

The 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 treatments and policies. The Cancer Prevention and Treatment Fund is our major program.

www.center4research.org
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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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Who Decides Which Medications Work?

How can we get new, safe and effective medical treatments approved by the FDA and on the market as quickly as possible? Companies complain that doing large studies of patients takes too long and costs too much, especially if we want to find out if the treatment will save the patient's life or make an important difference in their health.

Their solution: instead of comparing the health or survival of patients taking a new drug to patients taking an older drug, the companies like to study how the drug affects easy-to-measure, short-term changes. For example, if a company has a new diabetes drug, they want to measure how patients' glucose (sugar) levels are controlled, instead of how long patients live or how many times patients are hospitalized. If they have a drug for cancer, they prefer to measure whether it delays the cancer from spreading rather than whether the patient lives longer.

These are called **surrogate endpoints**. They are proxies for the outcome patients really care about, which is survival or good health. How well do these surrogates predict what will happen to you? Do they accurately reflect what really matters to patients?

Osteoporosis drugs

Hip fractures are a major risk that can be extremely painful and even deadly. Women over

65 are encouraged to get a bone mineral density test to measure their risk for osteoporosis, because porous bones are at higher risk for fracture. How well do these drugs work?

You might be surprised to learn that none of the osteoporosis drugs on the market are proven to prevent hip fractures for more than 99% of the women who take them. Some of these drugs, like calcitonin, were only tested to see if they improved bone mineral density. Bone mineral density scores are used to diagnose osteoporosis, but they are not good at predicting who will get a bone fracture.

The most popular drugs, such as Fosamax, Actonel, and Boniva (all bisphosphonates), all improve bone mineral density. They also reduce the chances of spinal fractures that show up on x-rays. That sounds important but, in fact, these spinal fractures did not cause pain and there is no clear evidence that they are harmful.

Unfortunately, there is also no evidence that women taking osteoporosis drugs because of lower bone mineral density test results will benefit by having fewer hip fractures or better health. In fact, research shows that bisphosphonates, if taken for more than 3-5 years, may increase the risk of leg fractures and possibly jaw problems.

Policy Matters

Our top goal is to keep you and your family healthy. Unfortunately, there are government policies that don't always require that medical products be proven safe and effective! We sometimes need to fight powerful special interest groups that are trying to influence government officials—too often at your expense.

Advising the Advisors. Did you know that most artificial hips and knees are not tested in people before the FDA approves them? That tanning beds are causing skin cancer but are not required to be tested for safety; new drugs are sometimes less effective than older, less expensive drugs; and that osteoporosis drugs don't necessarily prevent hip fractures? (See page 1). That's why we have testified at FDA meetings about dozens of dangerous and ineffective drugs in the last few years. Too often, we are the only speakers, other than FDA scientists, who aren't paid by the company to say how great their product is.

Powerful Partners. To leverage our influence, we play a key organizing role in the Patient, Consumer, and Public Health Coalition, which is an informal alliance of non-profit organizations. Our partners include the National Consumers League, Union of Concerned Scientists, Consumers Union, Our Bodies Ourselves, TMJ Association, and many others (to see a complete list of member groups go to www.patientsandconsumers.org).

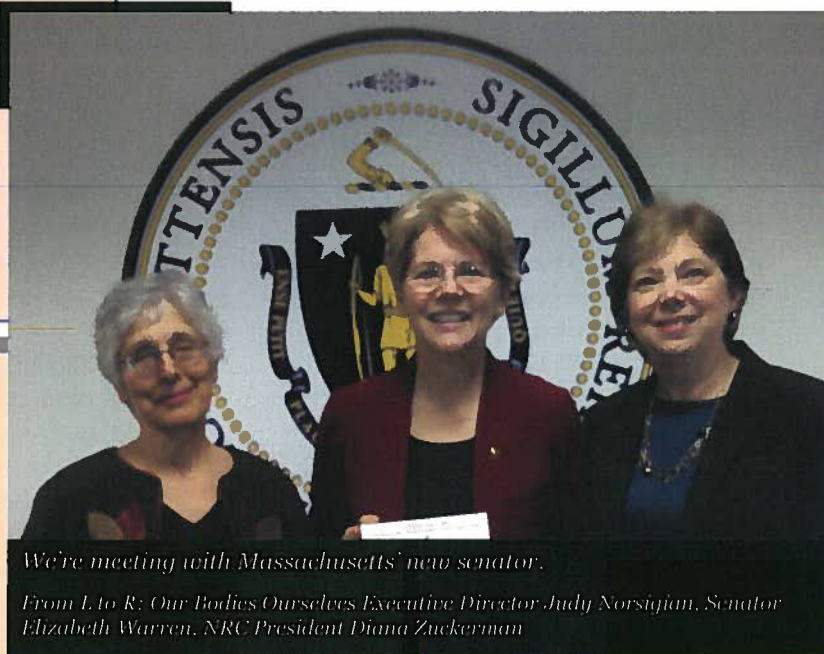
Protecting Healthcare Coverage. President Obama's Affordable Care Act will give millions of uninsured Americans access to health coverage—but only if it's fully funded. An important part of its funding is a small (2.3%) tax on medical devices, which will raise \$29 billion over 10 years. The medical device industry will make billions more dollars than ever before because more patients will have insurance coverage for hip implants, heart valves, glu-

cose test strips, and other devices. But, device companies are spending millions of dollars to convince lawmakers to repeal the tax. NRC and our allies such as *Consumer Reports* and *Families USA* are asking lawmakers to stand up to the powerful medical device industry by protecting this essential source of funding used to provide insurance coverage for those who need it most.

Compounding Problems

The meningitis outbreak that killed 51 people resulted from a lack of safeguards at a huge pharmacy in Massachusetts. But the problem is much larger than one pharmacy in one state. All over the country, companies that are manufactur-

ing drugs call themselves compounding pharmacies so they won't have to prove to federal inspectors that their drugs are safe and effective. In some cases, cancer patients died because the compounders' drugs were either too weak or too strong. In other cases, contaminated medicines killed patients who didn't even know their treatments weren't proven safe or effective. We're working with key members of Congress to fix this problem, but there are so many well-paid lobbyists working against our efforts.



We're meeting with Massachusetts' new senator.

From L to R: Our Bodies Ourselves Executive Director Judy Norsigian, Senator Elizabeth Warren, NRC President Diana Zuckerman

Overuse of Antibiotics. Did you know that more than 80% of antibiotics are used in animals grown for food, often to fatten them up? With farmers unwilling to reduce that use, we're asking Congress to take the first baby step: requiring data be collected on exactly how and why antibiotics are so widely used in chickens, cows, and pigs. We're also fighting to achieve the second step: reduced use of antibiotics by the food industry as part of the *Animal Drug User Fees Act*.

Could an Inexpensive Heart Medicine Help Cancer Patients Live Longer?

Beta-blockers are often prescribed for high blood pressure, irregular heart beat (arrhythmia), or after a heart attack has already occurred. They stop the body's "fight or flight" response to stress or danger, helping the body feel more relaxed, lowering blood pressure, and increasing blood flow.

Beta-blockers are the fifth most widely prescribed class of drugs in the U.S. Since they are safe and inexpensive, wouldn't it be great if they were effective for treating cancer, too?

Doctors and researchers noticed that when cancer patients took beta-blockers because of their heart disease, they tended to live longer than other cancer patients. Researchers decided to study whether beta-blockers significantly improve survival for several different types of cancer.

Lung cancer

A study by researchers at the MD Anderson Center in Texas reviewed data from 722 patients with non-small cell lung cancer, the most common type of lung cancer. All patients received radiation therapy to treat their lung cancer, and some were also taking beta-blockers for heart conditions. Almost all the patients in the study had stage III cancer, which means it had started to spread.

The 155 patients taking beta-blockers survived for an average of almost 24 months while the 567 patients not taking beta-blockers survived for an average of 18.5 months. Patients taking beta-blockers lived longer without their lung cancer returning (disease-free survival) and without it spreading to other parts of their body. The researchers statistically controlled for other factors that could affect survival, such as the patient's age, the stage of the cancer, the use of aspirin, and use of chemotherapy, to be sure that the beta-blockers were truly helping slow down the cancer.

Breast cancer

Six studies published since 2010 have examined breast cancer patients who had been taking beta-blockers for heart disease. All six studies found that breast cancer patients lived longer if they were taking beta-blockers.

Ovarian cancer

Researchers at Cedars-Sinai Medical Center in California studied 248 women who had surgery and chemotherapy for ovarian cancer. The 23 patients who were also taking beta-blockers for heart conditions lived an average of 56 months after cancer treatment, compared to 48 months for women not taking beta-blockers. In fact, women who took beta-blockers were 54% less likely to die during the more than 12 years studied after surgery, compared to the women who did not take beta blockers.

Pancreatic cancer

University of Tennessee researchers found that beta-blockers

halted the progression of pancreatic cancer in animals. Research is needed to determine if beta-blockers are effective for pancreatic cancer in humans.

Why might beta-blockers help cancer patients?

Adrenaline and noradrenaline, which stimulate the "fight or flight" response, probably trigger tumor growth. When beta-blockers stop these neurotransmitters, that may help stop cancer from spreading.

When the FDA makes a decision to approve a drug, they weigh the risks and benefits for specific diseases. The risks of beta-blockers can include fatigue, headache, upset stomach, constipation, diarrhea, dizziness, cold hands, shortness of breath, and trouble sleeping. With all these side effects, it is not a good idea to use beta-blockers to treat cancer unless there is clear evidence that they work. A new breast cancer study is underway to determine if beta blockers are effective if given for 2 days before and 3 days after cancer surgery.

Beta blockers are approved by the FDA for heart disease; preventing migraines; treating essential tremor (ET) in the head, arms and legs; and as eye drops to treat glaucoma. Doctors pre-

scribe beta blockers for other reasons, but taking medicines for non-approved uses can be risky, if there is no proof that the benefits outweigh the risks. More research is needed, but, unfortunately, when drugs are inexpensive and already on the market, companies don't have the financial incentive to spend the money on clinical trials to get approval for a new indication, even if it would help cancer patients. The research funds need to come from elsewhere.

The Bottom Line

- ◆ Beta-blockers are usually used to treat heart conditions. New research shows that these inexpensive drugs may help cancer patients live longer.
- ◆ More research is needed to know which beta-blockers work best for which cancers. If you already take beta-blockers for a heart condition, keep taking them if you are also diagnosed with cancer.
- ◆ If you don't take beta-blockers and are diagnosed with non-small cell lung cancer or early breast cancer, ask your doctor whether you should be taking beta-blockers. ■



Health Matters

Continued from page 1

Sleeping Pills

Some of the most popular—and controversial—pills are used by millions of people to help them sleep. Many people swear by them – so you'll be surprised what happened when *Consumer Reports* looked at the research to see how well they work (see box below).

Consumer Reports Best Buy Drugs: Treating Insomnia with Sedatives Effectiveness and Differences – The Newer Sedative Drugs						
Drug and Year it Went on Market	Average Time to Fall Asleep ¹	How much faster than placebo on average?	Helps You Stay Asleep?	How much longer than placebo on average?	Percent With Next-Day Drowsiness ¹	Risk of Dependency?
Zolpidem (Ambien) (1992)	33 to 46 minutes	20 minutes	Maybe	34 minutes	2%-3%	Yes
Ambien CR (2005)	33 to 46 minutes	About 10 minutes	Yes	About 30 minutes	15%	Yes
Lunesta (2004)	50 minutes	19 minutes	Yes	46 minutes	8%-10%	Yes
Rozerem (2005)	75 minutes	8 minutes	No information	3 minutes	5%	No
Sonata (1999)	36 to 55 minutes	14 minutes	Evidence weaker than for zolpidem and Lunesta	19 minutes	5%-6%	Yes
Zolpidem sublingual tablet (Edluar)	20 minutes	6-10 minutes vs regular zolpidem tablets (No comparison to placebo)	Maybe	Not assessed	4%	Yes
Zolpidem oral spray mist (Zolpimist) ²	33 to 46 minutes	Same as regular zolpidem tablets	Maybe	Same as regular zolpidem tablets	2%-3%	Yes

*Extracted from "Evaluating Newer Sleeping Pills Used to Treat Insomnia" *Consumer Reports Best Buy Drugs*, January 2012: Table 2, p14.

1. As assessed in one major study or, if range given, several studies. Figures are not meant to imply that drugs were necessarily compared to each other in a study with consistent design.

2. Based on studies showing bioequivalence to zolpidem.

of cancer, patients and their physicians assume that means the patients live longer. Unfortunately, it doesn't. Cancer drugs are so toxic that they can kill patients even while they kill cancer cells. That's the reason why Avastin, a widely used drug for several types of advanced cancer, is no longer approved by the FDA for breast cancer. Although Avastin delayed the progression of breast cancer, the patients on average died sooner and they suffered from more strokes, gastrointestinal perforations, and other very painful side effects. This is a dramatic example of why studies should measure health outcomes that patients care about, not surrogates.

Antibiotics

Antibiotics get rid of bacterial infections and save lives. Patients who are suffering from a bacterial infection may be very sick and have other complications, and doctors may not even be able to identify exactly which bacteria are making them sick. Because of these uncertainties, when companies want to prove to the Food and Drug Administration (FDA) that an antibiotic works they often rely on how well the drug kills bacteria in a test tube. But does this method of testing produce drugs that actually improve our health and save lives? Not necessarily.

In 2012, the FDA approved a new antibiotic, Sitro, that stopped tuberculosis bacteria from growing in patients after 24 weeks of treatment. Unfortunately, this did not mean they were cured: instead patients were 5 times as likely to die after taking the new antibiotic, often from tuberculosis the antibiotic supposedly killed! ■

For example, Ambien is one of the most popular sleeping pills, but patients taking Ambien fell asleep only 10 minutes faster than when they took a placebo! Consumers spent \$8 per pill to get that 10 minutes, stayed asleep a little longer, and then 15% felt drowsy the next day. Lunesta, Sonata, and other popular sleeping pills also have limited benefits at about the same cost. These findings are especially important because taking sleeping pills is associated with increased risk of cancer and of dying at a younger age.

Cancer Drugs

When researchers report that a new drug delays the progression

What's a patient to do?

Who has time to read all the medical research to figure out if one treatment is better than another—or if none are especially worthwhile? Visit these great sites for information that can improve your health and the health of your loved ones:

1. Medical groups representing half a million doctors have come up with *Choosing Wisely*® recommendations of tests, procedures and medicines that are unnecessary and cause harm. Visit www.choosingwisely.org to see their 135 "Things Physicians and Patients Should Question."
2. Our website, www.center4research.org, scrutinizes research findings and translates them into plain language that anyone can understand.
3. *Consumer Reports*' "Consumer Health Choices" at www.consumerhealthchoices.org includes links to their "Best Buy Drugs" section which has guides, like the sleeping pills comparison table above, to help you see which drugs are most effective.
4. AHRQ's Effective Health Care program at www.effectivehealthcare.ahrq.gov can help you find the best type of medical treatment.

Comparative Effectiveness Research: Which Hips, ADHD Treatments, and Cancer Drugs Get the Best Mileage?

When you buy a new car, do you make a decision based on what the salesperson tells you is best, or do you check *Consumer Reports* to compare different cars and decide which is best for you? Do you just check which car has the best total score, or do you also look at what is important to you, such as price, leg room, size of the trunk, and how far it goes on a gallon of gas?

When you need to make an important medical decision, wouldn't it be great to always have a *Consumer Reports* type of comparison of your different treatment options?

Medical decisions are often more complicated than decisions about a car, but there are many similarities. For example, if you are having a hip replacement or a heart valve, you'd want to know how well it works, how long it usually lasts, and what kinds of complications are likely for people like you (your age, sex, and how physically active you are).

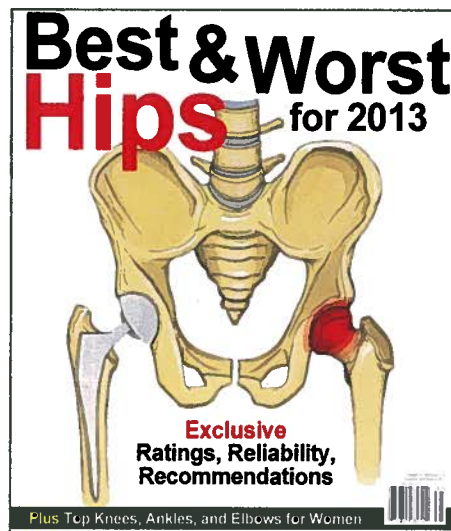
Ideally, you'd like to know whether this product is going to deliver on its promises for you. Whether the product is a car or a medical treatment, that's almost impossible to know. However, scientific comparisons can help us make an informed decision—helping us choose the product or procedure that's right for us. That's why we hosted a conference with *Consumer Reports* on comparative effectiveness research—research that compares how safe and effective different medical treatments are, and for whom. Funded by the Agency for Healthcare Research and Quality (AHRQ), a small U.S. government agency, the goal was to bring leaders of non-profit health organizations together to help figure out how patients, consumers, and medical professionals can get the information they need to choose the best possible care.

How Do We Compare?

The U.S. has one of the most expensive healthcare systems in the world, and yet American men live shorter lives than men in 16 other wealthy countries. U.S. women live shorter lives than women in 15 of those

same countries, and Americans are less likely to survive to age 50! Even Americans with health insurance don't live as long as people in many other countries—including countries where smoking is much more common. How can that be?

Even wealthy, insured Americans can be victims of expensive, ineffective treatment.



Wouldn't it be great if there were objective comparisons of medical products, not just cars and toasters?

More \$\$\$ and Less Safe

When good comparisons are not available, most consumers and doctors just assume that newer, more expensive drugs are better.

Have you ever seen ads for Yaz birth control pills? Would you be surprised to learn that they are no better than older, less expensive pills at preventing pregnancy, clearing up skin, or reducing menstrual mood swings, and that they are much more likely to cause dangerous blood clots? A study of more than 800,000 women found that Yaz, Yasmin, Beyaz, Safryal and other birth control pills that contain a newer kind of hormone called drospirenone almost doubled the risk of blood clots, which can be fatal. Unfortunately, you and your doctor would have to carefully read page 4 of a 24-page label to find that out.

When new metal-on-metal hip implants went on the market, doctors were told they would last longer than other hips—a great benefit

because hip surgery is terribly painful with a long recovery time. Instead, metal-on-metal hips released toxic metal debris into patients' blood and were much more likely to have to be replaced within 5 years. Recent research reveals that hip implants are especially likely to fail in women. If comparative effectiveness research is done early on, patients can choose the implant that's best for them, insurance costs can decrease, Medicare won't run out of money, and companies can avoid costly recalls.

The Affordable Care Act (also called Obamacare) funds research to compare treatments and figure out which ones work best for which patients. Congress did not allow these studies to compare cost-effectiveness, but these studies can save lives and save money at the same time.

For example, 11% of U.S. children between the ages of 4 and 17 are diagnosed with attention deficit hyperactivity disorder (ADHD), and two-thirds of them will be prescribed Ritalin, Adderall, or similar drugs, at a cost of \$9 billion per year. These drugs can be addictive and sometimes cause mental health problems. But new comparative effectiveness research shows that special training for parents with 4 to 6 year olds with ADHD works better than drugs—without any dangerous side effects!

If you want to find out more about how comparative effectiveness research can improve your health, check out the websites in the blue box on page 4. ■

Choosing Wisely®

Medical organizations representing more than half a million US doctors have compiled 135 recommendations based on comparative studies. This *Choosing Wisely®* campaign can save money, save lives, or both. For example:

- Don't use anti-nausea gels because the drug can't be absorbed through the skin, so they don't work.
- Antipsychotics are not effective to treat Alzheimer's or dementia patients and can cause stroke or death.

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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
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NRC News

We're in the Headlines!

Dangers of Antipsychotic Misuse in Nursing Homes

Poor Baby: Daddy's Got a Text Message

New York Times,
March 29, 2013

Healthcare Policy Podcast
December 22, 2012

**U.S. fraud alert warns of
doctors' ties to implant devices**

Journal Sentinel
March 27, 2013

**FDA proposes stricter regula-
tions for tanning beds**

Washington Post
May 7, 2013

**Making the dangers of
swordfish more obvious**

Washington Post
February 1, 2013

**Metal Hip Implants
Face Tighter Controls**

Wall Street Journal
January 17, 2013

Antibiotics: When Science and Wishful Thinking Collide

Health Affairs
January 25, 2013

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

NRC president Diana Zuckerman spoke to **CBS Radio** and appeared on **CBS TV** affiliates across the country talking about the increased risk of failure for hip implants in women. NPR's **Diane Rehm Show** interviewed her on the dangers of metal-on-metal hip implants for women and men.

Dr. Jennifer Yttri's letter to the editor of the **Washington Post** explained how overuse and misuse of antibiotics leads to drug-resistant diseases and how curbing antibiotic use in animals can help prevent superbugs.

Brandel France de Bravo's letter to the editor was published in the **New York Times** about how parents being glued to their technology can adversely affect children's development.

Diana Zuckerman and Jennifer Yttri wrote a blog for **Health Affairs** raising concerns that the FDA approved a new TB drug in spite of its patients' higher death rate.

We were quoted in the **Wall Street Journal** and **Washington Post** about stronger FDA safeguards for patients and consumers against unsafe medical devices such as defective hip implants and tanning beds.

The **BBC** (British Broadcasting Company) interviewed Diana Zuckerman about the risks of cosmetic surgery.

We were quoted in a **Milwaukee Journal Sentinel** article about the Inspector General's fraud alert warning patients to beware of doctors who own businesses that sell medical devices. These doctors tend to choose medical devices that benefit their business but may not be in the patients' best interests.

Diana Zuckerman was interviewed for a 30-minute **Healthcare Policy Podcast** about the abuse of antipsychotics in nursing homes. Despite increased risk for older persons, antipsychotics are widely used as chemical straightjackets in nursing homes. These drugs are usually given without consent from the patient or the patient's family and can be fatal.

Join Us for Our 5th Annual Cancer Prevention and Treatment Fund 5k Run/Walk on September 22, 2013!



This year's Cancer Prevention and Treatment 5k will be held on the beautiful C&O Canal Trail in Georgetown. The 5k Run/Walk (and a shorter Fun Run) will be on September 22, 2013 starting at 10 am. This is a wonderful event the whole family can enjoy, whether you are running, jogging, walking, or cheering from the sidelines. The C&O Canal trail is the perfect location, because you can spend time after the race eating, shopping, and enjoying the fall weather.

The highlights of the 5k are our wonderful fundraising teams, who raise money and race in memory of a loved one or in honor of a cancer survivor, whose name will be printed on the race T-shirts. Many businesses will be sponsoring and providing prizes to the winning teams! Last year's team winners were **Team Mathias** and **Team Olson**. Can't be there in person? You can participate virtually in your own home, gym, or community.

If you are interested in sponsoring, registering a team, or would like more information, please visit our website at firstgiving.com/cptf or contact our race coordinator **Kristin Olson** at ko@stopcancerfund.org. ■

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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.

Donate online at stopcancerfund.org or CFC #11967

Board Spotlight: Sarah Deutsch

Sarah Deutsch knows firsthand what it is like to receive confusing medical information and need help figuring out what it means and what to do. "It is an incredibly eye-opening experience to be lost in the sea of medical misinformation, and it's especially jarring as a lawyer who has always been comfortable gathering information and making decisions. I am personally indebted to the Center for its help, and I am determined to use the advocacy skills I have learned at Verizon for the larger good of the community," Sarah tells us.

And that's why Sarah is our newest Board member. She is Vice President and Deputy Counsel for Verizon Communications, making her our second Verizon-related Board member, joining former Verizon vice president, Steve Bozzo.

Sarah explains that "Although my legal background is not in a health-related field, much of my career has been devoted to working on consumer legal and public policy issues, such as online privacy and combating online fraud and abuse." Sarah has also worked with Wired Safety, a non-profit group devoted to keeping children safe online and educating the public about the dangers of cyber-bullying, and she's done volunteer work for the Massachusetts Advocates for Children.

"Sarah's personal and professional interests fit perfectly with our work on behalf of consumer and patient health and safety," says Diana Zuckerman, NRC's president. "We are so lucky to have her join us and look forward to working with her towards our mutual goal of helping families across the country." ■



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Photo by Diana Zuckerman



Here's some of the NRC Staff "springing forward" at the peak of the cherry blossoms in Washington, D.C., April 2013.

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