

National Center for Health Research

We are dedicated to improving the health and safety of adults and children by using research to develop more effective treatments and policies. The Cancer Prevention and Treatment Fund is our major program.

www.center4research.org

Twitter: @NC4HR

The Cancer Prevention and Treatment Fund

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

www.stopcancerfund.org

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CFC # 11967



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We've changed our name!



National Center for Health Research

A better fit for who we are and what we do

This is our 15th anniversary, so we decided it was time for a change.

Friends and supporters let us know that our name, *The National Research Center for Women & Families*, was not remotely memorable. And that wasn't the only problem.

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Cancer and then something worse?

When friends told Barry Levine last year that he looked great and asked how he had lost so much weight, his deadpan response was "cancer." His treatment was challenging but his non-Hodgkin's lymphoma went into remission and he kept his sense of humor. But, this year his health took a mysterious and terrible turn for the worse, and this time, it wasn't cancer.

"I feel like 7 miles of bad road," he tells us. After 5 weeks in the Intensive Care Unit, "I'm so weak I couldn't lick a postage stamp."

His mysterious symptoms started at the end of February, about 3 months after a chemo treatment. The inside of his mouth hurt and eating anything became increasingly painful. Then he started getting hives and feeling too weak to go to work. When he saw his sister, Diane Ambur, during a weekend in early March, she noticed he looked very red, as if he were badly sunburned – odd considering the Maryland weather. The next day, the bottoms of his feet hurt, making it difficult to walk, so after toughing it out, Barry called his oncologist Monday morning and made an appointment for as soon as possible – the next day.

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What's New

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We can't be bought.

Our Center doesn't accept funding from drug companies or device manufacturers, so we rely on the generosity of individual donors. You can donate online at stopcancerfund.org.

We've changed our name to

the National Center for Health Research!

Continued from page 1

We always defined “families” to include everyone who ever had a parent, but based on our name, some people thought we didn't care about men—an (ahem) significant proportion of the population that we care about deeply. Sometimes people confused us with other organizations that have “women,” “children,” or “families” in their name, whose mission is very different from ours. And sometimes, because the word “families” has taken on political implications, people assumed we had a political agenda. We don't. We're nonpartisan.

So from now on, we will be known as “The National Center for Health Research.” Same organization (and many of the same words in the name), but with the introduction of one word that defines what we're really all about: HEALTH. We've never focused only on women and children, and we've ALWAYS been focused on health research:

- 1) We conduct research and scrutinize research that can be used to improve policies and programs that affect our health.
- 2) We provide patients and consumers with the information and assistance they need to make smart health decisions.

We will be describing the National Center for Health Research as “The Voice for Prevention, Treatment, and Policy.” That's our tagline and also the name of our newsletter. We want everyone to know that we're here for you, here to explain what is known and not known, and to provide information that is meaningful and that you can use. We are the voice that you can trust for health information. We are, as always, an independent voice because we accept no funding from companies that manufacture medical products. When we say something is safe or effective, it's because we have scientific evidence to back it up. No wishful thinking, no anxious shareholders biasing what we tell you.

So, what's in a name? We hope that by choosing a name that more accurately reflects what we do, we can be even more effective in the years to come. ♦

Advising Medicare

Medicare saves lives by providing healthcare to millions of Americans over the age of 65, as well as younger people with certain disabilities. However, as millions of baby boomers reach 65, and as Congress tries to reduce government spending, this essential program faces enormous challenges.

We are excited to announce that our president, Dr. Diana Zuckerman, has been selected to serve on the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). The MEDCAC supplements the Medicare program's own experts and helps provide unbiased deliberation on “state of the art” technology and science. According to the Center for Medicare and Medicaid Services (CMS), the MEDCAC “reviews and evaluates medical literature, technology assessments, and examines data and information on the effectiveness and appropriateness of medical items and services that are covered under Medicare, or that may be eligible for coverage under Medicare. The MEDCAC judges the strength of the available evidence and makes recommendations to CMS based on that evidence.”

MEDCAC includes experts in medicine, science, public health, patient advocacy, health care data analysis, health care economics, and medical ethics. “I feel so honored to have been selected for this extremely important national advisory committee,” says Dr. Zuckerman. ♦



Will this new medical product work for women? Minorities? People your age? You?

Would you be shocked if you saw this label on your medication? It's 2014, after all, not 1950. Unfortunately, this kind of warning would be accurate for many of the prescription drugs and devices that you and your family rely on. A recent report by the FDA admits that approval decisions are made on the basis of clinical trials that include relatively few women, even fewer people of color, and often even fewer people over 65, even when those are the patients most likely to take the medication.

Since women make up half of our population, and they tend to agree to help with medical research when asked, why are they so underrepresented? More importantly, does it matter?

It does matter because women metabolize some drugs at a faster or slower rate than men. That's why, for example, the FDA finally warned women last year that they should take lower doses of sleeping pills – women were being dangerously over-medicated because the drugs were approved at a dosage that was appropriate for men, but not for women.

Sex differences aren't the only ones that can affect whether a drug or device is likely to be safe or effective for a patient. Patients over the age of 55 tend to metabolize drugs much more slowly than younger patients, making an enormous difference in safety or effectiveness. Some ethnic groups (not racial groups in the usual cultural sense of the term) also metabolize certain drugs differently or may be more sensitive to materials used in implanted medical devices. For example, Japanese patients metabolize certain antidepressants differently than Chinese patients or white patients. African Americans and Hispanics may be more vulnerable to autoimmune reactions from certain types of implants.

Congress agreed that the lack of diversity in clinical trials used as the basis for FDA's approval was a problem, so in 2012 they passed a law requiring the

FDA to calculate diversity in clinical trials approved by the agency the previous year.

WARNING
This drug is approved only for white men under 55. It has not been proven safe or effective for women, people of color, or men and women over 55.

The FDA report pointed out that diversity was improving but admitted that even when there was diversity, the FDA rarely required companies to analyze the data separately for different groups (such as all women or men over 55) to make

sure the new medical product was safe and effective for them. FDA was even less likely to make sure that the labels admitted who the product was tested on and whether there were differences in safety or effectiveness due to sex, age, or race.

Earlier this year, a drug that the FDA was considering for heart failure was studied on patients that were almost all white – fewer than 5% were African Americans, even though heart failure is the #1 killer of men and women of all races in the U.S. In studies for an antibiotic to treat MRSA, a resistant staph infection, only 6% of the patients were African American, even though African Americans are more likely to be diagnosed with MRSA than whites.

We recently testified at an FDA hearing that the agency needs to do a better job of analyzing new medical products separately on major demographic groups, such as women, older patients, African Americans, and Hispanics. To see our comments, go to the public policy section of our websites:

www.center4research.org and www.stopcancerfund.org.

Ultimately, in order to make the best health decisions for ourselves and our families, we all need to know whether the drugs and devices we use are safe for us. We've been urging the FDA and Congress to do this for over a decade. We hope they are finally listening. We continue to remind the FDA of this fact. ♦

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Puzzling new medications: Are they worth the risk?

Remember the puzzles and quizzes where you matched the name of a famous person with an important accomplishment? This puzzle is more challenging: Match the name of an “innovative new drug” that the FDA approved or was asked to reconsider in the last year or so with a dangerous risk, according to the companies’ own studies. Try your luck, and when you’re done, read on. (You might want to save this article to see if the drug is advertised or recommended to you by your doctor and whether you are given the warning about these risks.)

Draw a line between the drug or device and its side effect

1. Diabetes drug Farxiga	a. Pain, risk of perforation of uterus
2. TB drug Sirturo	b. Increased risk of bladder cancer
3. Brisdelle for hot flashes	c. Increase in suicide attempts
4. Essure birth control device	d. Uncontrollable bleeding
5. Blood thinner Pradaxa	e. Patient 5 times as likely to die

key: 1.b, 2.e, 3.c, 4.a, 5.d

Farxiga. All medications have some risks. Some popular diabetes drugs can increase the risk of stroke, for example. But the innovative new diabetes drug called Farxiga has a different “mechanism of action.” It works by preventing sugar from being absorbed during digestion, so that it “passes through” your body into urine. But all that sugar in the bladder can be dangerous, and as a result, patients taking Farxiga were 5 times as likely to be diagnosed with bladder cancer than diabetes patients taking other prescription medications. (They were also twice as likely to be diagnosed with breast cancer, but that might have occurred by chance.)

Brisdelle. Hot flashes are a drag, and women are concerned that the hormone therapy that helps with hot flashes can cause breast cancer, increase the risk of heart disease, and even contribute to dementia. If you don’t like hot flashes and don’t want hormones, the FDA has approved a new drug for you: Brisdelle. But Brisdelle isn’t new, it’s actually the same drug as Paxil, a popular antidepressant. When women who were NOT depressed took Brisdelle, however, they were 7 times more likely to think about killing themselves or tried to do so. Is it worth the risk? Compared to women taking placebo, women taking Brisdelle had an average of one less hot flash per day.

Essure. You love your children, but you don’t want more, so you consider Essure, a “permanent birth control” device (sterilization sounds so last century). The FDA says it is safe and effective, but some of the women who had Essure implanted say differently. The media reports that the device doesn’t always prevent pregnancy, and can cause terrible pains that Bayer, the manufacturer, didn’t always count as a side effect. Patients reported side effects that were sometimes crossed out by the staff doing the study.

Sirturo. The FDA proudly announced that they had approved Sirturo as the “first new TB drug in 40 years!” Sirturo was approved by the FDA because it killed more TB bacteria in the spit of TB patients than older TB drugs. There was a catch, though: TB patients taking Sirturo were 5 times as likely to die as patients taking the older TB drugs. You can call that innovation. We call it deadly.

Pradaxa. An article in the *New York Times* in February raised questions about the risks of Pradaxa, a popular blood thinning medication taken to reduce the risk of stroke in patients with mild irregular heartbeats. The drug has been linked to more than 1,000 reported patient deaths from bleeding. The problem is that many older patients have been getting an excessive dose of the drug. In the U.S. there is no way to reduce the bleeding risk, because neither a lower dose nor a blood test to detect the problem is available here, as they are in Canada and 30 European countries. The Institute for Safe Medication Practices has called on the FDA and the company to make these options available here, and we agree. But instead of doing so, the FDA has defended Pradaxa, and now the agency has approved it for other medical conditions, which could mean more patients taking it and risking uncontrolled bleeding.

Evidence for New Medical Products: Implications for Patients and Health Policy

Conference on June 13, 2014

Why is health care so expensive? Why are so many treatments costly and ineffective? And what can be done to fix this situation? We're bringing together experts to focus on this very issue at a conference in Washington, DC on June 13. Cosponsored by our Center, **The American Association for the Advancement of Science**, and **Harvard Medical School/Brigham and Women's Hospital**, we will be looking at how to improve health policies in ways that will save patients' lives and improve public health.

This groundbreaking conference will bring together researchers, medical and policy experts, and patients and consumers from across the country. Researchers will share and discuss their studies on what happens when the standards for FDA approval are lowered to speed up access to new drugs and devices. Will more lives be saved or lost? What are the medical and public health implications for patients, medical costs, and our country's healthcare system?

Confirmed speakers include Rep. Rosa DeLauro (D-CT); Dr. Jerry Avorn, Harvard; Dr. Greg Curfman, *New England Journal of Medicine*; Dr. Gerald Del Pan, FDA; Dr. Louis Jacques, Georgetown; Dr. Bernard Lo, Greenwall Foundation; Dr. Rita Redberg, *JAMA Internal Medicine*; Dr. Joseph Ross, Yale; Dr. Patrick Ryan, Janssen; Dr. Lisa Schwartz and Dr. Steven Woloshin, Dartmouth; Dr. Joe Selby, PCORI; Dr. Robert Yarchoan, NCI.

For the agenda and registration info go to www.aaas.org/oZT.

Registration is free but space is limited and advance registration is required.

Continued from page 1 But he didn't last that long at home. As Barry felt and looked worse, his sister read medical articles and realized his symptoms sounded like Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), two forms of a rare and life-threatening skin condition caused by a reaction to medication. By Monday night, Diane and her husband Owen persuaded Barry to go to the Holy Cross Emergency Room, where he was admitted. By the next day, his skin was peeling all over his body, his mouth was blistered and bleeding, and he was hallucinating from the medications needed to cope with the horrible pain. A few days later, he was transferred to the intensive care unit at Washington Hospital Center.

His SJS had graduated to the more severe TEN, resulting in second degree burns all over his body and to the mucous membranes inside his body. This made eating impossible and the pain and itching skin unbearable. These conditions are not usually caused by cancer medication (although they can be), and are more likely to be caused by rare reactions to some antibiotics or common painkillers, such as ibuprofen and acetaminophen. The doctors have not yet been able to identify what medications set off the disease for Barry.

It was touch and go for a while, and his memory of the first few weeks is foggy, but today Barry is in a regular hospital room and will soon go to rehab. He's lost at least 50 pounds and grown a beard from weeks of being unable to shave. His skin is still fragile and prone to infection. However, he has progressed from bedridden to taking a few steps with a walker, to walking short distances on his own. He is still very weak, but step by step is getting stronger each day. He has come to terms with being patient as a patient. And he has a new appreciation for life.

"My parents had a great *joie de vivre* and they passed that on to their kids," Barry tells us. "I wasn't willing to give up, and that's how I got through this. And my sisters, brother, other family, and friends have shown me so much love, it was amazing and really made a difference.

"For some reason, the lymphoma wasn't much of a wake-up call, but this sure was. I realize I should have sought medical help more quickly. My sister Diane saved my life by getting me to the ER. When the doctors seemed mystified by my symptoms, she got helpful advice from your staff at the National Center for Health Research to make sure I got treatment from the right experts when I was in the hospital. Now I'm really going to try to take better care of myself, eat healthier foods, get a new oncologist, and be more careful about my medical care. And I'd like to help other patients who are going through the hell I've been through, to let them know I made it and they can too." ♦



Annie Ammons died from the side effects of Yaz. We're very proud to offer a fellowship in her honor.

Leaving a Legacy

Is there someone you would like to honor? Internships and fellowships provide training that can result in a lifetime of good work. Honor a loved one through a donation of cash or stock, a distribution from a retirement plan or life insurance policy, or a will. For more information, contact Brandel at bfb@center4research.org.

We're in the Headlines!

Here's a recent sample of our impact on the news:

FDA warns against procedure to remove uterine fibroids; says it could spread hidden cancer

Washington Post
April 18, 2014

DNA alternative to Pap smear sparks medical debate

The Associated Press
April 15, 2014

Worst new drug of 2014?

Huffington Post
February 4, 2014

Medical device recalls nearly doubled in a decade

Wall Street Journal
March 21, 2014

Alternative to Pap Test Is Approved by F.D.A.

The New York Times
April 25, 2014

President Dr. Diana Zuckerman was quoted in the **Washington Post** and the **Wall Street Journal** about a device used to chop up **uterine fibroids** so that they can be removed using laproscopic surgery instead of “open” surgery. But if the fibroid contains undetected cancer, these **morcellation devices** can spread the cancer, making it impossible to completely remove. “When you consider what the benefit is, which is a shorter hospital stay and less pain, then consider what the risk is—this could kill you—most women would not choose that risk if they really understood what was at stake.”

Dr. Zuckerman wrote an article for the **Huffington Post** and **Rodale.com** about the diabetes drug, **Farxiga**, dubbing it “the worst new drug of 2014.” She said, “The agency just approved a diabetes medication that doesn’t noticeably improve health but may in fact be linked to cancer.” She also wrote an article for those same websites about the risks of the FDA approving the **HPV test** as a replacement for Pap smears.

Staff member Paul Brown explained in a letter to the editor of the **Washington Post** that patients can seek experimental drugs through the FDA’s **compassionate-use program**. This allows drug companies to provide medicines that have not been proven safe and effective only to people who desperately need them and have little to lose, rather than lowering FDA approval standards and putting the public at risk.

We were quoted in two **New York Times** articles about FDA approving the HPV test to replace Pap smears to screen for **cervical cancer**. We are concerned that the more expensive HPV test will frighten many young women unnecessarily, since HPV usually goes away by itself. Our Scientific Advisor, Dr. Anna Mazucco, was quoted saying that this proposal “represents a radical shift in clinical practice which would affect millions of women for most of their adult lives.” Our president Dr. Zuckerman expressed similar concerns on **NPR**, California **Public Radio** station **KPCC**, and in two **Associated Press** stories carried in dozens of newspapers and websites across the country.

Dr. Zuckerman was interviewed for a podcast produced by **Let America Know** about drugs and devices that injure women. In an interview with **Modern Healthcare**, she explained that, “With **new drugs**, there is often an exaggeration of the benefits and underreporting of the risks. There is so much emphasis on drugs being the latest, the most innovative and novel—but unfortunately this usually means it’s just new, not necessarily better.”

We were quoted in the University of Houston **Signal** on the potential health risks of “vaping” (smoking **e-cigarettes**). Because the FDA hasn’t finalized its plan for regulating them, they can be sold to anyone regardless of age, are popular with children and teens because of flavors like cherry crush and chocolate treat, and can contain nicotine and chemicals such as antifreeze.

Can't see all your options? Limits to the Affordable Care Act

The Affordable Care Act (ACA) has been a political football since it passed 4 years ago and is likely to remain so for the foreseeable future. But, whether you're a fan or a foe of "Obamacare," there is no denying that the law has benefits as well as shortcomings.

The good news is that more than 8 million Americans have signed up to purchase health insurance through virtual marketplaces. The not-so-good news is that the information about different insurance policy options was not as clear as we expected. Some consumers will find that the insurance policy they signed up for won't cover one or more of the treatments that they knew they would need and that other policies would have covered.

We have been working to improve how the new insurance marketplaces work. Is your health insurance in 2014 better than it was in 2013? Did the company refuse to cover something you thought was included in the policy? We'd like to hear from you at info@center4research.org.

Making an informed choice

The ACA requires that all insurance products sold on the Exchanges provide a "Summary of Benefits Coverage." These charts are very clear and helpful for comparing how much different insurance company policies cost and co-payments for services and prescription drugs. But, they only include some of the essential information about which medical services are covered and which aren't.

Consumers who know, for example, that they want certain kind of smoking cessation services, obesity surgery, mental health services, or fertility treatments would need to see exactly what is covered by the insurance in the "Evidence of Coverage," as well as the insurance company's internal medical policies. Unfortunately, there usually aren't links to these documents on the Exchanges or anywhere publicly online. As a result, a man who knows he wants smoking cessation services or a woman who knows she will want certain types of fertility services will not have the information they need to choose the insurance carrier or policy that is best for them.



Cancer care

Some of America's top cancer centers, such as Memorial Sloan-Kettering in New York City and MD Anderson in Houston, are off-limits under many plans sold on the marketplace. There is no way for consumers shopping online to tell which hospitals their plans will cover. While it is wonderful that cancer patients no longer can be denied insurance coverage for pre-existing conditions or have a limit on the lifetime amount of dollars in care they receive, patients also deserve to know what their options are before they decide which insurance policy to purchase.

Discrimination not allowed

For the first time, the ACA outlaws discrimination in health programs on the basis of race, color, national origin, sex, sex stereotypes, gender identity, age, or disability. In the past, women were typically charged more for health insurance than men, but that is now illegal. However, it is not yet clear whether women consumers will be protected from other types of discrimination. ♦

Blue Cross Blue Shield Says NO

Sarah called our Cancer Hotline, her voice breaking with fear and frustration. Her breasts were swollen and painful, and her oncologist told her she probably has anaplastic large cell lymphoma (ALCL), a cancer of the immune system which was caused by her breast implants. Experts agree that the first step would be to remove the implants and the scar tissue and fluid surrounding them. This is often enough to cure ALCL – sometimes radiation is also needed. But Sarah's Blue Cross Blue Shield insurance policy refused to pay to have her implants removed because they had been put in for cosmetic reasons. The irony is that the insurance company was also paying for numerous surgeries to try to treat her symptoms – which were caused by the ALCL, which was caused by the implants. They could save money and possibly save Sarah's life by paying a surgeon to remove her implants. But they refused.

Under the Affordable Care Act, insurance policies are supposed to pay for medically necessary procedures, and they are not supposed to discriminate against women. Refusing to remove breast implants specifically, while not refusing to remove the types of cosmetic implants that men use (such as pectoral implants) is sex discrimination.



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The Voice Issue 24 Spring/Summer 2014



Some of our staff enjoying the cherry blossoms at the Tidal Basin in Washington, DC

Left to right: Laurén Doamekpor, Maura Duffy, Paul Brown, Brandel France de Bravo, Anna Mazzucco, Melanie Brown, Sara Exler

www.center4research.org

Even though our name is changing, our website URL will continue to remain the same: www.center4research.org