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.

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 Helpline: info@stopcancerfund.org

Websites: www.center4research.org www.stopcancerfund.org

How Can We Cut the Cost of Medical Care?

Everyone agrees that health insurance is too expensive and prescription drugs cost much too much – some cost more than patients’ annual income! The amount Americans spend on prescription drugs has nearly doubled since the 1990s, and today the most expensive drugs cost $500,000 or more per year.

What’s the solution?

This article isn’t about Medicare for All, Medicaid for All, or other major legislation, all of which face enormous political and corporate opposition. Instead, this article focuses on the issues that would be easier to fix in the near term.

How to Spend Less on Drugs and Medical Tests

Too many patients are being priced out of the medical treatment that they need – or think they need. As prices have risen, companies have broken one record after another, so that it seems there is no limit on what they will charge. For example, Spinraza, a treatment (not a cure) for a rare disease called spinal muscular atrophy, is priced at $750,000 per patient for the first year, and several hundred thousand dollars per patient in subsequent years. Even if insurance will cover the cost for some patients, we all pay for these and other exorbitant drugs because these prices increase the insurance premiums that everyone pays – even those of us who don’t need such expensive treatments.

But an even bigger problem is the cost of treatments that aren’t proven to work or aren’t needed. Physicians from Mayo Clinic and Stanford recently published an article in a prestigious medical journal stating that many of the billions of dollars spent on diagnostic screening tests such as MRIs and CT scans, are not saving lives. Instead, they are exposing patients to unnecessary radiation, anxiety, and heavy metals (see our article on page 3). In fact, Americans don’t live as long as residents of 25 other countries, despite spending the most per capita on health care.

Our own research on cancer drugs found that many that were recently approved based on their success at shrinking tumors provided zero benefit to the average patient in terms of living longer or having a better quality of life. Since cancer drugs so often cause nausea, vomiting, exhaustion, and other debilitating side effects, it is unconscionable that these drugs are being approved without clear evidence that they work – or which patients have at least some chance of benefitting even if most don’t.

Does Competition Matter?

Instead of lowering the cost of medical care by requiring solid evidence that every drug and device that is approved has benefits that outweigh the risks for most patients, the FDA has focused on the possible benefits of competition between medical products. The agency claims that getting more drugs on the market more quickly will lower prices.

FDA is proud of their current efforts to get generic drugs on the market more quickly. We support those efforts, but unfortunately, generic drugs often cost almost as much as the brand name drugs. And those prices are increasing.

For example, the price of digoxin, a commonly prescribed heart medication, increased by 2,800% in a single year. The price of 315 generic drugs went up by 100% or more in a recent year, causing financial difficulty for many patients.
FDA put breast implant safety in the spotlight at a public meeting in March and by making an announcement in May. NCHR President Dr. Diana Zuckerman told The New York Times, NBC News, Fox News, The Daily Mail, and other media that women with certain types of family medical histories might be more likely to be seriously harmed by breast implants. After the meeting, Dr. Zuckerman told AP and The Washington Post about powerful patient testimonies that convinced some FDA advisors about the potential harm, but that most plastic surgeons told the FDA that their patients were very happy with their implants. When FDA announced in May that they would help warn patients of the risks, we were quoted in AP, Washington Post, Fox News, NY Post, and NY Daily News that the FDA needs to do more to ensure women know the risks before deciding whether to get implants.

FDA announced in April that companies must stop using surgical mesh for women with pelvic organ prolapse. It took decades for the FDA to admit that the surgery is just as effective (and safer) when done without mesh. NCHR explains to The Wall Street Journal and Drugwatch that mesh was not studied in clinical trials for any medical purposes before it was put in the bodies of men and women for incontinence, hernias, breast reconstruction, and other surgeries. The result? Thousands of harmed patients.

The International Consortium of Investigative Journalists (ICIJ) has continued reporting stories in “The Implant Files”—a huge online trove of device horror stories. We explained to ICIJ why patient registries were unlikely to be the great source of safety information that the FDA was claiming. Meanwhile, a Kaiser Health News’ expose revealed that for years, FDA has allowed companies to summarize rather than individually report how many patients were harmed by medical devices. Physicians are supposed to report problems to help inform other doctors and patients which devices are safe and which aren’t. NCHR’s President was quoted explaining that including information about harmed patients should be required rather than voluntary, and the data should be made public.

In an effort to treat more patients, experienced surgeons may schedule overlapping operations where they leave a patient to be “closed” by another health professional. A recent study found almost no differences in surgical success rates regardless of who finishes the surgery. NCHR’s Dr. Zuckerman explained to National Public Radio that while there seems to be no greater risk for patients, most would be unhappy to learn that the surgeon they selected is not the one who completed their surgery.

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.
Another Reason to Avoid MRIs
by Diana Zuckerman, PhD

I’ll be honest: I have tried to avoid Magnetic Resonance Imaging (MRIs) because I am a little bit claustrophobic. Being in a very small enclosed space does not appeal to me, but I know that millions of MRI scans are performed every year to help diagnose serious health problems and improve patients’ treatment outcomes.

I was advised to undergo an MRI last year to make sure that a tiny spot on a CT scan was nothing serious. So I did it, hated every second, and got the good news that the spot was – as expected – nothing. So imagine my surprise to learn in the course of our work at the National Center for Health Research that many MRIs rely on a contrast agent that is based on a heavy metal called gadolinium, which can accumulate in your brain or bones and potentially cause serious health problems.

In the early 2000s, it was found that some patients with severe kidney dysfunction who underwent MRIs with some types of gadolinium-based contrast agents (GBCAs) were developing a serious – sometimes fatal – condition called nephrogenic systemic fibrosis (NSF). Experts in the field recommended that patients with kidney problems should avoid several types of contrast agents used for MRIs. European agencies banned those specific GBCAs, but the U.S. did not.

What about people whose kidneys are fine? That’s the million dollar question that hasn’t yet been answered.

Once the Metal Contrast Agent is in Your Body, Will it Ever Completely Disappear?

Does anyone want a heavy metal accumulating in their brain or bones? I don’t think so, and I sure don’t. FDA’s outside advisors had recommended that all patients being prescribed an MRI with contrast be warned by their doctors of the risks, but unfortunately, the FDA decided not to require or even encourage doctors to do that. I can assure you that the risks of contrast were never mentioned to me before my MRI.

One of the ways that we know that gadolinium accumulates is that if a person gets a brain MRI with some types of GBCAs, the next time they get a brain MRI without contrast, there is contrast left over from the previous MRI. In addition, researchers have found gadolinium in tissues that were removed in surgery or from autopsies – in the brain, bones, and other tissues in patients who had received GBCAs for imaging with contrast.

All types of GBCAs can accumulate in your body; however, some types are worse than others.

How Does Gadolinium Affect the Body?

How gadolinium affects the body is largely unknown and varies from person to person. At this point, nobody knows how many people are being affected.

NSF in patients with severely reduced kidney function typically affects patients’ skin first, causing hardening, discoloration, and swelling. Over time, patients’ tendons, muscles, and organs may become similarly affected. Pain is common, and NSF can be fatal.

Patients with exposure to gadolinium that have well functioning kidneys sometimes experience similar, though less severe symptoms as NSF patients. These patients also report symptoms such as headaches, cognitive impairment, and pain.

There are no comprehensive studies to answer the key questions about the safety or lack thereof of MRI contrast agents. How many people are being affected? How many MRIs with contrast will increase your chances of health problems? How can doctors predict who will be affected long-term and who won’t?

Worried yet? Two final questions: how much gadolinium is accumulating in bodies of water near cities with large healthcare systems, and should tap water be tested and treated?

If you or someone you know is undergoing MRIs, read our report online for more information at www.center4research.org

Bottom line: While there is evidence that gadolinium can accumulate in the body, more research is needed to determine who will develop health problems, what symptoms will be experienced, and how to prevent and treat these gadolinium-related conditions. But the first step is to inform patients of the risks and reduce the number of contrast-enhanced MRIs for everyone, not only for patients with impaired kidney function.
We’re Speaking Up!

As a think tank, we frequently share our views with policymakers, government leaders, partner organizations, and health agencies, such as the Food and Drug Administration (FDA). You may wonder what these comments have to do with you, or how you are affected by our work. Every day, we are testifying and sharing research on your behalf, speaking up for patient safety and consumer views. Here are a few examples:

**Alzheimer’s Disease**

An effective treatments for patients with Alzheimer’s disease is urgently needed. A device called neuroAD, which is a type of transcranial magnetic stimulation (TMS) treatment, sought approval from the FDA.

Unfortunately, when neuroAD was compared to a sham [placebo] treatment, the patients getting the real treatment were no better off.

The company (Neuronix) kept trying to prove that the brain stimulator worked, studying small numbers of patients, all of whom knew their brains were being stimulated. That causes a placebo effect because patients tend to believe that a new treatment will work. After doing numerous studies and analyzing the data in many different ways, the company finally reported their patients performed slightly better on a cognitive test, equivalent to remembering two additional words. But dementia patients’ memory varies from day to day, and they may often recall two more or two fewer words from one day to the next. We agreed with FDA’s experts that there was no evidence that neuroAD benefits patients in a noticeable way.

We’re glad that the FDA’s Advisory Committee agreed with us. But the FDA doesn’t always do what their Advisory Committees recommend. We’ll keep you posted.

**Synthetic Playgrounds**

In May, we wrote to the Mayor and City Council of Washington, D.C. and testified before the U.S. Consumer Product Safety Commission to express strong concerns about the high levels of lead in school playgrounds made of synthetic rubber. Recently released lab tests showed that while most of the material had low levels of lead, some pieces of playground material contained more than 10 times the level of lead that is allowed in children’s products. Since these playgrounds are used by small children, who tend to spend a lot of time close to the ground and put what they find in their mouths, lead in play environments is very dangerous. We pointed out that engineered wood fiber is a much safer alternative for playground surfaces under swings, slides, and jungle gym equipment.

**Breast Implants**

In March, 2019, we were invited to speak at an FDA Advisory Panel meeting about our research on autoimmune symptoms among women with breast implants. Our study of 449 women found that most women with serious symptoms reported that their health improved greatly when their implants were removed — especially if the scar capsules surrounding the implants were removed at the same time. We also pointed out that the patient registry that was being developed to study women with breast implants was inadequate, because it would only include information about women undergoing additional operations after getting breast implants. Our work with thousands of women shows that many women who are very ill from their breast implants are unable to afford to have them removed, and therefore would not be included in a registry of patients who undergo additional surgery.

**Vaginal Mesh**

In In March, 2019, we were invited to speak at an FDA Advisory Panel meeting about our research on autoimmune symptoms among women with breast implants. Our study of 449 women found that most women with serious symptoms reported that their health improved greatly when their implants were removed — especially if the scar capsules surrounding the implants were removed at the same time. We also pointed out that the patient registry that was being developed to study women with breast implants was inadequate, because it would only include information about women undergoing additional operations after getting breast implants. Our work with thousands of women shows that many women who are very ill from their breast implants are unable to afford to have them removed, and therefore would not be included in a registry of patients who undergo additional surgery.

In February, we spoke at an FDA Advisory Committee meeting, urging FDA to require companies to stop selling surgical mesh used for women with pelvic organ prolapse (POP), a condition that can be caused by childbirth. The FDA started warning doctors and the public about the risks of mesh in 2011, and we urged them in 2011, 2014, and again in 2017 to protect women from the terrible pain that mesh can cause. In April, 2019, FDA finally announced that they would no longer allow mesh to be sold for pelvic organ prolapse, but the agency hasn’t required clinical trials of surgical mesh for other types of medical problems such as for hernias or stress incontinence, as we have repeatedly urged them to do. Thousands of women and men have been harmed.
Can an Aspirin a Day Keep Cancer and Heart Disease Away?

Many healthy adults take a “baby” dose of aspirin every day to prevent cancer and heart disease. But the latest research suggests that is not a good idea for most of us.

Guidelines for aspirin in 2016 made it seem like aspirin really is a miracle pill. The U.S. Preventative Services Task Force (USPSTF), a respected independent group of medical experts, recommended daily low-dose aspirin to reduce the risk of colon cancer and heart disease – but only for people that met the following criteria:

- Ages 50-59 years old;
- Who have never had heart disease;
- Have a 10% or greater risk of developing heart disease within 10-years;
- Are not at increased risk for bleeding;
- Have a life expectancy of at least 10 years; and
- Can take low-dose aspirin daily for at least 10 years.

Even if you fit those criteria, however, the American College of Cardiology and the American Heart Association released recommendations this year that disagree. Based on more recent research indicating that the risks of bleeding balance out the small benefit of preventing heart disease, those medical societies decided that people who have not yet developed heart disease are unlikely to benefit from taking daily low-dose aspirin. These two medical societies did not express an opinion about the possible benefits for preventing colon cancer, but they did caution that aspirin presents substantial risks for any patients with an increased risk of bleeding, such as patients on certain medications or with a history of intestinal ulcers, kidney disease, or severe liver disease.

What’s the Bottom Line?

The recommendations above are specific to healthy patients who have not developed heart disease but are at risk of developing it. (This is called primary prevention). There are different recommendations regarding aspirin for prevention for patients who previously had a heart attack or a stroke, for example. Those recommendations are also influenced by medical history and medication use, and depend on numerous specific health issues and so they need to be discussed with your doctor.

Test Your Knowledge!

Side effects for drugs are on the label, but where is the label? If they aren’t included with your pills, they can be found online on the drug company’s website, on the FDA homepage (www.fda.gov) using the search box, and on product safety information sheets that the doctor who prescribe the pills or the pharmacy that provides it should be able to give to you. Much like product manuals for appliances, patients rarely read the dense drug patient booklets that come with their prescriptions. There is crucial information inside, however, such as what you shouldn’t eat or drink while taking the drug, negative reactions to the drug that patients might experience, the types of patients who should not take the drug (contraindications), and much more. Look them up online or read the print label, and then talk to your doctor or pharmacist to be better informed.

1. Sleeping pills such as Ambien, Lunesta, and Zolpimist.
2. Chantix, a smoking cessation drug.
3. Addyi, the “female Viagra.”
4. Anti-psychotic drugs, such as Abilify, Risperdal, and Seroquel.
5. E-cigarettes such as Juul.
6. Anticoagulants for atrial fibr, such as Pradaxa, Xarelto, and Eliquis.
7. Farxiga, a medication for diabetes.

The Medical Device Safety Act

The Medical Device Safety Act of 2019 (HR 2669) was introduced in the U.S. House of Representatives on May 10, 2019 by Congresswoman Rosa DeLauro (D-CT), and co-sponsors Brian Fitzpatrick (R-PA), Jan Schakowsky (D-IL), Lloyd Doggett (D-TX), and Bobby Rush (D-IL). The bill would amend the federal Food, Drug, and Cosmetic Act so that patients who are injured, disabled, or killed by high-risk medical devices may pursue litigation in state court. This would give these patients the same legal rights and protections as patients who were harmed by prescription drugs or by medical devices that the FDA did not classify as high-risk (also called Class III devices).

The bill is retroactive, and would apply to pending civil actions. It ensures that state laws are not preempted by a federal prohibition.

“The United States has a systemic problem with medical device oversight, and the FDA is not living up to its mission as a regulatory agency,” Congresswoman DeLauro points out. "Faulty medical devices have had tragic and life-changing effects on the lives of people across the country. It is heartbreaking, and we have a moral obligation to right these wrongs. That is why Congress should step up and pass the Medical Device Safety Act to give patients the legal resources they deserve."

The FDA designates thousands of devices, including most implants, as low or moderate risk (also called Class I and Class II), and about 150 that are currently on the market are considered high-risk. The current legal protection for companies that make these high-risk devices has served as a disincentive for companies to take these devices off the market, even when the devices are clearly harming many patients. At the same time, patients whose lives have been devastated by dangerous medical devices have been unable to obtain financial compensation for the harm caused by the devices. This is true even if the device was later recalled or voluntarily taken off the market.

Restoring the Rights of Patients

The bill would restore a patient’s right to litigation should he or she be harmed by a high-risk medical device. Under current law, if an approved Class III device is later proven to be ineffective or proven to cause harm, individuals still cannot hold the manufacturer liable for injury. That restriction applies even if the device was recalled because it caused harm.

“This Americans deserve to know that the medical devices they rely on for their health and wellbeing are safe,” said Congressman Schakowsky. “If those devices are not safe, manufacturers should be held liable and consumers should have full access to the power of our justice system to seek recourse.”

Congressman Fitzpatrick stated “Americans injured through faulty medical devices—through no fault of their own—deserve the legal recourse necessary to sustain themselves.”

The Medical Device Problems Action Campaign is a volunteer group comprised of consumers harmed by medical devices. They are rallying Members of Congress to gain support for the Medical Device Safety Act. Amanda Rusmisell, the group’s Legislative Liaison, describes their efforts: “We are thankful for the support of Congresswoman DeLauro and the co-sponsors for this legislation, which will protect the millions of American consumers and patients who have been injured, disabled, or killed by Class III medical devices, or might be in the future. Instead of protecting their health, the current law protects the manufacturers from liability even when they are responsible for selling a harmful device.”

As the National Center for Health Research has explained to Members of Congress, the Medical Device Safety Act is absolutely essential to correct a Supreme Court ruling that was based on a misunderstanding of FDA regulations. Because of that misunderstanding, patients who are seriously harmed by high-risk medical devices such as cardiac implants, breast implants, sterilization devices, and brain stimulators currently cannot seek legal redress in the courts. NCHR president Dr. Diana Zuckerman points out, “That makes no sense, since experts agree that FDA standards for prescription drugs are higher than those for high-risk medical devices, and yet patients who are seriously harmed by prescription drugs can seek legal redress. The bottom line is that the risks of many high-risk medical devices have not been made public, the scientific standards for FDA approval for medical devices are much lower than for prescription drugs, and yet when patients are harmed by high-risk devices they have almost no legal rights. This bill would correct that situation, which currently is putting millions of patients at risk.”

How Can We Cut the Cost of Medical Care? (Cont.)

When many manufacturers are making the same or similar products, the average price usually falls. But not always. In too many cases, one drug company raises the price and its competitors soon follow. A glaring example is the cost of Hepatitis C drugs. When Gilead put Sovaldi on the market in late 2013, they charged $84,000 for a 12-week course of treatment. The public and policymakers were incensed at what was considered an outrageous cost, but experts assumed the price would soon drop because other similar drugs were in the pipeline. Instead, the official price increased more than 10%, despite two competing drugs.

Are these Prices Justified?

Pharmaceutical companies justify high prices because developing new drugs is expensive. But research shows that even when drugs were first developed by federally funded academic researchers, drug companies take over and charge very high prices. In addition, when old drugs are approved for a new use, their price can increase dramatically, such as the $2,000 old drug for a type of Duchenne muscular dystrophy, deflazacort, that got a new name (Emflaza) and a new price tag, $89,000 per year (more than a 4,350% increase).

What Can You Do to Help?

As noted above, billions of dollars could be saved if MRIs, CT scans, and other diagnostic tests were only used when needed. Billions more could be saved if the FDA only approved drugs and devices that were proven to work, or only approved them for a targeted type of patient or treatment that it is proven to benefit. And if physicians and patients paid less attention to ads for medications and more to the information available on labels for drugs and devices, there would be much less inappropriate use and tremendous cost savings. (See page 5 for a quick quiz on side effects of several popular medical treatments).
“80,000 Deaths. 2 Million Injuries. It’s Time for a Reckoning on Medical Devices.”

That was the headline of a groundbreaking editorial in the May 4, 2019 *The New York Times*, which also stated “Patients suffer as the FDA. fails to adequately screen or monitor products.”

We couldn’t have said it better ourselves, so we will quote from the editorial and encourage you to read the entire editorial online:

“It seems incredible that products meant to reside inside the human body would be used on patients without any proof of safety or efficacy. But thanks to regulatory loopholes and lax oversight, most medical devices are poorly vetted before their release into the marketplace and poorly monitored after the fact.

“Problems can take years to emerge and can be impossible to correct, in part because permanent implants are not easily extracted from the body. (Removing mesh from pelvic tissue has been likened to removing chewing gum from long, thick hair.) When trouble does arise, device makers often equivocate, regulators dither and patients seeking redress are forced into lengthy and expensive court battles. In the end, faulty products can remain on the market for years ....

“The risks of waiting loom large: in the past decade, nearly two million injuries and more than 80,000 deaths have been linked to faulty medical devices, many approved with little to no clinical testing, according to a global investigation by the International Consortium of Investigative Journalists.

“Women are particularly well acquainted with this cycle. But that’s not to suggest that only women are affected: there have been metal hips that released poisonous debris into the body, implantable defibrillators that shock people at random (causing indescribable terror) and artificial heart valves with questionable shelf lives. In operating rooms, there have been staplers that misfire; temperature control machines that spray bacteria into open chest cavities; and robotic surgeons that slap, burn and, in some cases, maim patients.

“In every one of these cases, a combination of dubious regulatory approvals, skimpy post-market surveillance, and faltering responses from regulators caused irrevocable harm that might have been avoided.

“After searing investigations by journalists and patient advocates, the FDA has promised to make “transformative” changes to medical device regulation. But so far, the agency’s suggestions have been meager at best. And in the meantime, regulators have accelerated the device approval process, not slowed it down. Dr. Jeffrey Shuren, head of the agency office in charge of device regulation, has suggested that the benefits of bringing innovative products to market quickly are worth the increased risks.

“It’s true that devices have restored hearing, vision and the ability to walk and have provided many other benefits to millions of people. But the drive to innovate does not justify the growing catalog of medical device disasters. Patients should not have to wonder whether devices will save their lives or destroy them.”

The editorial recommends that FDA tighten approval standards, fix post-market surveillance and loosen industry’s grip. It points out:

“Dr. Shuren reportedly referred to device makers, not consumers, as his office’s main customers at a recent industry gathering. The industry maintains a well-oiled revolving door with the FDA — as The Associated Press has noted, the last four people to hold Dr. Shuren’s position have gone on to lucrative industry gigs. Device makers also spent more than $300 million lobbying Congress in the decade ending in 2017, according to the Center for Responsive Politics. What’s more, they pay doctors and hospitals hundreds of millions in consulting fees every year, according to the National Center for Health Research [emphasis added]. None of this violates any rule, but all of it contributes to the current crisis.

“Medical institutions and professional societies should establish, or amplify, guidelines discouraging such payments. Stronger laws that provide more funding for the work of device regulation — so that the FDA is not as reliant on industry dollars — would also help the agency to fulfill its mission.

“That mission is to protect patients.”

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**We’re proud to have the Janice Bilden Cancer Prevention Internship, thanks to a generous donation from her daughter, Holly Bilden-Stehling.**

Holly tells us that her Mom “loved to laugh, have fun, and help her family in any way she could. Mom worked hard all her life starting when she was very young with paper routes, babysitting, and even setting pins at the bowling alley. Mom grew up in a 3-room house with 6 siblings, never even having indoor plumbing until she was married. She never complained. Instead she freely gave of herself to her family, friends and church. She was my best friend and my Matron of Honor.

“Cancer took a devastating toll on her family. She lost 2 sisters and 2 brothers to cancer. Mom also died from cancer. I am glad to have the opportunity to have an internship named in honor of my Mom that will help train a young professional to help others to prevent cancer. I believe wholeheartedly that prevention is the only sure way to save lives and prevent the type of pain my Mom felt, and in losing her the type of pain we feel everyday.”

*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 us at info@center4research.org.*
Cancer Prevention and Treatment Fund (our largest program)

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

Donate online at www.stopcancerfund.org
Or CFC #11967
We’re here for you so you can be there for them. Let’s fight cancer together!

Thanks to The New York Times!

What does The New York Times editorial mean by their headline “$80,000 Deaths, 2 Million Injuries” and what does it have to do with you and the National Center for Health Research? You might be surprised. Find out on page 7!