

## 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.

## 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.

### Cancer Hotline:

[info@stopcancerfund.org](mailto:info@stopcancerfund.org)

### Websites:

[www.center4research.org](http://www.center4research.org)

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**CFC #11967**



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## Chantix helps you quit smoking but is risky

We all know that smoking kills thousands of Americans and that it's often difficult to quit. In addition to lung cancer, smoking can increase a person's chances of developing prostate cancer, breast cancer, pancreatic cancer, emphysema, and many other serious and potentially fatal diseases.

Any medication that helps people quit smoking can save lives. But every medication also has risks. Which risks are worth taking and how can we best warn people about the risks? What if your treatment can kill you or someone you love?

In addition to acupuncture, cognitive behavior therapy, and hypnotism, smokers who are trying to quit often try: 1) nicotine replacement treatments (such as gum and patches) to slowly wean off nicotine, 2) e-cigarettes, which deliver nicotine and some other dangerous chemicals, but may be less deadly than cigarettes, or 3) smoking cessation medications like Chantix and Wellbutrin (also called Zyban or Bupropion).

You've probably seen the TV ads for Chantix, a prescription medication which is intended to

help adults stop smoking by curbing the craving and reducing the symptoms of withdrawal. But like other drugs intended to affect the brain, Chantix has many serious side effects.

Scientific evidence shows that someone taking Chantix is more likely to become violent or suicidal, to have delusions, or to become depressed. Thousands of people taking Chantix have reported these side effects, some so serious that they caused death or severe disability. Symptoms can begin with the first dose, even before the person stops smoking, and many symptoms go away soon after treatment has stopped. Chantix side effects have been reported in the U.S., Canada, New Zealand, France, and Australia.

### A troubled history

Chantix has been sold since 2006, but based on information from clinical trials and reports to the FDA, Pfizer was required to add a black box warning on the Chantix label in 2009, cautioning doctors and patients of the dangerous psychiatric risks. A black box warning is the

## Examples of patients harmed by Chantix

### Case # 1: Anger/aggression

She swung at her mother (who was in her late 90's) due to the extreme rage, as she almost struck her and missed. She went out in the back yard and broke a weed wacker, a couple of glasses, the frame work on a couple of lamps, she threw concrete in the backyard and she began stabbing chunks of wood with the garden tools to get her rage out.

### Case #2: Terrifying nightmares and violent thoughts

She had a nightmare on 23 Dec 2007 that she was in prison lying on a cold, wet floor shackled to a corpse. On 26 Dec 2007 she wanted to get the key to the gun cabinet and shoot her husband. She stopped taking Chantix and "everything setting her off resolved on 28 Dec 2007." (age 43)

# We're in the Headlines!

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**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](http://stopcancerfund.org).**

**Can the war on cancer be won? A surprising answer**

The Huffington Post  
Sept. 16, 2014

**Medical company may be falling short of its patient safety ideals**

NPR  
Oct. 6, 2014

**Ebola outbreak: A teachable moment for scientists**

AAAS blog  
Aug. 12, 2014

The Wall Street Journal  
Sept. 29, 2014

**Medical devices lack safety evidence, study finds**

**Safety advocates seek stronger warnings on Chantix**

The Associated Press  
Oct. 8, 2014

The National Center for Health Research explains that the FDA must increase incentives for companies to test their medical products on men, women, older patients, and people of color. Instead, the FDA urges diversity but approves drugs and implants that might benefit only some of these types of patients but not others. We were quoted in **MedPage Today** and blogs by the **Wall Street Journal** and **The Scientist**.

As Ebola made headlines, Dr. Zuckerman wrote in the **AAAS** blog that experimental drugs are not always magical cures. "We don't know yet if ZMapp or any other Ebola drugs in development will save lives or cost lives," she cautioned. "Urgent situations show us how important good science is, but good science takes time."

Dr. Zuckerman also wrote a second blog post for **AAAS** about the disconnect between science and public policy regarding **antibiotic resistance**.

Dr. Zuckerman wrote an article for the **Huffington Post** and **Rodale.com's Maria's Country Kitchen** about better communication with cancer patients about their treatment options, since **cancer treatment** is often worse than the disease. She explained, "Research has clearly shown that for a substantial minority of patients, 'active surveillance'—no surgery, no radiation, but just regular screening—is a very safe alternative to treatment." She wrote three other blog posts for those websites about the proliferation of unproven cancer treatments, steps to take when making a medical decision, and the controversy about "pink Viagra."

We co-authored a Citizen Petition asking FDA to keep black box warning labels on the **smoking cessation drug Chantix** even though its U.S. maker Pfizer wants to remove it. **The Associated Press** quoted our petition, saying, "It would be illogical to discount the reports of thousands of consumers who told of frightening...[Chantix] experiences." When the **Wall Street Journal** reported that Pfizer had lost their bet to remove the Chantix warning, they quoted Dr. Zuckerman: "They obviously wouldn't have done it if they didn't think they could convince people, but they failed completely."

Our study on the lack of scientific evidence for **implanted medical devices** in **JAMA Internal Medicine** was cited by the **Wall Street Journal**, **Reuters**, **Modern Healthcare**, **CBS**, and **HealthDay**. We found that sufficient data were only available for 8 out of 50 new medical implants. CBS and HealthDay quoted Dr. Zuckerman: "If you are a doctor who wants to know what the scientific evidence is that this device is safe and effective, there is no publicly available evidence."

A **medical device** company, Masimo Corporation, promised to reduce the number of deaths from medical devices, but FDA found it didn't sufficiently investigate many reports that its devices might have malfunctioned. When **NPR** interviewed Dr. Zuckerman on the subject, she pointed out, "It's not very credible" that the company blamed the doctors instead of the product every time the doctors complained that the company's product put patients at risk.



## Was that new implanted medical device tested to make sure it can save your life?

If you or someone you love needs an implant, such as a heart valve or a radiotherapy implant to treat cancer, wouldn't you like to know it was carefully studied to make sure it works? Our new study, published in *JAMA Internal Medicine*, is the first proof that scientific data are not publicly available on most implants—even the ones we rely on to save lives.

We started the study for a simple reason. For the last several years, we have been asking the FDA why they don't require that every medical implant be studied on patients, instead of studied by engineers. FDA officials kept telling us we were wrong—that all medical devices (including implants) are very carefully studied with solid scientific evidence before they can be sold. We wanted to believe them. So, we set out to learn more about that “solid scientific evidence” we had heard so much about.

We started the study in 2013, by selecting 50 implants that the FDA had approved in the previous 5 years, representing 5 different types: cardiac, dental, general and plastic surgery, orthopedic, and neurological. We didn't pick any devices in particular; we just chose the first implants in those categories that were cleared through the quicker and less stringent 510(k) process each year.

### What's the evidence?

We wanted to know how many devices were studied on patients. For those not studied on patients, we wanted to know what kind of scientific studies were conducted. For example, we thought perhaps hip implants were studied on robots that were programmed to move like humans. Maybe cardiac implants were studied on primates. We didn't know, and we wanted to find out.

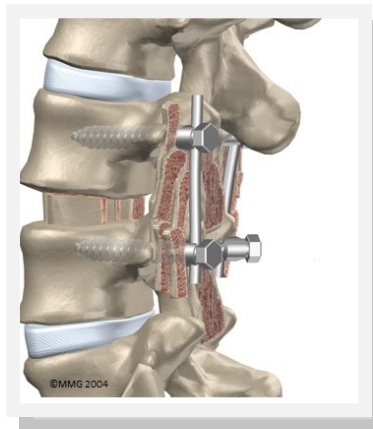
Fortunately, the law requires that a summary of all the scientific data provided to the FDA must be available online. If for some reason it isn't, the law requires that companies provide those data within 30 days to any individual who requests it in writing.

Silly us! The law isn't enforced! Of the 50 implants in our study, only 16% provided data of any sort. And when we wrote to companies that had no information available online, most did not provide it within 30 days. In fact, it is now nearly 400 days, and most still haven't provided any scientific data.

We thought that perhaps those 50 implants were not representative of all implants, so we took the next step. Since all 50 of the implants were approved as “substantially equivalent” to another medical device on the market (called a “predicate” in FDA lingo), we studied all **1105 devices** that were listed as predicates for those 50 implants. Sadly, those implants were even less likely to provide any scientific evidence—only 3% compared to the 16% for our 50 original implants.

### Implications for your health

This lack of information means that if your doctor is wondering which implant is best for you, they are unlikely to have any scientific evidence that can answer that question. And if you want to try to find that information yourself, you too will be out of luck.



*Did this spinal implant provide scientific data proving safety?*

The law is on your side, but the companies aren't abiding by the law and the FDA isn't enforcing the law.

If you think this is not fair to patients, please contact us at [info@center4research.org](mailto:info@center4research.org). Just say “I think we should know what the scientific evidence is.” We want to hear from you.

For more information about our study see: Zuckerman D, Brown P, Das A. Lack of Publicly Available Scientific Evidence on the Safety and Effectiveness of Implanted Medical Devices. *JAMA Internal Medicine*. 2014. ♦

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# Foremother Awards

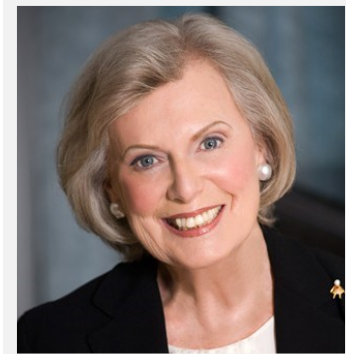
## Inspiring women and investigative reporters: Our 2014 honorees

We held our 10th annual Foremother and Health Policy Hero Awards Luncheon on May 9th. This year's lunch had a new venue: the historic (and sometimes infamous) Mayflower Hotel in Washington, D.C.

With the help of our wonderful Mistress of Ceremonies, **Maureen Bunyan** of WJLA-TV 7, we celebrated the achievements of three Foremothers: Health advocate **Irene Pollin**, children's author **Phyllis Reynolds Naylor**, and **Congresswoman Louise Slaughter**. We also honored a reporter and an editor from *ProPublica* for their contributions to improving the health of men and women by pointing out major flaws in our Medicare system.

### 2014 Foremother Honorees

**Irene Pollin** has dedicated her life to improving the lives of others, as a psychiatric social worker, writer, advocate, and philanthropist. She is the founder and chairperson of *Sister to Sister: The Women's Heart Health Foundation*, the first organization to address the public health crisis that heart disease is the number one killer of women. As Ms. Pollin noted in her remarks, "My area of professionalism was in health, and I didn't know that heart disease was the number one killer of women. And I said, well if I don't know, who does know? And that was my impetus really to get going." *Sister to Sister* provided more than



*Irene Pollin*

100,000 free heart health screenings and counseling nationwide. Her activism also stems from personal tragedy: two of her children died from congenital heart disease. With her late husband, Abe, she co-owned the Washington Wizards and the Washington Capitals, and together they helped revitalize Washington, D.C., through philanthropy, public service, and an unwavering commitment to the community.

**Phyllis Reynolds Naylor** is one of our nation's most beloved authors. She has written 140 children's and young adult novels, including the popular "Alice" books, which have frequently been praised—and banned—for their frank representation of teenage sexual curiosity and adolescence. Her remarks were the biggest surprise of the event. Even more outspoken in person than in her books, she mesmerized the audience with tales of her own adolescence, including a Maryland grandmother who taught her how to pee in the woods standing up, "projecting a stream as skillfully as any man," and an austere Midwestern grandmother who "would've faced a firing squad before she would have exposed herself that way." Naylor credited her mother with "breaking the chain" of



*Phyllis Reynolds Naylor, Maureen Bunyan, and NCHRP President Diana Zuckerman*

repression about sexuality and the human body and honestly answering her childhood questions about sex. Naylor concluded, "Sex is only a small part of the Alice books, but I do hope they help readers differentiate between normal teenage sexual curiosity and risky behavior...and to value themselves and their own choices."

**Congresswoman Louise Slaughter** (D-NY) delights in taking on the fights no one else will, which made her a perfect fit for our Foremother Award. As a powerful and unique Member of the U.S. House of Representatives who is serving her 14th term, Rep. Slaughter joked, "they don't call me Slaughter for nothing." As the only Member of Congress with a degree in microbiology, she has played a central role in the major health and science issues of our time, achieving landmark legislation such as federal funding for research on the synthetic hormonal drug DES, the inclusion of women and minorities in clinical trials, and increased federal funding for breast cancer, at a time when virtually no NIH research was being done on cancers that primarily affect women. As Slaughter stated, "We lost a Vietnam Wall full of women every single year to breast cancer. And absolutely nothing at that time was being done about it."



*Congresswoman Louise Slaughter (D-NY)*



# Health Policy Heroes

Rep. Slaughter is the original author of the *Genetic Information and Non-Discrimination Act (GINA)*, which became law in 2008, and the original author of the *Preservation of Antibiotics for Medical Treatment Act*, which would drastically reduce the epidemic of antibiotic resistance—if only Congress would pass it. Rep. Slaughter is also one of the original co-authors of the *Violence Against Women Act* and is now on the forefront of fighting sexual assault in the military.

## Health Policy Heroes

We were thrilled to honor *ProPublica's* **Charles Ornstein** and **Tracy Weber** with our 2014 Health Policy Hero awards. Ornstein and Weber's investigative series of articles delineating Medicare's reimbursement for doctors prescribing massive quantities of inappropriate medications—and wasting billions on needlessly expensive drugs—has resulted in Medicare proposing new regulations to give itself the authority to kick doctors out of Medicare for abusive prescribing, criminal history, or other serious infractions.



Tracy Weber and Charles Ornstein.

In May 2014, for the first time Medicare also made public its annual payments to doctors, making it easier for reporters and providers to investigate questionable billing by doctors across the country.

Ornstein expressed enthusiasm for an increase in Medicare's transparency and praised NCHR's work as a watchdog: "By drawing attention to Medicare's inaction we hope that we empower consumers to ask questions of their doctors, but also encourage Medicare to take on a level of responsibility and oversight for those that have none, much like this Center does in encouraging the FDA...to base their decisions on research."

Ornstein and Weber won the Pulitzer Prize for Public Service in 2005 as well as the Robert F. Kennedy Journalist Award, and they were finalists for the same Pulitzer Prize in 2010. They have made a huge impact with their top-notch investigative reporting, and we were truly honored to have had the opportunity to thank them with our Health Policy Hero award.

## Thanks to Our Supporters

We are always grateful to Board Member **Judith Harris**, but this year she outdid herself, offering to match, dollar for dollar, any donations made in the 10 days following our Luncheon. The result was a combined gift of almost \$10,000. We are also grateful to the very generous nonprofit organizations and corporate sponsors who made our 2014 Luncheon possible: **American Association for Justice; the Air Traffic Controllers Union; the Cooper-Rothenberg Group at Morgan Stanley; Catherine Joyce at Morgan Stanley Wealth Management; Phyllis Wiesenfelder of Long & Foster Real Estate; Congressional Federal Credit Union; Net-Centric Enterprise Solutions (NES); Sixth & I Historic Synagogue, and the International Brotherhood of Electrical Workers.**

We are also grateful to the other nonprofit organizations who co-sponsored our luncheon: **American Medical Women's Association, Consumers Union, Hadassah, Jacobs Institute of Women's Health, Kaiser Permanente, National Business Group on Health; National Consumers League; National Organization for Women; National Physicians Alliance, National Women's Health Network; and the U.S. Public Interest Research Group (PIRG).**

Special thanks to individual patrons including **Leaders Omega Logan Silva and Susan Wood; Champions Steven Bozzo, Janette Sherman, George Tom Beall; and Supporters Benjamin Gitterman, Bobbie Greene McCarthy, Steven Grossman, Judy Harris, Claudine Homolash, Isabel Jasinowski, Anne Hale Johnson, Kitty Kelley, Linda Kramer Jennings, Kitty Lansdale, Beth Newburger, Vivian Pinn, Audrey Sheppard, and Duchy Trachtenberg.** ♦

## 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](mailto:bfb@center4research.org)



The new Ruth Nadel internship honors our Foremother and donor on her 100th birthday!

## A Patient Advocacy Workshop to empower patients

It seems so obvious: Medical products should be tested to make sure they are safe and effective in ways that matter to patients. If patients are facing life-threatening diseases, they might be more willing to take a risk with a new drug than if there are already 38 other drugs available that are proven safe and effective. And if a drug helps a dying patient live 4 months instead of 2 months, but all 4 months of life are completely miserable, should that be considered a success?

The Patient Centered Outcome Research Institute (PCORI) was created as part of the Affordable Care Act (“Obamacare”) to improve the quality of medical care. Their mission is:

1. To compare the safety and effectiveness of different treatments and make that information widely available;
2. To include patients in the process of deciding the kinds of treatment outcomes that matter.

The Food and Drug Administration (FDA) approves medical products that it believes will benefit more patients than it will harm. But, that doesn’t mean the product will benefit you. And the FDA’s assessment of benefits and harms might be different from what some patients care about.

The FDA welcomes patient input at some points in its approval and regulatory process, but few patients know about these opportunities or are able to take advantage of them.

### Our solution: Training patients to be advocates

Many patients, activists, and advocates do not understand how the FDA works or makes decisions about approval. This has resulted in many complaints by patients and by Congress that the FDA is delaying access to life-saving drugs or devices. But when a medical product is found to be defective compared to

*Continued on next page*



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

### Our National Conference



*Rep. Rosa DeLauro (D-CT) at our “Evidence for New Medical Products” conference.*

Scientific research has the power to improve the lives of patients across the country and around the world, but too often that research gets drowned out by competing information. As a result, patients, physicians, policy makers, and other opinion leaders miss out on important information that can save lives.

The current head of Pharma, which lobbies for the financial interests of pharmaceutical companies, was until recently a Republican Congressman. The head lobbyist for Adva-Med, which represents device companies, was a key staffer for Sen. Ted Kennedy (D-MA) when he wrote laws shaping how the FDA makes approval decisions. Those two insiders know how to lobby effectively, and they are spending millions of dollars every year to persuade Congress and the FDA to get their products approved as quickly as possible. But is that what most patients want?

We partnered with **Harvard Medical School** and the **American Association for the Advancement of Science** to hold a national conference in Washington, D.C., to examine the standards used for FDA approval, and determine which need to be improved.

Most medical researchers study the effectiveness of medical treatments, but a growing number are scrutinizing the impact of FDA policies that themselves have risks and benefits. An impressive body of research shows that getting drugs and devices on the market more quickly often exposes patients and consumers to medical products that don’t work or that aren’t safe.

Our keynote speakers were **Rep. Rosa DeLauro (D-CT)**, a strong voice for patient and consumer safety, and **FDA Commissioner Margaret Hamburg**, whose dedication to the FDA as a public health agency has been sorely tested by Congressional pressure to approve drugs and devices more quickly with little regard for safety. Congressional calls to “support innovation” and “reduce the burdens on companies” can result in a higher burden on physicians and their patients, who too often need to make potentially life-saving decisions regarding enormously expensive new treatments on the basis of completely inadequate information. ♦



*FDA Commissioner Margaret Hamburg*



other options, such as many metal-on-metal hips or surgical mesh, patients and their loved ones feel betrayed by an agency that is supposed to protect them.

We brought together 30 patients and family members from across the country who have been advocates for others and wanted to do more. Most had limited information about the kind of research the FDA relies on to decide if a drug or device is safe or effective. The major goal of our free June 12 workshop was to explain the FDA process and to teach patients about the many opportunities available to provide their perspectives to the FDA.

Thanks to partial support from a PCORI Program Award, we were able to bring together patients who would not otherwise be able to attend a workshop in Washington. The day after our workshop, participants also attended a conference that we co-hosted with Harvard Medical School and the American Association for the Advancement of Science, *Evidence for New Medical Products: Implications for Patients and Health Policy*. Patients made their voices heard at the workshop and conference.

Ten advocates made workshop presentations or moderated sessions on topics such as *How does the FDA make decisions to approve, rescind, or recall a medical product?* and *Is the FDA too fast or too slow?* HIV/AIDS activist and co-director of the Yale Global Health Justice Partnership, **Gregg Gonsalves**; WoodyMatters founder **Kim Witzak**; and National Consumers League Executive Director **Sally Greenberg** were among our dynamic speakers. Participants were so actively engaged and asked so many great questions that our only difficulty was getting through the entire jam-packed agenda.

Continued from page 6



*At our workshop, patient advocate Diana Levine discusses her experience with a drug that resulted in her arm being amputated.*

After the workshop, 96% of participants reported that they would like to be involved in FDA issues as a patient or caregiver advocate. Before and after surveys showed an increase in knowledge on all aspects of the FDA approval process as well as on research issues such as *What does statistical significance mean?*

In the few months since the workshop, most of the organizations that were represented there have signed on to written comments submitted to the FDA on issues such as providing accurate safety warnings on social media ads and promotional material to doctors, and ensuring that drugs and implants are proven safe and effective for women, men, racial/ethnic minorities, and people over 65. ♦

## A drug to help you quit smoking has serious risks

Continued from page 1

most serious type of warning that the FDA uses to caution doctors and patients about risks linked to a drug.

But the reports of serious side effects kept coming. In July 2010, the FDA learned that Pfizer did not properly submit 26,000 adverse event reports, including 589 serious cases (such as 150 suicides, 102 cases of violent thoughts and actions, and 56 cases of psychosis).

In December 2010 and January 2011, two reports by independent researchers documented more deaths and violence attributed to people taking Chantix than any other medication.

### The saga continues

Despite the evidence, Pfizer asked the FDA to remove the boxed warning earlier this year, because several studies funded by Pfizer showed that Chantix is safe. The FDA scheduled an Advisory Committee meeting to seek expert advice.

Meanwhile, we partnered with *Consumer Reports*, Institute for Safe Medication Practices, National Physicians Alliance, and Public Citizen to submit a Citizen Petition to the FDA in

October 2014. The petition is a scientific document explaining why the FDA should strengthen the black box warning, not remove it.

On October 16, 2014, we testified at the FDA Advisory Committee meeting, emphasizing that Pfizer is relying on fatally flawed studies to prove safety. We strongly urged the advisors to recommend that the FDA keep a strongly worded black box warning.

Consistent with our testimony, 11 Advisory Committee members voted to retain the current box warning, 6 voted to strengthen the language, and only one voted to remove the boxed warning.

Smoking can kill. That's why we support keeping Chantix on the market. Anyone who wants to quit smoking is taking a difficult step towards a healthier life. They deserve a clear warning about the risks of treatment, so that if they start feeling violent, suicidal, or out of control, they know to stop taking the drug. Our task is to ensure that patients have the information they need to make the right health choices for themselves and their families. ♦

# National Center for Health Research

## Cancer Prevention and Treatment Fund (our largest program)

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*Inside the issue: Why did we honor this woman, who is one of the most banned authors in the U.S.? See page 4.*

### Cancer Prevention and Treatment Fund

We don't accept funding from drug companies so you can rely on our candid and accurate help to prevent and treat cancer.



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*We're here for you so you can be there for them. Let's fight cancer together!*