



THE VOICE

for Women & Families

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National Research Center for Women & Families

www.center4research.org

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

Cancer Prevention and Treatment Fund

www.stopcancerfund.org

Our Cancer Prevention and Treatment Fund helps adults and children reduce their risk of getting cancer and helps everyone get the best possible treatment.
CFC # 11967

The Perils of Weight Loss Products

Do you want to lose 10 or 20 pounds, then possibly gain it back after a year or so? Are you willing to risk serious health complications such as high blood pressure, heart disease, hospitalization, or even death? If you are wondering who would answer yes to these questions, this article is for you.

The approach of swimsuit season prompts many Americans to try to eat healthier, exercise more, and pick up those forgotten New Year's resolutions in hopes of looking a little better on the beach. Swimsuit catalogs, billboards promising a better life, and ads for new weight-loss products remind us of our shortcomings. Unfortunately, some weight loss products have greater risks than benefits.

Drugs vs. Surgery

Last fall and winter, NRC President Dr. Diana Zuckerman testified at several FDA Advisory Committee meetings regarding the safety and effectiveness of weight loss drugs and gastric lap-band surgery. When the FDA considers approving or expanding approval of any drug or medical device, we want the agency to ensure that the drug or device is safe and effective. We are disappointed when new weight loss products don't meet those criteria.

The weight loss drugs considered by the FDA in recent months—Meridia, Lorcaserin, and Contrave—have

been shown to help people lose just a few pounds, and people who tried any of these drugs tended not to keep the weight off. Most studies give weight loss counseling to dieters whether they are taking the pills or in a control group, so the results are likely to be even less impressive for people who do not take the drug under a carefully monitored clinical trial with counseling.

When you pair these modest results with the safety concerns, it is obvious that the FDA did the right thing in deciding not to approve Lorcaserin or Contrave, and in asking the manufacturer to voluntarily take Meridia off the market. The people most likely to take these drugs are extremely overweight or obese; therefore, losing 5–10 pounds is unlikely to improve overall health. At the same time, these are the people most likely to have high blood pressure and other health problems that can be exacerbated by diet pills.

An obese person with undiagnosed cardiovascular disease, for example, might request a diet drug based on a persuasive advertisement, not realizing that the health benefits of losing a little weight are far outweighed by the dangers of a heart attack the drugs may cause. Other short-term risks include attention disorders, dizziness, depression, and amnesia. The companies didn't

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Millions of Recalled Medical Devices Put Patients at Risk

What Would the Six Million Dollar Man and Bionic Woman Think?

by Paul Brown, NRC Government Relations Manager

When I was a kid, I was awed by *The Six Million Dollar Man*. After they were severely injured, scientists and doctors rebuilt the TV program's title hero and his counterpart, the Bionic Woman, with medical devices that were significantly better than their original body parts.

Now that I'm older and may actually need replacement parts like knees or hips, I am less than thrilled. Like most Americans, I assumed that the Food and Drug Administration (FDA) required medical device makers to test all medical devices on people. If only that were true.

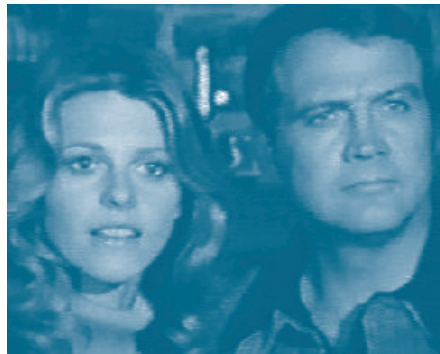
Our peer-reviewed study of high-risk recalls, published in the medical journal *Archives of Internal Medicine*, found that 79% of high-risk medical devices (devices that were recalled because they could cause serious injuries or deaths) were not tested in humans before being sold to (and often implanted in) patients. These devices were cleared by the FDA through the 510(k) process—a process that is supposed to be used only for low- or moderate-risk devices.

Front Page News

Does this study sound familiar? You may have read about it in *The New York Times*, *The Wall Street Journal*, *The Washington Post*, or the *Los Angeles Times*, or watched it on the evening news on CBS and ABC. All ran in-depth stories on our report. Co-authors Dr. Diana Zuckerman (NRC president) and Dr. Steven Nissen (Cleveland Clinic) both testified before Congress about the changes needed to protect patients.

Why Aren't Implants Tested on Humans?

Although the more rigorous FDA approval process—called the pre-market approval process (PMA)—is meant for high-risk devices, only 19% of recalls for devices that could kill or permanently harm you were approved through the PMA process. Shouldn't devices that can kill a person when they fail be reviewed through the rigorous PMA process?



The Bionic Woman (Lindsay Wagner) and Six Million Dollar Man (Lee Majors)

Industry representatives argue that only a small percentage of medical devices are recalled as “high-risk.” However, a small percentage can mask a huge number of recalled devices. Our study examined FDA data from 2005–2009 and found 113 high-risk recalls that involved more than 112 million medical devices. Some were already in people when they were recalled. Tens of thousands of “moderate-risk” recalls are of hips and other implants that harm millions of patients every year, and often require more surgery.

Because so many medical devices are not held to a higher safety standard, people who wouldn't otherwise die are dying, and many more are being unnecessarily harmed.

Cardiovascular devices such as stents and automatic external

defibrillators comprised the largest recall category (35 recalls), affecting more than one million devices. Two-thirds of those devices were cleared by the less-than-rigorous 510(k) process.

General hospital devices such as insulin pumps and IV infusion devices made up the second largest high-risk recall category (27 recalls), affecting more than 33 million devices. Three out of four of those were cleared by the 510(k) process.

Innovation vs. Health

Industry prefers the 510(k) process because it is faster and cheaper than the more thorough PMA process. They say it fosters innovation. Many public health advocates disagree.

We think the 510(k) process gives short shrift to safety. The FDA's #1 goal is to promote and protect public health. Innovation should never trump patient safety.

Recently, the FDA came out with recommendations for improving medical device regulations. Unfortunately, the agency watered down its safety recommendations after pressure from the medical device industry (see cartoon, page 3). This summer, the Institute of Medicine will release its recommendations on how to improve the safety of medical devices, focusing particularly on the 510(k) process.

We do not expect medical devices to perform flawlessly and miraculously, like they did on the *Six Million Dollar Man*. We do, however, expect them to be rigorously tested on people before being sold and implanted in people.

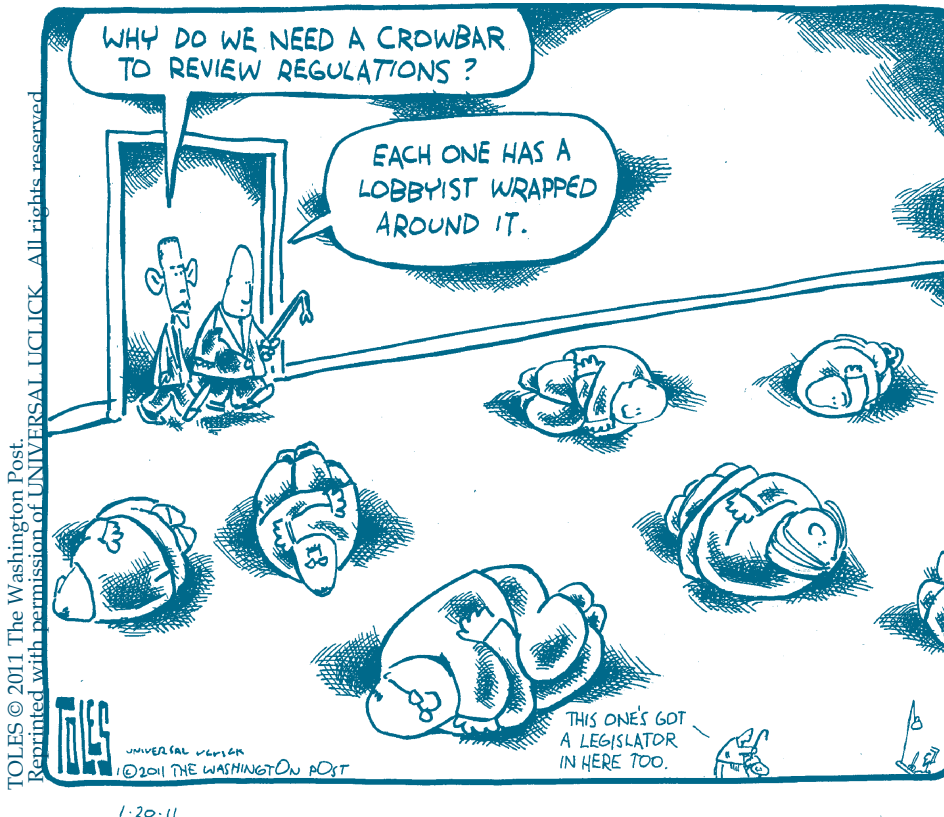
Health & Safety Regulations Under Attack

The medical device approval process (see previous page) is just one example of how government regulations can help protect us from dangers like tainted peanut butter, unsafe medical products, unfair practices by financial institutions, radiation from nuclear power plants, and environmental pollution. That may change if Congress decides to weaken a broad range of government regulations. Many lawmakers are complaining on behalf of companies in their states and districts that regulations are too burdensome to businesses, stifle innovation, and send jobs overseas.

Industry lobbyists are out in full force, urging lawmakers to prevent the EPA from enforcing clean air standards, pressure the FDA to weaken medical device safety recommendations, and pressure the Consumer Product Safety Commission to kill its new public database of unsafe products. The database is intended to warn families about cribs, batteries, and other products that have injured or killed children and adults.

The REINS Act (Regulations from the Executive in Need of Scrutiny) would require Congress to approve all major federal rules within 70 legislative days. Rules not approved in that short time frame would be nullified. If passed, the REINS Act would kill regulations that currently protect adults and children across the country.

NRC supports common-sense regulations designed to protect all of us. The REINS Act is a threat to these regulations, and to public health and safety.



Save the Date!

Our Cancer Prevention & Treatment 5K Race returns to Bluemont Park in Arlington, VA on Saturday, September 17.

Go to cancer5k.com to register or to honor a family member whose life has been affected by cancer.

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

Another Questionable Test for Prostate Cancer?

Prostate cancer is a slow-growing cancer that is more than 90% curable if caught in time, but treatments often cause incontinence and impotence. The screening tests are controversial because they are often inaccurate, resulting in men being harmed by unnecessary treatments. That's why the U.S. Preventive Services Task Force, the leading authority on medical recommendations, concluded that there is insufficient evidence to recommend prostate cancer screening in men under 75 and recommends against screening in men 75 and older.

Our Cancer Prevention and Treatment Fund supports efforts to improve the detection and treatment of prostate cancer. As the most common cancer in men and the second leading cause of cancer deaths for men in the United States, many lives are at stake. One in every six men will be diagnosed with prostate cancer in his lifetime, with about 90% of cases occurring in men 55 and older, and 71% of deaths occurring in men 75 and older.

The prostate gland is an important part of the male reproductive system. Screening can be performed quickly and easily in a physician's office. Two commonly used screening techniques are the prostate-specific antigen (PSA) blood test and the digital rectal exam (DRE), a manual exam of the prostate area. Each of these tests often indicate a man may have prostate cancer when he doesn't, or indicate he doesn't have cancer when he does. Using both screening methods together will miss fewer cancers but also increase the number of men being told they might have prostate cancer when they don't, resulting in biopsies that can cause medical complications such as pain, bleeding, infection, and rarely can cause sepsis, sexual dysfunction, or incontinence.

A biopsy involves inserting a needle—usually through the rectum—to remove a small sample of prostate tissue.

PSA Velocity in Prostate Cancer Detection

In recent years, the National Comprehensive Cancer Network (NCCN) and the American Urological Association (AUA) guidelines have recommended that the *rate of change in PSA level from one test to the next* could be a warning sign for cancer. That's why doctors recommended a biopsy when PSA velocity showed a dramatic increase, even if there were no other indications of cancer, such as high PSA or positive DRE.

Dr. Andrew Vickers and his colleagues recently tested these guidelines in a study of more than 5,500 men who had received regular PSA tests and a biopsy at the end of a prostate cancer study. Vickers' goal was to determine whether PSA velocity helped detect cancer in men with low PSA and negative DRE results.

They found that following the NCCN or AUA guidelines would detect an additional 115 cancers, but also result in 433 unnecessary biopsies on men who did not have cancer. They concluded that this was not accurate enough to justify the additional biopsies.

What Should Men Do?

Common treatments like surgery or radiation aim to remove or kill all cancerous cells in the prostate. If the cancer spreads beyond the prostate before it is treated, it is often fatal. However, the cancer usually grows so slowly that is often equally safe to wait until there are

symptoms before attempting to diagnose prostate cancer. That's why the velocity guidelines should be rejected, and why even PSA and DRE screening methods are controversial ways to try to detect prostate cancer. Men should immediately seek medical treatment for symptoms of prostate cancer, however, such as urinary problems, difficulty having an erection, or blood in the urine or semen.

Now that we know the PSA velocity test falsely detects cancer almost 80% of the time in men who otherwise have no signs of cancer, it is important to stop using it as a test and focus more research and more dollars to find other, more accurate screening tests.

Leaving a Legacy

In 2011, friends and loved ones are helping us honor Lenora Moody and Omega Logan Silva by naming internships in their honor.

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

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

Pets & Health: Impact of Companion Animals

Animals play an important role in many people's lives. Dogs can be trained to help blind people live independently, to detect seizures, or to help patients recover as part of occupational therapy, speech therapy, or physical rehabilitation.

Of course, the companionship that animals provide can improve our lives. Is that companionship beneficial to our health as well?

Blood Pressure and Pets

Research findings suggest that the social support a pet provides can decrease stress and make a person feel more relaxed. Researchers have found that in the presence of their dog or cat, adults are less likely to have spikes in heart rate and blood pressure when under stress, and that their heart rate and blood pressure return to normal more quickly following a stressful situation.

Does having a goldfish offer the same health benefits as having a dog or cat?

Children's exposure to companion animals may also ease anxiety. In one study, the presence of a dog during children's routine physicals lowered children's blood pressure, heart rates, and behavioral distress compared to when the dog was absent. It's especially interesting that the dog wasn't even the child's pet. It was just a pet hanging out in the doctor's office.

Social Support and Health

Among elderly people, pets can be an important source of social support. In addition, researchers have found that elderly men and women with a dog or cat were better able to perform certain physical activities deemed "activities of daily living," which include preparing meals and

other activities that help people maintain their independence.

People who have pets tend to visit doctors less often, but the research did not determine if that meant that having a pet makes one healthier, or just busier. There is some evidence that people with dogs tend to exercise more often, but other studies found no difference. There is also research evidence that having a dog may increase social interactions with people, possibly due to the likelihood of meeting other dog owners when walking the dog, reducing feelings of isolation or loneliness.

As is true with any relationship, some human-animal relationships are more rewarding than others. Some people are more attached to their pets than others and those feelings could influence the impact of the animal on the person's health. For example, one study found that having a dog was associated with

lower rates of depression among women but not men, and among single individuals but not married people.

Research Challenges

The effects of human-animal interactions on health are not fully understood because they are difficult to study. Most evidence on the benefits of having a pet comes from surveys of current health, but that means it is impossible to know if people are in good health because they have pets or if they are more likely to get a pet because they are in good health. Someone whose health is poor may decide he or she does not have the time or energy to care for a companion animal.

Does having a goldfish offer the same health benefits as having a dog or cat? Most pet studies focused on people who had a dog or cat, making it difficult to draw conclusions about the health benefits of a bird, lizard, fish, or other pet. How much time the person spends with his or her pet could be strongly influenced by the type of pet and in turn could affect the health benefits.

The research findings are encouraging, but we don't yet know precisely what types of animals have an impact on what types of health issues (physical, mental, or social well-being) or what characteristics of human-animal interaction are most important to human health. There are many benefits to having a companion animal, but we do not yet know under what circumstances those benefits are most likely.

For more information about the research studies discussed above, please visit our article at <http://www.center4research.org/2011/04/human-animal-interaction-and-health/>.



Eloise (L) and Sophie (R), friends of NRC for Women & Families

Weight Loss

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conduct long-term studies, so we don't know what possible complications might occur years later.

Lap-Band Surgery

Unlike pills, gastric lap-bands can be effective in helping obese people lose 50-100 pounds, which has a positive impact on health. However, weight loss may not be maintained, and the health benefits will disappear if the weight returns. Worse, the lap-band has serious risks of its own.

It's hard to predict who the lap-band will work for in the short term, and there aren't enough data about long-term risks and benefits. Many patients have adverse reactions (including some deaths) and many need additional surgery within just a few years. Data on health outcomes are very limited. We are also concerned that the studies submitted to the FDA didn't include anyone over 55, or many men, African-Americans, or Latinos.

Another problem is that people at risk for autoimmune diseases were excluded from safety studies because lap-bands could be dangerous for them. That's why NRC wants a "black box" warning, like those on a cigarette pack, to warn that lap-bands have not been tested on this population. African-American and Latina women especially need to be cautiously studied because they are more likely to develop lupus or other autoimmune diseases. We need to know whether the lap-band is safe for them.

The FDA recently decided to lower the BMI required to get lap-band surgery for those who have an obesity-related medical condition, from 35 to 30 (it kept the required BMI at

40 for those who are healthy). The FDA is now considering lowering the age limit for the surgery, which is currently 18. Meanwhile, Medicare is paying for lap-band surgery, even though there is evidence that it is less safe and less effective for people over 65.

Dr. Zuckerman appeared on the *Dr. Oz* show in March to discuss the issue, and she urged Dr. Oz and his viewers to be wary of the lack of long-term studies. After taping the *Dr. Oz* program, a new study came out showing that most people with lap-bands don't keep the weight off. NRC agrees with the **American Heart Association**, which recommends bariatric surgery only for the dangerously obese.

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

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

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



If you were in Times Square recently, you may have seen our billboard on healthy eating. Our Cancer Prevention & Treatment Fund teamed up with Walmart to promote the benefits of healthy eating, including cancer prevention.

What can you do to lose weight and reduce your risk of cancer or a cancer recurrence?

- **Eat more fruits and vegetables.** Fruits and vegetables make you feel full and reduce cravings, helping you maintain a healthy weight and reduce your risk of heart disease and diabetes. They also provide fiber, vitamins, and minerals, which help you look and feel your best.

- Replace refined or "white" grains with **whole grains**. Try whole wheat pasta or whole grain rice.

- **Try alternatives to salt and butter.** Experiment with new flavors, herbs and spices.

- **Cut out trans fats.** Avoid foods that say "partially hydrogenated" or "trans fat."

- **Reduce portions** by using smaller plates and bowls. Leave extra food in the kitchen, not on the table.

- **Get active!** As your diet changes, so may your mood. Celebrate by moving—walking, taking the stairs, dancing, or trying a new sport.

Breast Implant Cancer Scare Reminds Women of Unknown Risks

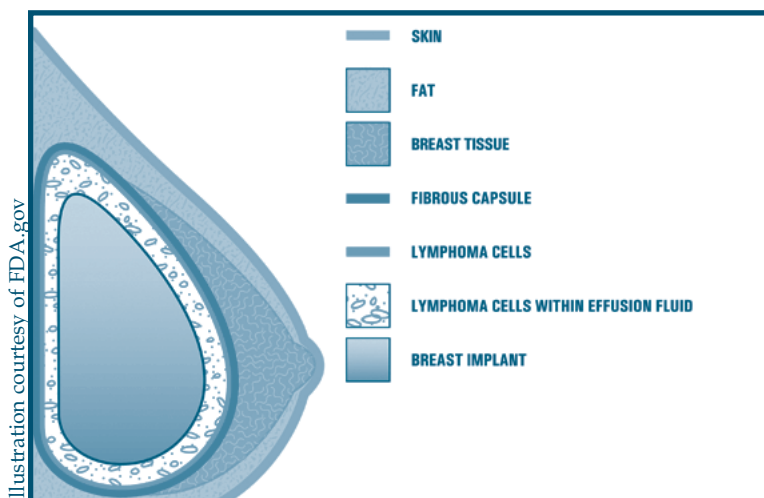
Women with breast implants may be more likely to develop a rare lymphoma known as ALCL, the FDA recently announced. This is not a breast cancer, but has been found in the breast between the implant and the fibrous scar capsule that grows around it (see below). In April 2011, an industry-funded analysis confirmed the finding that there is a significant link between ALCL and breast implants.

NRC and our Cancer Prevention and Treatment Fund are very concerned about this finding because ALCL is a potentially fatal cancer of the immune system. The link between ALCL and breast implants has important implications for autoimmune disorders reported by many women with implants, in research conducted by independent scientists.

The new finding is an important reminder that long-term risks of breast implants have never been studied. Meanwhile, women with breast implants may have them for decades, so women need to be vigilant and tell a doctor when they notice symptoms that could possibly be related to their implants.

Most of the published research on the safety of breast implants was paid for by implant companies or plastic surgeons, and those studies almost always conclude that breast implants are safe. Many implant patients write to our Center, telling us that their plastic surgeons criticize them for thinking that any health problems could be related to their implants. Many of these women were surprised to find that breast pain and debilitating autoimmune symptoms (such as joint pain, chronic fatigue, and flu-like symptoms that lasted for years) cleared up after their implants were removed.

The FDA warns that women with any kind of breast implants should report any swelling or pain to their doctor. The FDA also warns that women should undergo breast coil MRIs three years after getting silicone gel breast implants, and every other year after that, to check for breakage. Mammograms should not be used to test for implant breakage because the pressure from mammography can cause breast implants to break or leak. MRIs can also help detect breast cancer, in addition to implant breakage. NRC recently met with FDA officials to urge them to require better long-term studies to determine all the risks of breast implants.



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*Why is NRC President Diana Zuckerman
chatting with Dr. Oz? See page 6.*

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