

## 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.

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CFC #11967



## Finding a Solution to the Skyrocketing Cost of Treatments for Cancer and Other Serious Diseases

*Diana Zuckerman, PhD*

When the cost of her medication increased by 500% last month, Sarah was shocked. For the first time, she wondered if she could afford to recover.

Sarah is not alone. Everyone is talking about the exorbitant prices of promising new treatments for cancer and other serious diseases. But so far, neither Congress nor the White House nor the pharmaceutical industry have come up with likely solutions.

There are many examples of drug prices that have had breathtaking increases in recent years. For example, the price of 50-milligram capsules of the antidepressant clomipramine HCL, which is used to treat obsessive-compulsive disorder, increased by more than 2000% in one year: from 34 cents per capsule to \$8.43 per capsule. The price of digoxin, a commonly prescribed heart medication, increased by 2800% in a single year.

The availability of generic drugs helps keep prices down, and the cost of generics has recently decreased by 59% on average. But thousands of patients were hit with increases at the same time, even for generic drugs – 315 of them went up by at least 100%.

### IS THE FDA PART OF THE PROBLEM?

The Food and Drug Administration (FDA) is under tremendous pressure to approve medical products more quickly. Unfortunately, that has meant approving dozens of cancer drugs that are effective at shrinking tumors in the short-term, but not proven to save lives in the long-term. The FDA is doing the same for treatments for rare diseases, as well as treatments for common diseases such as diabetes, which already have many effective treatments available.

FDA approval of new drugs creates competition but does not necessarily lower prices. Congress has passed laws that require the FDA to approve drugs and devices more quickly. Over the past two decades, this has lowered standards and contributed to the high cost of medical care.

The problem is unique to the U.S. because the National Health plans in other countries pay less for prescription drugs and only cover the cost of treatments that are proven to be cost-effective. In contrast, Medicare and private insurance in the U.S. will often pay for any drug the FDA approved, even if it is less effective and more expensive than other treatments that are available.

Since the United States is one of only two countries in the world that allows direct-to-consumer advertising, doctors and patients are encouraged to use more expensive drugs that are widely and persuasively advertised on TV.

Several major insurance companies recently broke with tradition and refused to pay for several very expensive FDA-approved drugs that had not been proven to work. However, the precedent of the FDA approving unproven products combined with astronomical price increases are putting the U.S. on a path to unsustainable medical costs.

### THE PERFECT STORM RESULTS IN SKYROCKETING COSTS

The math is simple: overall medical costs will continue to increase when the FDA approves treatments that are not proven to work, are inferior to less expensive treatments, or cause complications that are expensive to treat. This gets worse as companies charge whatever the market will bear.

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# WE'RE IN THE HEADLINES!

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**Special Report: Many Expensive New Cancer Drugs Are Useless (or Worse)**  
*Bottom Line Inc., July 3, 2017*

**EpiPen Maker Failed to Investigate Product Flaws Associated With Patient Deaths, FDA Says**  
*The Washington Post, September 7, 2017*

**Replacing Faulty Heart Devices Costs Medicare \$1.5 Billion in 10 Years**  
*The New York Times, October 2, 2017*

**Streamlined FDA Reviews Fail to Catch Dangerous Glitches in Health Software, Study Finds**  
*STAT News, September 12, 2017*

**Is The Birth Control Device, Essure, Safe?**  
*The Washington Post, July 26, 2017*

**FDA Approval Does Not Guarantee Drug Safety**  
*Drugwatch, May 8, 2017*

**Cigarette Maker Stocks Plunge on FDA Announcement, But Health Experts Are Skeptical**  
*Marketwatch, July 28, 2017*

When EpiPens failed to work, resulting in more than 100 complaints including several deaths, the company did not adequately prevent future failures, according to the FDA. "This is a product where you don't know, until you use it, whether it works or not. I think it's safe to say no patient — and no parent — wants to find out the hard way that the product that they have isn't effective," NCHR president Dr. Diana Zuckerman pointed out to **The Washington Post**.

We explained to **Bottom Line** why so many new cancer drugs have so few benefits, and our president Dr. Diana Zuckerman gave tips on how to make sure your cancer treatment is right for you.

Why are women experiencing pelvic pain, hair loss, unusually heavy periods, severe fatigue, and pregnancy from a device that is supposed to be a permanent contraceptive? NCHR president Dr. Diana Zuckerman was one of the experts quoted in **The Washington Post** magazine cover story on Essure.

A new report from the Inspector General concluded that 7 types of defective pacemakers cost Medicare billions of dollars. The report pointed out that Medicare could save lives and money if they did a better job of tracking defective devices. We agreed, pointing out to **The New York Times** that these are just a few of many defective devices that have harmed patients in recent years.

Woody Witzak committed suicide because of a pill he was prescribed to help him cope with stress at work. NCHR president Dr. Zuckerman explained to **Drugwatch**, "FDA approval is based on evidence - provided by the company that makes the medical product - that the benefits of the product outweigh the risks for most patients for a specific use. It doesn't necessarily mean the product is safe."

What happens when the software and IT gadgets in hospitals fail? A study by NCHR's Dr. Jay Ronquillo and Dr. Diana Zuckerman, reported in **STAT News**, showed how thousands of patients can be harmed by a small number of software glitches in electronic medical records and other hospital software.

The FDA announced a proposal to lower nicotine levels in cigarettes to non-addictive levels, but at the same time delayed planned restrictions on e-cigarettes. We told **Marketwatch** that lowering nicotine levels could help prevent cancer by lowering the rates of smoking, but only if the restrictions are enforced.



## What is Akathisia? Knowing the Answer will Save Lives

Stewart Dolin was married to his high school sweetheart for 36 years. He was close to their two grown, successful children and was a senior partner of a large international law firm. He enjoyed his life – his work and also traveling, skiing, dining, and joking around with his family and friends.



Stewart developed some anxiety regarding work, and was prescribed a generic version of Paxil (paroxetine), an antidepressant. Although both Paxil and the generic versions warned about suicidal behavior for adolescents, that did not apply to Stewart, who was 57 years old.

Within days, Stewart felt restless, had trouble sleeping, and kept saying, “I still feel so anxious.” He developed extreme and dangerous thoughts. Six days after beginning the medication, right after having a typical business lunch, Stewart left his office and walked to a nearby train platform. A registered nurse standing nearby later reported seeing Stewart pacing back and forth and looking very agitated. As a train approached, Stewart jumped in front of it, taking his own life. This loving, dedicated husband and father left no note or explanation.

Unknown to his family and friends, the pills had a terrible side effect called akathisia that can cause such intense inner restlessness that the patient is driven to violence or suicide. In studies, the side effect was sometimes labeled “restless leg syndrome,” which is dangerously misleading.

Stewart’s wife, Wendy Dolin, was devastated but she was determined to help other patients and other families. She founded **MISSD** (The **M**edication-**I**nduced **S**uicide education foundation in memory of **Stewart Dolin**), a non-profit organization that educates the public about the dangers of akathisia. (<http://missd.co/>)

But to really warn all patients, it is crucial that there be clear warnings on Paxil, all generic versions of the drug, and any other drugs with the same side effect. Antidepressants are marketed as a way to reduce suicides, and companies have not wanted to admit that their products could have the opposite effect. They have not warned consumers about akathisia.

When Paxil was submitted to FDA for approval in 1989, its maker SmithKline Beecham (now Glaxo Smith Kline) provided data to the FDA indicating that patients taking Paxil were half as likely to commit suicide as those taking a placebo. However, documents made public as part of the Dolin lawsuit indicated that the only suicides in the placebo patients actually occurred before the patients started taking placebo – and therefore should not have been counted according to FDA experts. Without those inappropriately counted placebo patients, suicide rates were clearly higher among Paxil patients.

At the trial, Glaxo officials blamed the FDA for the lack of better warnings on the label. The jury blamed Glaxo, and awarded Wendy Dolin \$3 million. Rather than admitting wrong-doing, Glaxo has appealed the verdict.

Wendy Dolin is one of the 100 dedicated patient advocates that we have trained in free Patient Workshops aimed to help advocates better understand research and FDA decision-making. “She has shared her story with many other patients and family members, and we are very proud to also work with her as part of the Patient, Consumer, and Public Health Coalition” says Diana Zuckerman, president of the National Center for Health Research and founder of its Cancer Prevention and Treatment Fund.

“After starting MISSD I was so honored to be asked to participate in the Patient Training Workshop,” Wendy tells us. “To be in the company of so many national advocates that are trying to make a difference in the health care system is inspiring and motivational. Most of the advocates have turned their personal issues into organizations that raise national attention and awareness. A true honor to be supported and a part of such a talented group!”

*Thank you to our wonderful*

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## Health Technology: Fun. Useful. Safe?

Whether you wear a fitbit, have a pacemaker, have a loved one in the hospital, or your doctor remembers all your medications because they are listed on your electronic medical record, your life is probably influenced by medical software.

We depend on all kinds of innovative software, but that also means that hacking of medical IT has become a fear in real life, not just in the movies. Medical centers have had to pay ransoms to regain access to hacked medical records, and sometimes lives have been at stake. But, hacking isn't the only risk. That's why the National Center for Health Research conducted a study to find out which medical devices were recalled because of software defects that could seriously harm patients.

Led by Dr. Jay Ronquillo, we analyzed all recalls of software-related devices that the FDA identified as having serious flaws.

Over a recent 5-year period, a total of 627 different software-controlled medical devices involving 1.4 million units were subject to recalls. Twelve of the 627 – involving more than 190,000 units – were designated “high-risk recalls” that were recalled because they could be deadly or cause permanent serious harm. Most of the high-risk recalled products are commonly used in hospitals, such as infusion pumps that control medications, or ventilators that help very sick patients breathe.

Most of the remaining recalls were described by the FDA as having the potential to cause moderate harm. Five were electronic medical record (EMR) systems (9,347 units) that the

FDA stated posed a moderate risk to patient safety. Nine thousand EMR units doesn't sound impressive, until you realize that a single EMR unit helps doctors manage the care of hundreds or thousands of patients.

For example, one recall involved a medical record system that gave doctors medical information for the wrong patient. Another recalled product failed to warn doctors of serious patient allergies. And one recalled product calculated the wrong treatment doses for cancer patients. All of these could have serious consequences for patients.

**The good news:** These recalls took dangerous products off the market before large numbers of patients were harmed. The bad news: a new law, the 21st Century Cures Act, passed last year and will decrease the chances that EMRs and related defective software will be recalled quickly in the years to come.

Why would a “Cures Act” allow patients to be harmed? Unfortunately, lobbyists convinced Congress that software companies should be less “burdened” by regulations, even ones that could save lives. Instead of making sure that all new medical software is adequately tested before being sold, or making sure that defective software is quickly taken off the market, Congress changed the law to a “let the buyer beware” situation. And whether the defect makes the software inaccurate or vulnerable to hacking, the extra layer of protection that was available through 2016 will no longer be there in the coming years.

## Help Us Continue to Fight for You and Your Loved Ones



With the uncertain political climate, we promise to continue fighting for you, your health, and your safety.

This year, we have helped ban more phthalates from household products, urged the FDA to require higher safety standards, and worked with patients to advocate to speak out on medical treatments and devices.

This is a challenging time, but we will continue to fight with your help. Please consider donating to us today. Every donation big or small is very helpful and is greatly appreciated.

*Thank you in advance for supporting our work. It will help us continue to assist patients and family members every day. Just visit [www.stopcancerfund.org](http://www.stopcancerfund.org) or [www.center4research.org](http://www.center4research.org) and click the donate button.*

*You can also donate through CFC #11967.*

*Thank you!*



# Opioid Epidemic: One Simple Change Could Help

*Diana Zuckerman, PhD and Megan Polanin, PhD*

The opioid epidemic is overtaking many communities across the country, and there are many reasons why this epidemic grew so quickly.

There is no simple solution. Several important efforts are underway that will help prevent people from becoming addicted to prescription painkillers such as Oxycontin and Vicodin.

But here's one simple suggestion: Don't allow any of these highly addictive painkillers to be labeled "abuse-deterrent" unless they *really* deter abuse.

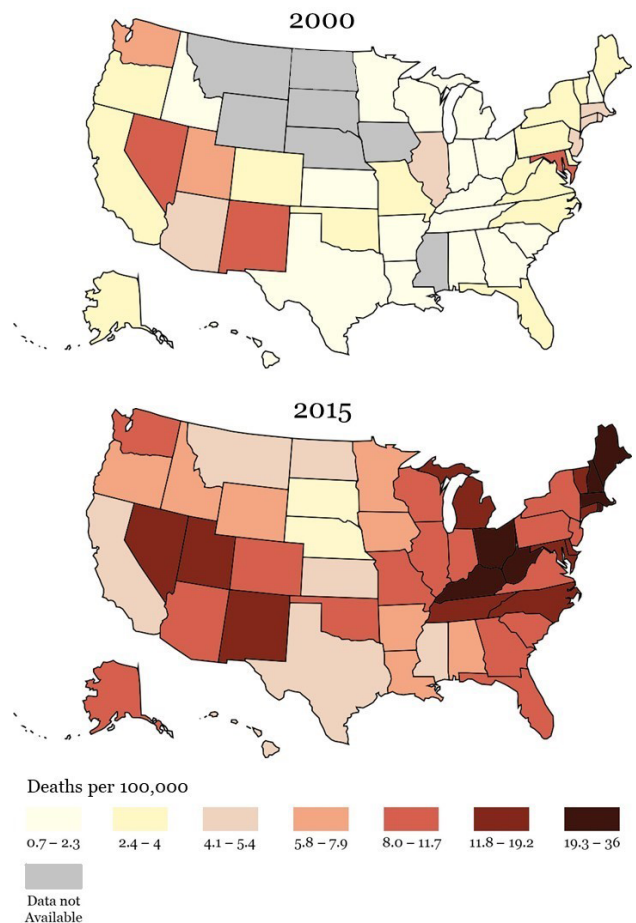
The Food and Drug Administration allowed opioids to be labeled "abuse-deterrent" if they were difficult to crush or make into a liquid because that made them difficult to smoke, snort, or inject. However, many doctors, patients, and family members incorrectly believe that if the drug is "abuse-deterrent," it is less addictive. Too often, this is a fatal misunderstanding.

Even drugs that are difficult to crush have been smoked, snorted, and injected by people who were addicted and thus highly motivated to find a way to abuse the drugs. Here is one example. Due to the opioid addiction crisis, one opioid that was already on the market, Opana, was re-designed to prevent abusers from crushing the drug to snort it. However, once the new version of the drug got on the market, abusers figured out how to inject it. This resulted in high rates of abuse and serious outbreaks of HIV and hepatitis C because of shared needles.

Labeling a drug as abuse-deterrent when it does not prevent abuse contributes to the opioid epidemic by misleading doctors, patients, and families. In addition, opioids labeled "abuse-deterrent" cost much more than other opioids. Experts estimate that prescribing them costs our healthcare system an additional \$231,500 to prevent just one new case of abuse. That money could be better spent on more cost-effective prevention and treatment strategies.

Drugs that are difficult to crush should be labeled "crush-resistant" -- not "abuse-deterrent." Only drugs proven to drastically reduce the chances of abuse should be labeled as abuse-deterrent. Even then, they should have warnings that they are "highly addictive but more difficult to abuse."

## Opioid Overdose Death Rates



*Data Sources: Centers for Disease Control and Prevention (CDC) and the National Center for Health Statistics (NCHS)*



*The Ruth Nadal internship continues the legacy of our Foremother and donor. We honored Ruth for her work on behalf of women's well-being and were very sad to learn she passed away in October at the age of 103.*

## 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 [info@center4research.org](mailto:info@center4research.org) or donate online at <http://www.center4research.org/get-involved/contribute/>*

## What are Artificial Turf and Playgrounds Made Of? Can They Cause Cancer? Obesity? Asthma?

Is your child playing on rubber and plastic instead of grass? Grass has been replaced with artificial materials at schools and parks all over the country.

Regardless of what they look like, there is growing evidence that all artificial fields and playgrounds are made with materials that can be dangerous for children and adults.

Many athletes don't like artificial turf, and only 2 professional ballparks now use it, and many football stadiums have also switched back to grass. In addition to plastic "grass," rubber and other synthetic materials are used to keep the "grass" in place and provide more cushioning. Unfortunately, artificial turf increases "turf burn" abrasions from sliding, puts additional stress on joints, and can become dangerously hot in the sun.



### Recycling Tires from Playgrounds

More than 20 million recycled rubber tires are processed every year for playground surface cover and sports surfaces.

Using tire scraps seemed like a great idea at first – keeping them out of landfills and providing a potentially softer landing on the playground. It was known that burning old tires released harmful, smelly chemicals into the air, but parents didn't realize that recycled tires and new rubber used on fields and playgrounds can also be dangerous.

You may think of rubber as a natural product – but rubber is a mix of latex from rubber trees mixed with petroleum products. That means it can include phthalates, polycyclic aromatic hydrocarbons (PAHs), volatile organic compounds (VOCs), and other chemicals known or suspected to harm human health. For example, phthalates are chemicals that affect hormones and many have been banned from children's toys because they can increase the risks of obesity, early puberty, attention problems, and cancer. The EPA warns that breathing air contaminated with PAHs may increase the chance of developing cancer, and the U.S. Agency for Toxic Substances and Disease Registry warns that PAHs may increase the risk of cancer and birth defects.

### Why Aren't They Proven Safe?

There is no government agency that requires synthetic playground surfaces to be tested before they can be sold. In fact, the materials used in these products are often not made public — the lack of disclosure is justified as "trade secrets." However, some researchers independently have examined the safety of these playground surfaces.

It would not be ethical to conduct a study exposing children to tire shreds, knowing they could be unsafe, so the California Office of Environmental Health Hazard Assessment conducted three studies that mimicked children's exposures instead. Results showed that a single incident of eating or touching tire shreds would probably not harm a child's health, but repeated or long-term exposure might. Five chemicals, including four PAHs, would get on children's skin if they played on these surfaces. One of the PAHs, chrysene, was higher than the level considered safe, and could increase the chances of a child developing cancer.

In addition, only 10 of the 32 California playgrounds studied met the state's safety standard for falls, which meant that falling could cause a brain injury or other serious harm. In contrast, all five surfaces made of wood chips met the safety standard. In Washington, D.C., 37 of their 51 artificial turf fields failed 2017 safety tests, due to hardness scores above 165. That's what the turf industry considers the maximum score for safety.

A 2015 report by Yale scientists analyzed 14 different samples used for school athletic fields and playgrounds. They detected 96 chemicals, most of which have never been carefully studied, so their health risks are unknown. However, 20% of the chemicals that had been tested are considered to probably cause cancer. In addition, 40% are irritants that can cause breathing problems such as asthma and/or irritate skin or eyes.

### What About your Schools or Parks?

Here are a few of the many materials to be concerned about:

- Loose tire shred ("crumb rubber") or other synthetic materials on a surface that can be raked, such as playgrounds or artificial "grass" fields. In some cases, triclosan, an antibacterial that is banned in soap, is used on this "infill."
- Tiles made from tire shreds and binder that have been factory-molded, then glued to a playground surface.
- Tire crumb or "virgin" colorful rubber that is "poured in place" (PIP) can contain many of the same dangerous materials as recycled tire shreds.

### How to Protect your Children

Children are much more likely to be harmed by exposure to chemicals in their environment than adults because they are smaller (so the exposure is greater) and because their bodies are



still developing. Pregnant women should be even more careful to avoid these exposures.

Parents in many communities are persuading local officials to conduct safety tests on artificial turf fields and playgrounds every year, and to install grass or wood chips because they are safer in terms of chemical exposure, heat, and if their children fall. But as you can see from the photo below from a school in Silver Spring, Maryland, there are more likely to be signs aimed at protecting the fields, rather than protecting the children using those fields.



## What can I do?

1. Children should avoid mouth contact with playground surfacing materials. Some of these materials are small and look like seeds, mulch, or small candies. They may pose a choking hazard as well as a dangerous chemical exposure.
2. Avoid eating food or drinking beverages while directly on playground surfaces and wash hands before handling food.
3. Limit the time at a playground on hot days. Children tell us they can often see the heat waves rising off the fields on warm, sunny days. The temperature of artificial turf can be 70 degrees hotter than the air or natural grass.
4. Clean hands and other exposed skin after visiting the playground, and consider changing clothes if residue from the rubber is visible on fabrics.
5. Clean any toys that were used on a playground after the visit.

These safeguards will help reduce your child's exposure. However, if your child is playing on these fields for hours every week, there is still reason for you to be concerned.

That's why our Center has testified before the Washington, D.C. City Council and why we are working with parents across the country who seek our help in convincing their communities to choose grass and avoid artificial turf whenever possible.

## Good News: New Safeguards on Products in Your Home

Thanks to a small government agency you may never have heard of, several risky chemicals are likely to be removed from many products in our homes.

The U.S. Consumer Product Safety Commission is a small agency composed of 5 Commissioners and their staff. It is responsible for making sure that a wide range of products that are used in the United States are safe.

The Commission started studying flame retardants decades ago because of growing evidence that they do more harm than good. Flame retardants are chemicals intended to make fabrics and other commonly used materials less likely to burst into flames when there is a fire. However, the chemicals themselves can be harmful because they get into the dust in our homes, and we breathe them in day after day. When there is a fire, these chemicals are part of the smoke and flames, making them more toxic. This increases the chances of firefighters developing cancer and other serious diseases.

Some types of flame retardants, such as Tris, were banned from children's pajamas in 1977. However, many of those older flame retardants are still in numerous other products in our homes, or have been replaced by other flame retardants that had not previously been studied.

We now know that all organohalogen flame retardants are semi-volatile organic compounds (SVOCs) that migrate into air, dust,

and films on surfaces such as walls and fabrics. They will also get on the skin, and although they can be washed off, they return to the air and then once again find their way onto the skin. **The bottom line is that once these compounds are indoors, they will stay indoors.** That means children and adults will be exposed to them day after day.

Unfortunately, many children's products contain these flame retardants, as do sofas, mattresses, pillows, and electronics. For example, Dr. Julie Herbstman from Columbia University has conducted research indicating that children, infants, and fetuses are more vulnerable to health effects resulting from exposure to a variety of environmental chemicals, including halogenated flame retardants.

We are pleased that the Consumer Product Safety Commission recently voted in agreement with our testimony that the public should be warned about these flame retardants in upholstered furniture, children's products, mattresses and casings for electronics. Scientific evidence shows these chemicals can contribute significantly to the levels of indoor air and dust contamination, harming the health of children and adults. These warnings will encourage companies to voluntarily stop using dangerous flame retardants. The Commission also voted to convene a Chronic Hazard Advisory Panel to provide scientific expertise to the Commission's staff as they determine next steps, such as a potential ban. In the past, these panels have done an excellent job of getting past the hype and focusing on the science.

# National Center for Health Research

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

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*Why does this sign from a field in Silver Spring, Maryland raise questions about the health of children across the U.S.? Open this newsletter to pages 5-6 to find out!*

## Cancer Prevention and Treatment Fund

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