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Can Sleeping Pills Cause Cancer? Can Avoiding Them Improve Your Health?

Americans spend more than \$41 billion each year on prescription sleeping pills, and that doesn't count the popular over-the-counter sleep aids such as Tylenol PM and Benadryl. If you are one of the many Americans that needs help sleeping, you'll want to know about a study showing that people who take these drugs are significantly more likely to be diagnosed with cancer or to die within the next two and a half years than people who don't take them. Published in the prestigious *British Medical Journal*, author Dr. Daniel Kripke estimates that sleep medications could be causing more than 300,000-500,000 deaths every year.

The researchers studied more than 10,000 primary care patients in Pennsylvania who were prescribed sleeping pills and compared their health to patients without such prescriptions who were the same sex, ethnicity, marital status, smoking status, and had similar health conditions, alcohol use, and BMI.

Sleeping Pills, Death, and Cancer

Patients who were prescribed sleeping pills were more likely to have died during the 2.5 years of the study than were the patients not prescribed sleeping pills. Even the patients who were prescribed fewer than 18 pills per year were more than 3 times as likely to die. Patients who were prescribed more than 132 pills a year were more than 5 times as likely to die.

When the study started, none of the patients had been diagnosed with cancer. Heavy users of sleeping pills (over 132 pills prescribed per year) had a 35% greater risk than those with fewer pills prescribed. Among those with prescriptions for sleeping pills, the increased risk of their developing lymphoma, lung cancer, colon, and prostate cancer was greater than the risk from being a current smoker.

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Even before this study, there were at least 18 other studies showing an increased risk of death for people taking sleeping pills, and several also showed an increased risk of cancer. However, this study is especially well-designed and the only one that includes the newer, short-acting class of popular sleeping pills known as non-benzodiazepines, such as Ambien, Lunesta, and Sonata.

Among study participants, the most commonly prescribed sleeping pills were Ambien (also known by other names) and Restoril. However, the higher risk of death was true for those prescribed any sleep aid, including Lunesta, Sonata, barbiturates, as well as antihistamines such as diphenhydramine (the active ingredient in Benadryl), which is also used in many over-the-counter sleep aids. The average age of patients in the study was 54, but the study found harm associated with sleeping pill use in every age group.

Are Some Sleeping Pills Safer than Others?

All the sleeping pills studied increased the risk of death, but Lunesta showed a more than 500% increased risk compared to any of the other sleeping pills. However, Lunesta was a relatively new drug at the time of this study, and relatively few people took it. For that reason, it is not possible to say whether the risk of Lunesta is really that high. This study did not evaluate cancer or death rates among patients taking Belsomra, a newer sleeping aid with numerous side effects.

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WE'RE IN THE HEADLINES!

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US Goal to be "First" on Devices Worries Former Regulators

Associated Press, November 11, 2018

Breast-Implant Injuries Hidden: FDA's Deal with Companies Made Thousands of Cases Look Like Just One

LA Times, November 26, 2018

New Drugs So Pricey They Need New Payment Plans

Politico, August 13, 2018

FDA Targets Vaping, Alarmed by Teenage Use

New York Times, September 12, 2018

What Are the Unexpected Dangers of Medical Devices?

NPR, May 24, 2018

This Popular Implant Prevents Pregnancy for Years. It Could Also Go Missing in Your Body.

Circa, October 8, 2018

To Improve Treatments, Researchers Want to Hunt for Clues in Medical Records

NPR, July 16, 2018

Bayer to Stop Sales of Birth Control Device Tied to Injuries

Today Show, NBC, November 26, 2018

Lasik Surgery Can Have Little Known Life-Changing Consequences

Legal Reader, June 19, 2018

The FDA announced fines for companies selling e-cigarettes to children and teenagers, as well as guidances to the manufacturers. NCHR president Dr. Diana Zuckerman told the ***New York Times*** that the FDA's plan will be much less effective than other strategies they should consider. Two months later, FDA finally announced more effective strategies.

The U.S. government keeps talking about streamlining the FDA approval process to get drugs and medical devices to patients faster. Unfortunately, this is adding to the cost of medical care and results in many medical products that don't work. NCHR's president explained to ***Newsweek*, *ProPublica*, *Medscape*, and *AP*** how patients are harmed when drugs or medical devices are approved too quickly.

NCHR's president wrote an article for ***Spectrum News*** about how the new "Right to Try" law can result in the exploitation of people with autism and other conditions, including cancer. Vulnerable patients and their families deserve better protections from treatments that don't work and could be very harmful.

One in 10 Americans has some kind of medical device implanted in their body. In an ***NPR*** podcast, NCHR's president warns that the FDA standards for approval of implants are much less rigorous than for prescription drugs. Most medical devices do not even have to be proven to be safe or effective. NCHR's president urges listeners to ask doctors questions about the scientific evidence that the device is good for them, and let Congress know you support better safety testing for new devices.

NCHR's president explains to ***MedTech*** how the FDA never takes devices off the market, and instead relies on the manufacturers to "voluntarily" withdraw them. FDA finds it hard to find the science to justify taking them off the market due to the lack of solid scientific research.

Nexplanon is an implanted contraceptive that lasts for 3 years. Though it's inserted into the upper arm, it can migrate and be difficult to remove if it causes dangerous side effects. Despite deaths and serious harm reported to the FDA, no action has been taken. NCHR's president tells ***The New York Post*** and ***Circa*** that FDA often delays action when devices are shown to be risky or ineffective.

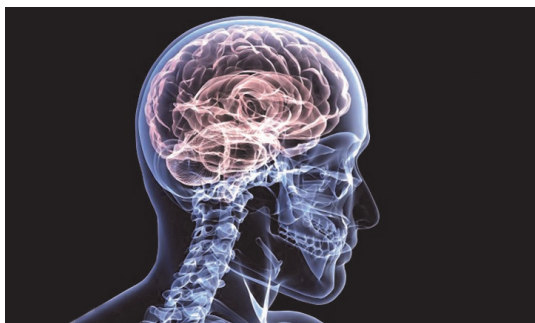
Brain Stimulation as a Treatment for Depression?

Transcranial magnetic stimulation (TMS) devices have stimulated the brains of tens of thousands of patients in the United States, often as a treatment for depression that hasn't responded to antidepressant medication. Millions of Americans suffer from depression, and most try one of the dozens of antidepressant medications on the market – most of which are available as relatively inexpensive generic medications. TMS treatment typically costs \$300 per session, usually 5 days/week for four to six weeks. That's obviously inconvenient and expensive, but the important question is: Does it work?

Most TMS patients do not improve substantially, and any improvement of any patients tends to disappear in the weeks or months after their TMS treatment ends.

Does it Work?

The National Center for Health Research released a report in November that examined dozens of studies of TMS. We were not impressed with the evidence in favor of TMS.



Depression can last for weeks, months, or years, but for most people the depression ebbs and flows, getting better or worse depending on various factors that are not always easy to identify. For that reason, the best studies of the treatment of depression are randomized, double-blind clinical trials, where patients are randomly assigned to get a new treatment compared to an older treatment or a placebo, and neither the patient nor the clinician involved in the study know which patients received which treatment or placebo.

Is There Scientific Evidence?

Unfortunately, many TMS “studies” evaluated patients who paid for TMS treatment for at least 2 weeks, for 5 days/week. Of course, anyone spending their time and money for this treatment is going to want to believe that it works, but the patients in many TMS studies were not compared to depressed patients getting other types of treatment. Any improvement could have been due to the TMS, to a “placebo effect” of believing in an expensive treatment, or could have been due to the natural ebb and flow of depression.

In our report, we instead focused on the smaller number of studies that compared patients that were randomly assigned to receive TMS with patients

receiving a “sham treatment” – they were hooked up to a TMS machine but the magnetic pulses did not reach their brains. The results of these studies were surprising because in most cases neither the TMS patients nor the sham patients had much improvement in their symptoms of depression. In fact, the placebo patients in studies of antidepressants often did as well as the TMS patients and improved much more than the sham patients. We analyzed this further and concluded that the sham treatment was often so obvious to the doctors involved in the studies that it probably contributed to a very weak placebo effect.

In the last few years, the sham treatments have become more convincing and the TMS treatments have been modified in an effort to improve them. In some of these studies, both the TMS patients and sham patients show some short-term reduction in their symptoms of depression. However, in most sham-controlled studies, most TMS patients still do not improve substantially during treatment, and any improvement tends to disappear in the weeks or months after their TMS treatment ends. In contrast, depressed people who try a different antidepressant than they had previously tried tend to improve as much as the TMS patients.

If you or someone you know is considering TMS, our report may save you thousands of dollars and a very discouraging experience.

Bottom line: There is still great uncertainty about whether TMS works. There is no clear evidence that this very expensive treatment is more beneficial than trying much less expensive and more convenient antidepressant medications. Our report also examines how TMS became a common treatment for depression in the United States despite what the research of the last decade shows about its very questionable effectiveness. Although the process was atypical in several ways, today's widespread TMS use illustrates how FDA's failure to require solid scientific evidence and willingness to ignore their own scientific advisors can contribute to years of very expensive, questionable treatments for patients.

Have Questions?

If you are looking for more information about a medical device or medication, email our helpline at info@center4research.org or info@stopcancerfund.org. We're here to help!

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What are the Implant Files? An International Exposé

More than 250 journalists worldwide have joined together to investigate the safety (or lack thereof) of medical devices. The **International Consortium of Investigative Journalists (ICIJ)** has made medical implants their focus, explaining that millions of injuries and thousands of recorded deaths have occurred to patients with these devices.

ICIJ took two years to plan and draw together research about the way devices are tested, approved, marketed, and subsequently monitored. They started releasing their stories in newspapers, websites, and TV on the Sunday after Thanksgiving. NCHR's Dr. Diana Zuckerman and Jack Mitchell were interviewed for several of their stories (**Associated Press**, **NBC TV**, and **British Medical Journal**), and are pleased that their reporting confirms what we at NCHR have been saying for years: The focus on speedier drug and device approval has led to implants that aren't safe – and in many cases, are not more effective than no treatment at all. As a result, patients all over the world have put their trust in government agencies that are not doing a good job to keep them safe.

One of the journalists, Jet Schouten from the Netherlands, told of submitting “evidence” that plastic mesh from a bag used for oranges

should be considered a safe and effective medical device. They were successful in getting it approved throughout Europe. Could they have fooled the FDA as well? To hear her story and better understand the impressive investigations of the **Implant Files**, search for “Implant Files ICIJ” on the Internet.



Dr. Diana Zuckerman

Is the Affordable Care Act Still at Risk? Will You Be Harmed?

By Diana Zuckerman, PhD

When the Democrats won control of the House of Representatives in November, experts assumed that the Affordable Care Act (ACA) would be protected at least until the 2020 elections. The math was simple: If the House won't pass legislation to repeal the law, the law couldn't be changed. There was a sigh of relief from patients with pre-existing conditions, advocates for reproductive health care, and people who previously couldn't afford health insurance.

That relief turned to concern weeks later when the Trump administration provided states with advice on how they could get around many of the key consumer protections of the ACA. Since these efforts will undoubtedly face legal and political challenges, it may take a while to know if the ACA will be destroyed as a result.

The “death by 1,000 cuts” approach of President Trump and his Centers for Medicare and Medicaid Services (CMS) has resulted in new recommendations. CMS suggested that states could obtain waivers from ACA rules, justified as giving states more flexibility. Healthcare experts say the waivers would enable states to circumvent some of the law's most important rules.

The Trump Administration announced that federal subsidies for low-income Americans to purchase health insurance would no longer be limited to ACA health insurance plans. Instead, the subsidies intended for ACA policies could be used for health insurance policies that lack essential medical benefits – the kinds of policies that the law was intended to ban. States could even allow their residents with employer-based coverage to set up accounts that would mingle federal subsidies with health-care funds from their employer or from personal tax-deferred savings funds. In addition, States could be granted waivers to design their own state-administered subsidy programs and determine what different types of health insurance plans are eligible for subsidies.

The reason why these waivers would be so dangerous is that it would reduce subsidies that are currently used and available for people who most need them. And, by encouraging the purchase of lower cost, inadequate health insurance, it would essentially reverse the progress that was made by the ACA. The only way good health insurance coverage can be affordable is if healthy people buy those plans. If healthy people buy skimpy plans, the cost of good insurance plans will skyrocket because only people with major medical expenses will purchase them.

Is it fair for healthy consumers to have to buy health insurance policies that they don't think they need? Even healthy people can have an accident, become pregnant, or suddenly be diagnosed with cancer or another very expensive disease. Having high standards for coverage in all health insurance policies benefits everyone, including those who don't think they need it.

The Trump Administration sees it differently. In a recent speech, CMS Director **Seema Verma** said, “Seeing the problems the ACA created, and seeing the lack of federal action to address these problems, should be proof enough for why it was such a mistake to federalize so much of health-care policy under the ACA.”

In contrast, **Sen. Patty Murray** (D-Wash) called the proposed waivers “nothing more than a how-to guide for health care sabotage.” Sen. Murray is the ranking Democrat on the Senate Committee responsible for health legislation. In the House of Representatives, **Reps. Frank Pallone Jr.** (D-N.J.) and **Richard E. Neal** (D-Mass.), expressed their concerns in writing that the proposals are “unlawful, will raise costs for older and vulnerable Americans, and will eliminate protections for individuals with pre-existing conditions.” The two men are likely to be the Chairmen of the two key health Committees in the House, *Energy and Commerce*, and *Ways and Means*.

What is Breast Implant Illness?

Debate swirls over the risks of breast implants, and physicians and patients are justifiably confused by the conflicting information available.

More than 50,000 women with breast implants have joined Facebook groups to share information about their serious symptoms, which they refer to as “breast implant illness.” But the FDA questions whether these symptoms are caused by implants. Instead, FDA’s official position is to agree with plastic surgeons and implant companies that the only proven complications are breast pain or hardness, implant rupture, and cosmetic problems in the breast area.



This fall, NCHR’s Dr. Diana Zuckerman and Claudia Nunez-Eddy accompanied 20 women who had been harmed by breast implants to a meeting with FDA officials. We expressed our concerns about the outdated and biased information that the FDA is providing on their website about a cancer of the immune system (ALCL) caused by breast implants. We also pointed out their failure to acknowledge the much more common symptoms that most of the women experienced. The women gave compelling descriptions of how sick

they became after getting breast implants, and their dramatic recoveries after their implants were removed.

In conjunction with the investigation of medical devices by more than 250 journalists with the **International Consortium of Investigative Journalists**, we released a new report that challenges the FDA and plastic surgeon’s reassuring statements. Our

report finds clear evidence that implants increase the chances of women developing the symptoms that women call “breast implant illness,” such as chronic fatigue, problems with memory and concentration, joint or muscle pain, and hair loss.

Who Says Implants are Safe?

We scrutinized 32 studies that were the basis of three very influential research reviews on breast implants dating from 1999 through 2016. We found that most of the 32 studies were either paid for by companies that make silicone or breast implants, or were conducted by plastic surgeons who studied their own patients. In addition to relying on very biased, flawed studies that are often not scientifically sound, the three influential reports tended to downplay the scientific evidence of harm. Instead, they summarized the results of numerous poorly designed studies, many of which included small numbers of women who had implants for a relatively short period of time. In addition, almost all the studies they reviewed evaluated whether a woman was diagnosed with a classic autoimmune or connective tissue disease, rather than whether she had developed symptoms of those diseases. When symptoms are evaluated, there is a clear increase among women with implants.

Equally important, there is growing evidence that women with breast implants who have serious symptoms usually see those symptoms decrease or disappear after their implants are surgically removed.

We are assisting thousands of women who asked us to help them convince their insurance companies to cover the cost of medically necessary implant removal. So far, 665 women have had their implants removed with our help, and 89% say their symptoms improved “a great deal” or “somewhat” as a result.

If you or someone you know has or are considering breast implants after mastectomy or for cosmetic reasons, you’ll want to read our report!

Can Sleeping Pills Cause Cancer? (Cont.)

One shortcoming of the studies is that getting a prescription for a sleeping pill is not the same as taking sleeping pills. It is possible that some of the people with prescriptions, never took any of them. It is also possible that people who did not have prescriptions for sleeping pills took Benadryl or other over-the-counter antihistamines to help them fall asleep, instead of the prescription version of the same pills. However, these shortcomings would tend to underestimate, rather than overestimate, the risks.

In addition to the major study cited above, there is other strong evidence linking sleeping pills to cancer. For example, a meta-analysis was published in 2018 that combined results from 6 studies of more than 200,000 Europeans and Koreans taking sedatives to help them sleep. Compared to patients who were not prescribed sedatives, those who were prescribed sedatives were more likely to be diagnosed with esophageal, kidney, prostate, liver, stomach and pancreatic cancers. The patients were studied for an average of 8 years. Of all the sedatives in the study, Ambien was most strongly associated with a diagnosis of cancer.

But Why?

What could possibly explain these increased risks? Are people who are prescribed sleeping pills more anxious or stressed out? There is evidence that they are more likely to have car accidents or to fall down, possibly because of the residual effects of the drugs during the day. The studies all suggest that sleeping pills really do increase the risk of dying and there are no logical explanations to explain away the findings, especially the increased risk of cancer.

While researchers can’t say for sure that the sleeping pills caused death or cancer, it is important to consider safer ways to fall asleep. The sleep specialists who conducted the research noted that sleeping pills have very limited benefits, and suggested old-fashioned sleep aids like warm milk instead. They also suggested cognitive-behavioral approaches to insomnia, which can be taught and used for the rest of your life.

Honoring Foremothers

Every year, we honor extraordinary women who blazed the trail for other women in their fields. We call them our Foremother Awards. With journalist Maureen Bunyan as our terrific emcee, we honored Dr. Rita Colwell and author Lynn Povich at our annual luncheon at the Mayflower Hotel in Washington, D.C.



Rita Colwell is an extraordinary scientist whose work has created safer water supplies around the world, saving lives while breaking down many barriers for women in science and serving as a mentor to many. Well after retirement age, she started her own bioinformatics company, with technology that will save lives by quickly identifying microbiome bacteria, viruses, fungi, and parasites, including those that can be used as biological weapons.

She is a woman of many firsts: She was the first scientist to link global warming with a potential rise in water-borne infectious diseases. She was the first woman to serve as Director of the National Science Foundation. She has served as the President of the American Association for the Advancement of Science and President of the American Society of Microbiology, and is a member of the prestigious National Academy of Sciences. At the age of 83, she is currently a Distinguished Professor at the University of Maryland at College Park and at the Johns Hopkins Bloomberg School of Public Health.

In her remarks at our luncheon, Dr. Colwell was self-deprecating and inspirational. She spoke of being accepted in medical school, changing her plans to marry Jack Colwell (married 61 years!), and then later asking the Department Chair for a graduate fellowship. He told her “we don’t waste them on women.” She later applied and was accepted to another medical school but was told she couldn’t go there because she was not a permanent resident of the state. She told us that she decided to “turn lemons into lemonade” and became a marine microbiologist instead. She travelled to Bangladesh, figured out how to remove cholera from drinking water by simply using a cloth to filter it, and taught village women to do so. This reduced cholera by 50% in the village. She concluded by saying that thanks to her husband Jack and thanks to the Department Chair who discriminated against her, “I probably saved more lives than had I been a physician.”

In a year of #MeToo stories, **Lynn Povich** is an award-winning journalist who was one of 46 women who filed sex discrimination charges against *Newsweek* in 1970. More than 40 years later, that experience inspired her book, **The Good Girls Revolt**, and the **Amazon Prime TV** series that followed. The book is a fascinating nonfiction account of her experiences in a workplace where even the most talented, intelligent, and well-educated women were assistants to a man. The TV series provided a fictionalized version that clearly illustrated the discrimination and sexual exploitation inherent in the workplace when jobs and power were so clearly segregated by sex.

The successful lawsuit against *Newsweek*, led by a young lawyer named Eleanor Holmes Norton, resulted in a tsunami of lawsuits at news organizations. Ms. Povich subsequently became the first woman appointed Senior Editor at *Newsweek*, and in 1991 she became Editor-in-Chief of *Working Woman* magazine. She joined *MSNBC.com* as East Coast Managing Editor in 1996 and in 2005 she edited a book of columns by her father, famed Washington, D.C. area sports writer, Shirley Povich.

Ms. Povich serves on the Advisory Boards of the International Women’s Media Foundation, the Women’s Rights Division of Human Rights Watch, and the CUNY Graduate Center Foundation Board.

In her remarks at our luncheon, Ms. Povich eloquently shared experiences about discrimination in journalism early in her career and how that continued in different forms. She expressed her enthusiasm about being honored at our Awards luncheon and thanked the National Center for Health Research for our work on behalf of patients, families, and consumers across the country.



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We are also very grateful to our Luncheon champions:

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Getting Past the Hype on Dietary Supplements

By Kousha Mohseni, MS, and Jared Hirschfield

If you're like most Americans, you take dietary supplements and have confidence in their safety, quality, and effectiveness.

Unfortunately, you should not be so confident. Dietary supplements – even those sold in reputable or expensive stores – are not tested to make sure they contain what they say they contain, or evaluated to prove whether they provide any health benefits.

Dietary supplements are advertised as solving all kinds of problems—extra flab, wrinkles, low sex drive, strengthening your immune system, you name it. Together we spend billions of dollars in the U.S. each year on these products, so it is important to know what they can and can't do.

Unlike drugs, dietary supplements (including vitamins, minerals, nutrition powders, probiotics, and herbal remedies) are not required by the Food and Drug Administration (FDA) to prove they are safe or effective. They don't need to conduct studies to provide evidence of any type, although the Federal Trade Commission (FTC) requires companies to have scientific evidence to back up any health claims. That process can take years, so typically companies make health claims and worry about being fined later, after millions of people have been exposed to those claims.

Supplement manufacturers can sell any products they wish, so long as the products do not contain any of the eight chemicals that have been banned by the FDA (such as acrylamide and benzene). Those were banned because research showed they were dangerous. But, as long as no research is done, most dietary supplements will stay on the market indefinitely.

Researchers at Einstein Medical Center in Philadelphia have reported that many dietary supplements sold in major drug store chains, natural food stores, and respected supplement websites do not

contain what they are supposed to, or contain ingredients not listed on the label. An FTC report on 300 weight-loss ads, most of which were dietary supplements, found piles of false and misleading claims of safety with no scientific evidence to back them up.

The evidence of problems is growing. A study published in October 2018 in the *Journal of the American Medical Association (JAMA)* reviewed 776 supplements that the FDA had discovered to contain unapproved ingredients. Most were supplements for sexual enhancement, weight loss, or muscle building. Many of these unapproved ingredients were drugs that can cause serious, even life-threatening, health problems, especially if someone is unaware that they are consuming them. Since there are no regulations to ensure that what's on the label is what's in the bottle, manufacturers can intentionally or unintentionally add ingredients that can affect the health of millions of people.

For example, protein powder is a dietary supplement that consumers often consider completely harmless. Unfortunately, it isn't. Additives such as creatine, caffeine, and large amounts of sweeteners, are sometimes in these powders but are not mentioned in the ads or on the label. But what if someone is already consuming several cups of coffee throughout the day and unknowingly consumes even more when they take a protein powder that contains caffeine? Depending on the person, too much caffeine could cause insomnia, tremors, migraines, or other health problems.

The Bottom line: There are two great unknowns with dietary supplements: 1) Most hype about how specific supplements will help you is not proven; 2) Even if the vitamin or substance on the label has been proven to work, there is no guarantee that the bottle contains the substance listed on the label or the amount listed.

Kousha and Jared are Fall 2018 interns at NCHR.



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 — all different types of cancers, but all with the same outcome. Mom also died from cancer — NK/T-cell lymphoma, nasal type.

“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 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.

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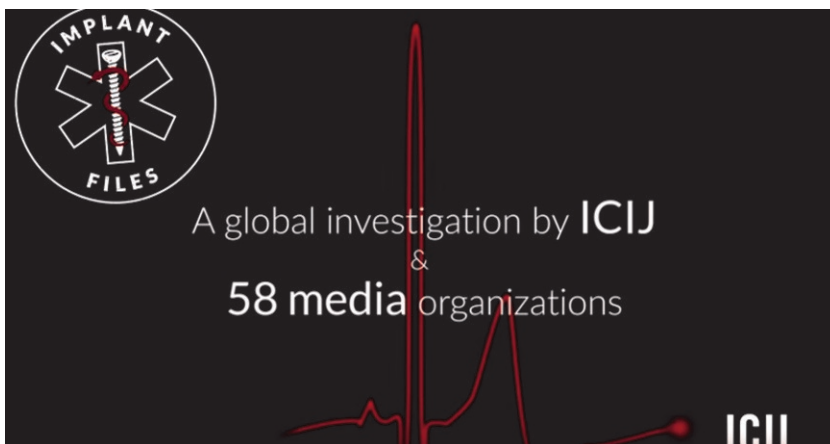
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What are The IMPLANT FILES?

Should you be concerned? See page 4 to find out why more than 250 investigative journalists have turned their attention to medical implants and how we're involved! And whether you should be, too!

Cancer Prevention and Treatment Fund

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



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