefits of regular screening. The PLCO found that **men who were screened annually did not live any longer** than men screened less often. ERSPC found that men who were **screened every 4 years were 20% less likely to die** from prostate cancer than men who were not screened, but were more likely to be overtreated. In fact, 1,410 men would need to be screened and 48 additional cases would need to be treated to prevent one death from prostate cancer.

Benefits of Not Screening

There is new evidence that some very early breast cancers and

prostate cancers may disappear, even without treatment. No statistics are available, unfortunately. However, experts estimate that in half the women diagnosed with Ductal Carcinoma in Situ (DCIS), a very common, very early breast cancer, the cancer would never spread and therefore would not need any treatment.

Other Ways to Prevent Cancer

Both these cancers are affected by sex-hormones, so reducing exposure to hormones in medications or chemicals can potentially prevent these cancers or prevent recurrence of these cancers. For women, avoiding hormone replacement therapy definitely reduces the risk of getting breast cancer. For men and women, avoiding hormones in chemicals such as BPA—which is in almost all canned foods and drinks and in many plastic baby bottles and sports water bottles—might lower risk. In addition, men and women who are not obese also are less likely to get these cancers.

The more fat cells you have, the more out of balance your sex hormones are likely to be. Dropping pounds is like telling breast cancer cells and prostate cancer cells that the restaurant is closed for business! Diets high in saturated fats, such as the animal fats found in red meat, may pose the greatest risk for prostate cancer. And, eating five or more portions per week of red meat (such as beef, pork and lamb) may increase your risk of breast cancer.

A recent study of young women found that those who ate more fruits and vegetables with carotenoids in them were less likely to develop breast cancer. Carotenoid rich foods are leafy greens like kale, spinach, and collard greens, and foods that are orange, red and sometimes yellow (carrots, mangoes, apricots, squash, tomatoes,

and sweet potatoes). Regular exercise also helps to lower body fat, which keeps sex hormone levels in balance.

Experts Don't Recommend Prostate Screening

The U.S. Preventive Services Task Force is an authority on which medical treatments work and which don't.

The Task Force concludes that there is insufficient evidence to **recommend for or against PSA or DRE screening for men under 75**, and they recommend against screening for men over 75. They make no exceptions for men at higher risk. They also state that annual screening is not more beneficial than screening every 4 years. In contrast, the American Urology Association and the American Cancer Society are somewhat more enthusiastic about screening.

The Task Force's views on screening, family history, and other risk factors should influence whether men have prostate cancer screening or not, and if so, how often. We suggest men bring the Task Force statement (www.ahrq.gov/clinic/uspstf08/prostate/prostaters.htm#clinical) with them to their doctors to decide, at age 50 if they are at average risk of prostate cancer; at 45 for men at high risk (African-American men and men who have a close relative diagnosed with prostate cancer prior to 65), and at 40 for men with several relatives with prostate cancer at an early age.

*We don't accept funding from drug companies, so we rely on individual contributions. We welcome donations online (www.center4research.org), by check, through United Way (just write in our name) or federal employees can designate **CFC # 11967***

Are These Popular Medications Safe?

Did you know that some of the biggest selling drugs in the U.S. are schizophrenia drugs that are usually prescribed to adults and children who are not schizophrenic?

Even more shocking, these widely used drugs are proven to frequently cause substantial weight gain, probably diabetes, and sometimes sudden death.

Will the new leadership at the Food and Drug Administration (FDA) do something to make this situation better—or worse? That's the question that we've been asking them.

Americans spend more than \$5 billion each year on **Seroquel**, **Zyprexa**, and **Geodon**. These three drugs are approved by FDA to treat psychosis, such as hallucinations and delusions, which are symptoms of schizophrenia and the manic phase of bipolar disorder (manic-depression). However, they are widely used "off label" for children with behavior problems and adults with sleeping problems, depression, anxiety, drug or alcohol addiction, Post Traumatic Stress Disorder (PTSD), or Alzheimer's disease.

Off-label means they are prescribed for treatments that **have not been proven safe or effective by the FDA**.

Despite their huge sales, these medications have serious side effects, including weight gain and diabetes, tardive dyskinesia (a severe facial tic), sleepiness, and sudden death. Unfortunately, many physicians are unaware of these side effects or assume they are rarer than they actually are.

Drug risks that may be acceptable for treating hallucinations may not be acceptable for diseases or problems that can be treated with safer drugs.

Are these drugs safe and effective for children or for treating depression or anxiety? The FDA is deciding whether these three drugs should be approved for schizophrenia in children and whether Seroquel should be approved for depression and anxiety in adults.

Too Risky?

NRC for Women & Families President Dr. Diana Zuckerman testified at two public meetings of the FDA Advisory Committee reviewing these drugs in the spring and summer of 2009 to decide whether or not to allow the drugs to be marketed to children or for depression and anxiety in adults. She questioned whether the risks were worth the drugs' benefits, especially since other, safer products are available and FDA approval for children and for less serious mental problems would falsely reassure doctors that they need not worry about the side effects.

USA Today and *Reuters* quoted Dr. Zuckerman pointing out that the studies are inadequate and "provide no useful information about the long-term risks of tardive dyskinesia, sudden death, or diabetes."

Prescriptions are likely to skyrocket if the drugs are approved for children or for depression or anxiety.

Seroquel is AstraZeneca's second biggest moneymaker, with sales over \$3 billion a year. Most prescriptions are off-label for depression and anxiety, and the drug is commonly used for adults and teens in treatment for PTSD, alcoholism or drug addiction. The drugs have also been widely used to sedate children and Alzheimer's patients with behavior problems.

At the FDA meetings, several men and women testified about how

their loved ones, veterans of the Iraq war, had died while taking Seroquel to treat PTSD.

Soldiers Die from Meds not War

Harold S. White, who lost his son, testified: "In my research, I have found at least 51 military men have died in their sleep in the past 6 years, 35 in the last 3 years." He added that it "was always the same story," with very healthy people dying suddenly after taking Seroquel.

Cassandra Harper, who also lost a family member, testified that "the doctors and nurses [at Walter Reed] should be given more information on the drugs they prescribe and possible side effects or interactions."

NRC for Women & Families' position is that it is irresponsible to prescribe drugs with potentially fatal side effects to anyone with depression, anxiety, or PTSD unless every other, safer drug has already been tried and failed.

The benefits to children are especially questionable in the context of these risks. FDA's mandate is to ensure that medical products are safe and effective for a specific use before they are approved for that use.

NRC is also concerned about the widespread use of two similar

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Save the date!
2010 Foremother Awards Luncheon on Friday, May 7, 2010.

Honoring Women and Health Policy Heroes

NRC's 10th anniversary was celebrated at our annual Foremother Awards Luncheon on the Friday before Mother's Day. For the first time, we honored two Members of Congress as Health Policy Heroes, in addition to honoring four extraordinary women for their lifetime achievements.

The sold-out event, held at Washington's elegant Cosmos Club, was attended by leaders of many nonprofit organizations, including the American Association of University Women, the Center for Science in the Public Interest, the Government Accountability Project, the National Consumer League, the National Organization for Women, the National Women's Health Network, and U.S. PIRG.

Dr. Diana Zuckerman, NRC's president, reminded the audience that "the tenacity, creativity, and dedication of our foremothers helped to break down barriers and open up a world of opportunities for women in the 20th and now the 21st Century. Our Health Policy Heroes forged their achievements in a system that does not easily bend to change, thereby improving health policies and ensuring that government agencies are accountable."

Opening remarks were made by **Katharine Weymouth**, CEO and Publisher of *The Washington Post* and granddaughter of the late Katharine Graham, who was made famous in *All the President's Men*. She spoke of the foremothers in her own family, particularly her great grandmother Agnes Meyer, who as early as 1944 began her crusade for the establishment of a cabinet-level department to deal with health, welfare, and education. "Anyone who knew Agnes Meyer knew that she never shrank from expressing herself. In fact, President Truman once

complained that not a day went by that he didn't get a letter from two people, 'Eleanor Roosevelt and that Meyer woman.'"

To watch honorees' remarks in their entirety, visit Youtube.com/nrc4wf.

Foremothers Lifetime Achievement Award Honorees:

Dorothy Height, a civil rights icon for decades, is best known as the president emerita of the National Council of Negro Women. Her lifetime of leadership, starting during the New Deal, made lasting contributions to the movements for equality and human rights for all people.

Dr. Height spoke of her efforts to bring women to the forefront of the civil rights movement. "Many don't realize that the only female voice you heard in the March on Washington, Aug 28, 1963, was the voice of Mahalia Jackson, who sang the National Anthem." Dorothy Height and other African-American women resolved to change the situation. "And I have to tell you that never again would you see a major march without having a woman there," remarked Dr. Height.

In spite of her historic role, Dr. Height's contributions were often overshadowed by male colleagues such as Dr. Martin Luther King, Roy Wilkins, and John Lewis. "I was the invisible one," she noted. A worker at the White House pointed out that she usually sat on the end and was therefore cut out of the group

photos. "Well, I learned to sit in the middle!" exclaimed Ms. Height to thunderous applause.

She thanked the Center for its work: "For years there have been stockpiles of studies, and women of color and minorities are always in the footnote or an asterisk. I want to thank the Center that I am no longer an asterisk."

Lillian Brown, with CBS News for more than 30 years, has been the make-up expert of choice for six U.S. presidents (from Kennedy to Clinton), a voice consultant, and former director of Radio-TV for Georgetown University. In her 90's she continued to teach at Georgetown and the Yale Women's Campaign School. Now 94, she is completing her fourth book, *Camera Ready*, which describes her

experiences helping U.S. presidents put on their "best face."

She regaled the audience with tales from her fascinating career, which began in the 1940's. Her first assignment on *Face the Nation* was Speaker of the House Sam Rayburn, who was not a willing subject. Ms. Brown insisted, "Mr. Sam, if you let me powder your nose, I will not relieve you of your manhood." When he recovered he said, "Well, you just go ahead, honey ..."

Ms. Brown's career brought her near to historical events that are seared in the public's memory. She reminisced about being alongside Jackie Kennedy when she hosted televised tours of the White House. She also applied Nixon's makeup



Front: Lillian Brown, Dr. Dorothy Height. Back: Dr. Diana Zuckerman, Katharine Weymouth.

before he made his resignation speech. As a media coach, it was Ms. Brown who worked with Governor Ann Richards to perfect her unforgettable “silver spoon” speech during the 1988 Democratic Convention.

Two Foremothers were unfortunately unable to attend because of ill health: **Zelda Fichandler**, award-winning stage producer, director, educator, and cofounder of the nationally respected Arena Stage theater in Washington, D.C. and winner of the National Medal of the Arts; and **Nan Robertson**, one of the early *New York Times* women reporters, starting in the 1950’s, who won the Pulitzer Prize in 1983 for her magazine cover story on toxic shock syndrome resulting from a defective medical device. She was the author of two books, *Getting Better: Inside Alcoholics Anonymous* and *The Girls in the Balcony: Women, Men, and The New York Times*, an exposé of how women reporters launched their battle to end sex discrimination at the newspaper. She passed away in October 2009.

Health Policy Heroes

Representative Rosa DeLauro is one of Congress’ most effective champions to improve the health and safety of all Americans. A survivor of ovarian cancer, DeLauro



Representative Rosa DeLauro with Dr. Diana Zuckerman

has been a leading voice for increasing essential cancer research. Her work led to the passage of *Johanna’s Law* to increase awareness of gynecologic cancers. From her position on the House Appropriations Committee, DeLauro has increased funding for breast and cervical cancer screenings and research. DeLauro has also authored legislation to ensure better medical care for women undergoing breast cancer surgery.

Rep. DeLauro praised her female predecessors in Congress, including Connie Morella, a 2008 Foremother who attended the luncheon, for “leading the way for those of us who came after, particularly on these issues of health care and women’s health.”

She has worked tirelessly to improve consumer safeguards at the FDA. She explained that her efforts to pass the *Food Safety Modernization Act* is about “restoring the confidence in our food supply and protecting public health, about building a system that is committed to actively preventing foodborne illness, not just reacting to it.” She has also been a key supporter for the FDA’s Office of Women’s Health.

Rep. DeLauro praised NRC’s work to ensure that drugs and devices are safe and effective. “You give the gift of life, and no one can do more than that in what their profession is all about. You’ve been so wonderful with your time working with me, working with my staff. As a policy-maker, there is no greater source of information than you bring to us, and you are unrelenting in your vigilance with regard to these issues and with regard to the Food and Drug Administration.”

Senator Charles Grassley (R-Iowa), the Center’s first male award recipient, is the Senate’s most outspoken

advocate on behalf of safeguards to ensure the safety and effectiveness of all medical products. His willingness to challenge the FDA has saved the lives of adults and children by helping remove unsafe medical products from the market.

His work has resulted in warnings to the public about risks of widely used medications, such as antidepressants by children. “As far as I’m concerned, the only person ever across the table from the FDA is John Q Public... an informed public ends up being a healthier public,” he stated.



Senator Charles Grassley

In his remarks, Senator Grassley emphasized the need for unbiased science: “You don’t ever want to use the word science without ‘sound science,’ because you want to emphasize that we leave the politics out of places where science ought to be the sole determinant.” He ended on a personal note, “Our family knows first hand that it’s hard to sort through the mountains of material and get good answers when a loved one has a cancer scare or other diagnosis. Your group helps people get unbiased information of what is needed when it is most needed. That’s an invaluable service, and yet just a small part of what you do.”

Legacy Internships Benefit Students and NRC

The Marcy Gross and Joy Simonson Legacy Internships provide real-life experience for students and new graduates, and also add to our productivity when interns write articles for our Web sites, and gather information at Capitol Hill briefings and hearings. Sometimes they even testify at the FDA: NRC staff guided the interns in preparing their testimony for the FDA hearings on an ovarian cancer drug and the risks of psychiatric drugs used by children.

Marcy Gross Internship



Meredith Van Tine

Meredith Van Tine, our Marcy Gross Intern for the summer of 2009, is in her final year at the University of Virginia's School of Law. She is

preparing for a career in women's health advocacy and her goal is to focus on public policy, public education, and research on health issues that affect women exclusively, disproportionately, or differently than men, including domestic violence.

In addition to being a law student, Meredith volunteers at the local Sexual Assault Resource Agency (SARA), at the Charlottesville FOCUS Women's Resource Center, and at Women's Health Virginia. She also provided pro bono assistance to the local Planned Parenthood office on women's and family advocacy projects.

During her internship with NRC, Meredith researched and wrote articles on a range of health issues, including depression and LASIK surgery; attended Hill briefings on the *Violence Against Women Act*;

participated in women's healthcare coalition meetings on healthcare reform; helped organize NRC's annual intern luncheon on the risks of medical products used by women with poor body image; and testified before the FDA on the unfavorable risk-benefit ratio of a drug for ovarian cancer. "Years ago, the National Research Center for Women & Families directly affected my life in a positive way by providing me with important health information," said Meredith. "Now, thanks to the generosity of Marcy Gross' family and friends, I have finally been able to return that favor by working to further NRC's wonderful mission."

Marcy Gross was a long-time champion of women's health who was widely respected for her work in the U.S. Department of Health and Human Services. When she was



Marcy Gross

director of Women's Health at the Agency for Healthcare Research and Quality, and after she retired, she was an enthusiastic and inspiring supporter of NRC until her death in 2005.

Joy Simonson Internship

Stephanie Portes-Antoine was our Joy Simonson Intern for the summer of 2009. A Martin Luther King scholar as an undergraduate, Stephanie holds a Master's in Public Health from Boston University and is now a second-year medical student at Boston University School of Medicine. Stephanie is keenly interested in health disparities, particularly racial, ethnic, gender, and socioeconomic. As part of her public health school practicum, she worked on a reproductive health project in

Haiti. Stephanie is NRC's first intern through the American Medical Association's Government Relations Internship Program. At NRC, Stephanie synthesized research information on treatments for ovarian cancer; attended Hill



Stephanie Portes-Antoine

briefings on the HPV vaccine; participated in coalition meetings on the health-care reform debate; and testified before the FDA on the potential risks of psychiatric drugs used by children. She also analyzed differences in drug response among African-American and Caucasian women suffering from breast, cervical, or ovarian cancer.

"My experience this summer was amazing, and there is no doubt in my mind that I will carry what I learned this summer, not only throughout my remaining academic career, but into my life as a future physician," Stephanie said.

Joy Simonson, one of NRC's first Foremothers, had a distinguished



Joy Simonson

career which included serving as director of the National Advisory Council on Women's Educational Programs, a

Congressional Investigator, President of the D.C. League of Women Voters, and founder of the D.C. Commission for Women. She participated actively in NRC events and was an important member of our National Advisory Board until her death in 2007.

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drugs, **Risperdal** and **Abilify**. "FDA needs to act immediately to drastically reduce the widespread sale of these five medications for insomnia, depression, and other conditions where the risks are likely to outweigh the benefits," says Dr. Zuckerman.

The newly appointed FDA Commissioner, Dr. Margaret Hamburg, has already met several times with NRC staff, including a one-on-one meeting with President Diana Zuckerman, to hear NRC's concerns regarding prescription drugs and medical device safety issues.

In addition to discussing these five "atypical antipsychotic" drugs, Dr. Zuckerman expressed concern that most medical devices – unlike prescription drugs – do not even require clinical trials to establish their safety and effectiveness. And, while prescription drugs must prove that they are "safe and effective," medical devices only have to demonstrate that they have a "reasonable assurance of safety and effectiveness." Dr. Zuckerman pointed out that "reasonable" is a subjective word that has been used as a loophole to get products on the market without good scientific evidence that they work or are safe.

Dr. Zuckerman and Paul Brown, NRC's Government Relations Manager, have also met with Deputy Commissioner, Dr. Josh Sharfstein, and the new director of FDA's Center for Medical Devices, Dr. Jeff Shuren.

NRC for Women & Families is particularly concerned about the FDA's quick and easy fast-track medical device clearance procedure, which is called the 510(k) process. Thousands of medical devices are cleared by the 510(k) process every year, including

life-saving devices such as heart valves. Two reports came out in 2009 that were critical of the 510(K) process: one by the Government Accountability Office, and one by the FDA itself about surgical mesh made by ReGen. FDA officials have promised to improve the process in the coming months.

NRC is urging the FDA to make the safety of patients their #1 priority. "The FDA should scrutinize the risk of drugs and devices much more carefully before making approval decisions," Dr. Zuckerman explains.

Announcing the 2010 Cancer Prevention and Treatment Fund 5K Run/Walk



**WHEN: Saturday,
March 27, 2010 at 9 a.m.**

**WHERE: Washington & Old
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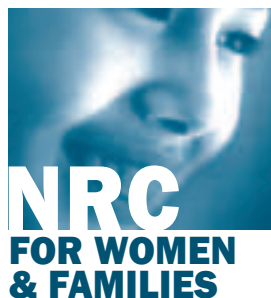
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