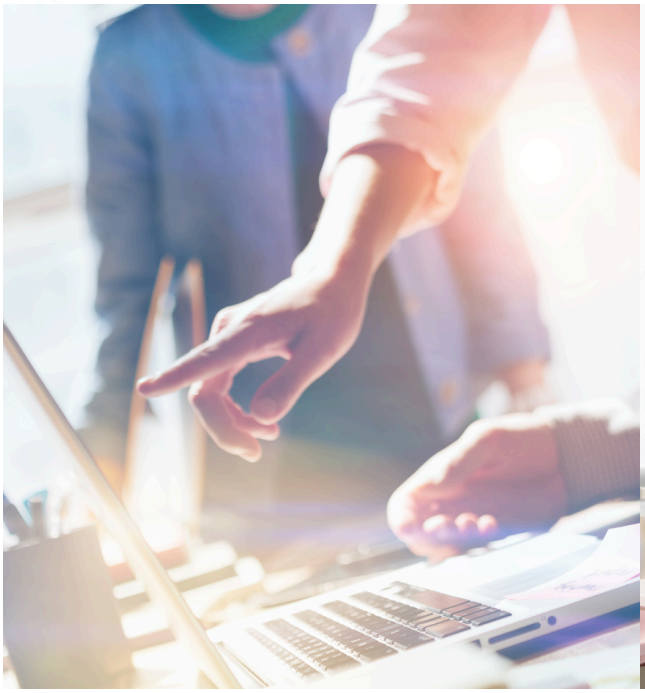
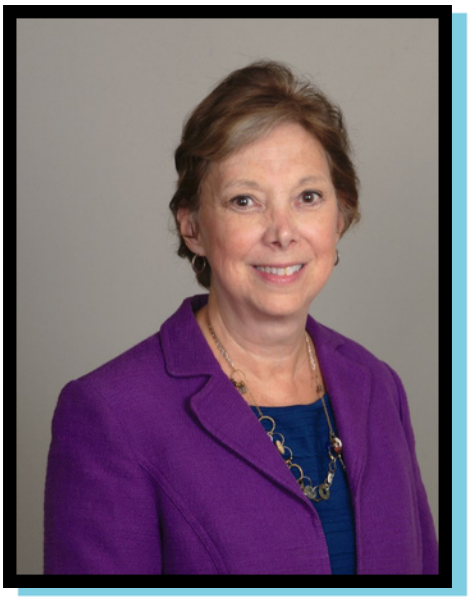
NATIONAL CENTER FOR HEALTH RESEARCH

The Voice For Prevention, Treatment And Policy



Biennial Report 2023-2024

MESSAGE FROM THE PRESIDENT



In 2023 and 2024, we helped thousands of adults and children get the best possible medical treatment; we published articles and reports that will continue to help physicians provide better medical treatment; and we had a major impact on the many invisible government policies that can reduce or increase our risk of infectious disease, cancer, heart disease, diabetes, and other major diseases. Here's how:

- Our health helplines helped women, men, and children across the country. We helped people decide which diagnostic tests and treatments were best for them, and which were likely to do more harm than good.
- We helped people reduce their risk of all types of illness and choose the safest and most effective treatments.
- We scrutinized all the studies of Long Covid causes, treatment, and prevention strategies, and made that unbiased information available to health professionals, patients, and journalists across the country.
- Several years ago, our ground-breaking study in JAMA Internal Medicine scrutinized 18 ineffective cancer drugs that were still being prescribed, and many remain on the market. We have continued to work with doctors and patients to pressure the FDA to rescind approval for any cancer drugs that do not work. We have let patients know that just because a drug is new and expensive, that does not necessarily mean it is more effective or even as effective compared to older, less expensive treatments.
- We persuaded Congress to protect all Americans' access to affordable health insurance, and explained to them that FDA's requirements of evidence of safety and effectiveness protects patients' lives and is not a barrier to innovation.
- We worked with researchers and journalists to better communicate the results of research on which treatments are best for which patients, and publicized important new study results.
- We urged the Food and Drug Administration (FDA) to require long-term studies of the safety and effectiveness of all medications, implants, and vaccines, so that consumers could make well-informed decisions for themselves and their children.
- We testified before the Consumer Product Safety Commission, urging them to ban chemicals in children's products and playgrounds that can cause early puberty asthma, attention problems, and cancer. We also urged them to ban unsafe sleep products for infants.
- We urged city and state legislators to change laws that have resulted in lead and toxic chemicals in artificial turf and playgrounds, and responded to community members' requests for information.
- We made our free patient booklets widely available to cancer patients and family members around the world.
- We testified before the FDA to ensure that medical treatments are analyzed for their effectiveness in women, people of color, and people over the age of 65. These patients are often overlooked in clinical trials, and we advocated to change that.
- We continue to work with hundreds of patient advocates from across the country on how to make their voices heard to improve medical research on treatments and prevention.

Whether we were explaining well-established and complex medical research findings to families and health professionals, or making sense of controversial new research on vaccines, medications, or toxic chemicals in our homes and communities, we scrutinized research and provided useful, understandable, and unbiased information to patients, consumers, policy makers, and the media.

Our research, training, and educational efforts continue to represent the interests and needs of all the men, women, and children who are otherwise left out of life-saving public health decisions. As always, we will continue to advocate for all Americans on matters that are crucial to the health of adults and children nationwide.

- Diana Zuckerman, Ph.D.

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The Cancer Prevention and Treatment Fund

Do Expensive Cancer Treatments Work Better?

There are many exciting new treatments for cancer, and the ads can make them seem almost miraculous. Some of these treatments are truly life-saving, but others are more hype than help. Unfortunately, some don't work at all, and many only work for a small proportion of patients. We want to make sure that patients and their loved ones know all the risks and benefits of cancer treatments, so they can make the decisions that are best for them.

Cancer drugs often drain a patient's energy and joy for living but do not always provide much benefit. In some cases, the cancer may stop growing or even begin to shrink, but ultimately the patient may not live even a day longer.

Cancer drugs do not have to be proven to prolong anyone's life in order for the Food and Drug Administration (FDA) to approve them. After drugs are approved, thousands of patients start taking them and paying for them, not realizing when there is no evidence of a meaningful health benefit. The FDA often requires that companies keep studying the drugs to find out if those medicines are actually extending lives. Unfortunately, these studies are difficult to complete, because patients are reluctant to risk being in a placebo group for a trial of an FDA-approved drug.

Bottom line, the FDA often approves cancer drugs on the basis of short-term, inconclusive data knowing that we may never know if those drugs truly are safe and effective or not.

Are Cancer Drugs Good Enough?

We have been especially concerned when FDA approves a treatment that is proven to work for one type of cancer but subsequently approves it for more than a dozen other types of cancer for which there is little evidence of benefit. We have learned that since the FDA believes that the first approval shows that the drug is safe, the agency is less likely to require evidence that it is effective.

All cancer drugs have risks in terms of patients' safety, quality of life, and financial burdens (often referred to as cancer's "financial toxicity"). Those risks and costs are worth it if the treatment helps a patient live longer with a good quality of life. Although the benefits of a specific treatment for one type of cancer may outweigh those risks, if the same drug is not effective for another type of cancer, then any risks are too many.

In addition, patients and family members often regret using treatments that at best increase a patient's life by a few weeks while harming the quality of life during months of nausea, vomiting, and unrelenting fatigue.

TV commercials and online ads can be very confusing and misleading and the FDA should do a better job of regulating what ads can say. The ads promise that patients "may live longer" or that there was a "significant" benefit, but that doesn't mean they will live longer, or that the time they have left will be enjoyable. We told the *Indianapolis Business Journal*, "When people hear 'significant,' they probably think an extra year or two of life, at least. For cancer drugs, living a few months longer is considered a meaningful benefit, but what if the side effects—nausea, vomiting, diarrhea, exhaustion, etc.—make a person's life miserable? Wouldn't you rather have 40 enjoyable months instead of 45 miserable months?"

Improving the Quality of Cancer Treatments

To help improve the quality of cancer treatments, we testified at numerous public FDA Advisory Committee meetings. Topics included:

- Making sure that cancer drugs that have been found to have risks that outweigh the benefits are no longer allowed to be sold in the U.S.
- Urging the FDA to do more to ensure appropriate doses of cancer drugs for children of different ages and for adults who differ in terms of age, sex, weight, and other traits that influence the safety and effectiveness of the drugs.
- FDA should require companies to carefully study whether certain cancer drugs are more effective if used before surgery, after surgery, or should be given both before and after surgery.

Federal agencies often request written public comments from experts regarding important policies that affect the prevention or treatment of cancer. Here are jus two examples:

- In 2023, we urged the U.S. Preventive Services Task Force to reconsider their plan to change their recommendation that women start undergoing mammography every other year at 40 instead of 50. We pointed out that although the younger age is more beneficial for women in certain demographic groups or women with a family history of breast cancer, starting at 45 or 50 is a reasonable age to start mammography for most other women. This is because mammograms are more accurate for women over 50 and more likely to help identify breast cancer.
- In 2024 we urged the U.S. Preventive Services Task Force to stress the importance of conducting research on how best to provide genetic counseling for breast cancer gene mutations.

"I'm confused about conflicting information about whether my husband should be treated for prostate cancer. His PSA is high, but since he is over 60, we were told that does not need a biopsy. One doctor even said he should stop getting tested every year. Isn't cancer screening always a good idea? Please help us understand why experts disagree."

"I sailed through the surgery, and am thrilled – a dramatic change in course for me after discovering your work. My gratitude to you is beyond words." —Harriet Lerner, psychologist and best-selling author of self help books such as The Dance of Anger and Why Won't You Apologize?

How to Prevent Cancer!

NCHR was the first nonprofit to focus on scientific evidence of risk-free prevention strategies. Decades ago we were educating patients and physicians on research showing that maintaining a healthy weight could reduce the chances of developing breast cancer and several other types of cancer, as well as the risk of recurrence after treatment. It took years for other experts to acknowledge that obesity and being overweight was causing more than 700,000 cancers in the U.S. each year.

We now know that it isn't just the weight that matters. So we are making sure that the consumers and health professionals know know that belly fat is more dangerous than other types of over-weight, and that diet and exercise – even walking -- reduce the chances of various types of cancer.

We've also raised awareness about the relationship between alcohol consumption and cancer. Our popular website article points out that the American Society of Clinical Oncology has stated that drinking more alcohol increases the chances of developing breast, liver, and colon cancer, as well as cancer of the mouth, throat, vocal cords, and esophagus. In fact, the American Association for Cancer Research's 2024 report identified alcohol as a possible explanation for an increase in breast cancer and colorectal cancer among younger adults.

As part of our efforts to educate the public, we have had to explain that many adults who consider themselves to be light or moderate drinkers are also more likely to develop cancer. It is shocking to many that experts define moderate drinking as 3 or more drinks per week, or as 1 drink per day or less for women and 2 drinks per day or less for men. It also surprises many to learn that experts define a drink as 1.5 ounces of hard liquor (vodka, gin, tequila, etc.), or only 5 ounces of wine, 12 ounces of beer, or 8 ounces of malt liquor. Many people in all walks of life drink much more than that week after week and month after month.

Working to Reduce Overtreatment of Breast Cancer

Every year, more than 250,000 women are diagnosed with breast cancer or "pre-cancerous" conditions such as ductal carcinoma in situ (DCIS) that may never become cancer. DCIS and other types of stage zero breast cancer will sometimes go away without any treatment. It makes sense that most physicians advise treatment, because experts cannot always predict which new cancers will go away and which will become dangerous. Unfortunately, research shows that many of these patients are overtreated with unnecessary procedures.

Despite years of research showing that millions of women undergoing mastectomies for pre-cancer or early stage breast cancer (stages 0, 1, 2, and 3a) would live longer if they underwent lumpectomies, medically unnecessary mastectomies have increased in the United States.

Some women will undergo a mastectomy because the surgery is less expensive than a lumpectomy— a decision that may be made by their insurance company, not by them. Some will be so frightened by the word "cancer" that they will make a hasty treatment decision they will later, and forever regret. Fully informed of their options, and free to choose, some women will decide to have a mastectomy that is not medically necessary, but thousands more will never even be told when there are safer alternatives available.

We are working with Congress, health professionals, patients, and insurance companies to improve the quality of care available to all patients. By explaining complicated research results in clear, everyday language and making that information widely available, we can reduce the number of mastectomies and improve cancer treatment at the same time. We can reach this goal by making sure that women understand their treatment options, doctors communicate more clearly with their patients, insurance companies cover the best treatments, and doctors and patients know the best ways to prevent cancer.

Meeting with Agency Officials on Treatments for Alzheimer's and Other Serious Diseases

When the FDA approved Aduhelm for all Alzheimer's patients despite no evidence of improving memory, we knew we had to act.

As we expected, Aduhelm's controversial approval in 2021 set a precedent for questionable approvals of other Alzheimer's drugs and other medical treatments in 2023 and 2024.

We spent hours with reporters to show them that FDA approval did not always mean that a treatment was proven to be beneficial to patients. We explained how a treatment could show signs of being effective in ways that were not meaningful or beneficial to patients.

We also let reporters and worried consumers know that there are many other ways to reduce the mild memory and concentration problems that are so common as we age.

For example, many widely used sleep aids and allergy medications have side effects that can cause memory problems that are mistaken for Alzheimer's. On the other hand, people who are physically active or spend time with friends and loved ones will find that helps their memory and ability to concentrate.

With our help, negative press coverage about Aduhelm resulted in limiting FDA approval only to patients with "mild cognitive impairment" instead of all Alzheimer's patients. Since physicians and patients came to understand that the drug had serious risks and no clear benefits, it was removed from the market in early 2024.

FDA and CMS Leaders

Meanwhile, we met with the FDA Commissioner in his first scheduled in-person meeting with nonprofit organizations in March of 2023. We expressed concern that the FDA was approving new treatments that the agency's own scientists said were not proven to work.

We also met with the leadership of the Center for Medicare and Medicaid Services (CMS) to express our support for Medicare's decision to require better research evidence as a condition of covering the cost of the three Alzheimer's drugs that were approved by the FDA. Although two of the recently approved drugs for early Alzheimer's and mild cognitive impairment are still on the market, physicians and patients are aware of the controversies about questionable benefits and potentially serious risks, and CMS is continuing to require additional research so that patients will be better informed.

Checking the Evidence for Medical and Consumer Products

Every year, the FDA reviews thousands of new diagnostic tests, implants, and other medical devices and allows them to be sold — without first requiring clinical trials. So long as the products are considered "substantially equivalent" to others on the market (a loose definition that often does not require that they be made of the same material or use a similar mechanism of action), they can be sold in the U.S.

It's therefore not surprising that many of these devices are later recalled because they are found to be dangerous. In addition, the vast majority of prescription drugs and implanted devices are approved on the basis of short-term safety and may not be proven safe for long-term use. Some prescription drugs for common ailments, such as diabetes, can even increase the chances of patients developing cancer. We are working to improve these policies to prevent products that are meant to help us from harming us instead.

We've worked with award-winning film-makers who created and disseminated documentaries about medical implants and other devices that have risks that aren't explained to patients or their physicians.

Training Researchers to Explain Their Study Results

Researchers across the country are doing life-saving work, but it can take years for the results of those studies to change the practice of medicine. We're working to change that.

Companies that make drugs pay experts to ensure that favorable research results get reported on TV, radio, newspapers, and social media. But when an important study shows that a popular treatment is not effective, or is harmful, who is going to pay a PR company to get the word out?

Thanks to support from the Patient-Centered Outcome Research Institute (PCORI) we helped researchers learn how to communicate their results in interesting, understandable ways to reporters. We also trained reporters to ask the right questions to determine the quality of new research findings and the implications for patients. In 2023, we completed our PCORI-funded training program on Long COVID.

Thank you for your work and constant patient advocacy!!!!! It is astounding anyone would advocate for medical products that are proven to NOT work!" – Tricia N.

Prevention and Patient Safety

Safety and Effectiveness of Medical Products

Our work on the safety and effectiveness of medical products has made us a very visible presence in the media, at the FDA, in the nonprofit health policy and consumer community, and increasingly among health policy researchers and scholars. We are the most active public health organization on FDA issues.

As can be seen in the list of activities on pages 9-10, we influence policies, educate Members of Congress and their staff; publish in medical journals and on popular websites; and speak at dozens of public meetings. No other nonprofit organizations participate as close to that level; at many meetings, we are the only speaker advocating for patient safety.

We conduct research that can improve healthcare, and we publish the results in medical, public health, and policy journals.

In addition, we are fighting to:

- Improve the quality of health care through studies that determine which treatments work best for which patients.
- Protect patients and protect the viability of Medicare by restricting the unsafe use of drugs for Alzheimer's Disease that are not proven to work but are proven to cause brain swelling and brain bleeds.
- Improve the accuracy of genetic tests, cancer screening, and other diagnostics by reversing policies that have made it illegal for the FDA to insure the accuracy of lab-developed in vitro diagnostic tests.
- Promote safer and more effective medical devices, such as joint replacements, mesh, mammography, contraceptive devices, power morcellators, spinal implants, cardiac implants, and breast implants.
- Promote safer and more effective pharmaceuticals, warning about birth control pills containing drospirenone.
- Ensure that antibiotics are safe and effective, and reduce resistant bacteria by preventing the overuse of older antibiotics in animals and humans.
- Improve legislation aimed at strengthening FDA decision-making and protecting patients who rely on Medicare coverage.

For several years, we've been on the forefront of efforts to ensure that medical products have been adequately tested and analyzed in all kinds of patients in order to determine safety and effectiveness for women and men, people of color, and adults of all ages. We have approached this issue by helping to write and support legislation, testifying about the lack of such information at FDA public meetings, conducting research to document the lack of such data, and meeting with decision makers at the FDA and Congress.

Despite our small size, NCHR continues to be instrumental in organizing nonprofit organizations to fight for safer, more effective, and more affordable medical products, and is the major consumer voice on medical devices. We help nonprofit organizations, consumers, and media who turn to us for unbiased information on a wide range of controversial topics. We are the major consumer voice on strengthening the standards for all medical treatments, to make sure they improve patients' lives.

Helping Women Harmed By Breast Implants

We continue to be interviewed frequently about the well-documented evidence that breast implants can cause symptoms known as "breast implant illness." We had previously helped organize several meetings with patient advocates and FDA officials, which gave the patients the opportunity to urge FDA officials to warn patients about breast implant associated anaplastic large-cell lymphoma (BIA-ALCL) and other serious health problems they had developed because of their breast implants. As a result of these meetings and other work, the FDA improved the information the agency gives patients about these risks.

In addition to our work with the FDA, we continued to provide research-based information about breast implant illness and BIA-ALCL to patients and their advocates, as well as to plastic surgeons. We also included advice on how to improve the accuracy of information about breast implant risks on their websites. As new research and opinion articles were written about breast implants in 2023-2024, we've been an important source of unbiased information to patients, health professionals, and the media.

We have surveyed and assisted more than 6,000 women with implant problems. Many had previously tried but failed to get insurance coverage to remove their problem breast implants.

Insurance coverage for implant removal is somewhat complicated, but it is sometimes possible thanks to the Affordable Care Act, which prevents exclusions due to pre-existing conditions. Nevertheless, most insurance companies rarely consider surgical removal "medically necessary," unless there is silicone leakage, chronic pain, or cancer caused by the implants. Many women have other implant problems, such as leaking saline implants or autoimmune reactions, which insurance companies do not consider sufficient justification for covering removal. We are helping women with implant problems obtain coverage for removal when they can meet the criteria, and if not, we encourage them to consider other ways to afford removal.

We also provide women with a credible source of information about breast implants at www.breastimplantinfo.org. Unlike most breast implant websites, we are not selling anything. That means the information on our website is not paid for by plastic surgeons or breast implant makers who want these women as customers. The website provides the most accurate information available, so that women can make the choices that are best for them.

Weight-Loss Options

Experts now agree that obesity and overweight increase a person's chances of developing cancer, heart disease, and diabetes. But losing weight is difficult, even with weight loss drugs.

In recent years, several drugs have become very popular for treating diabetes and/or weight loss, especially Wegovy, Ozempic, Mounjaro, and Zepbound. Although the FDA approved Ozempic in 2017 for the treatment of type 2 diabetes and Wegovy in 2021 for weight loss for adults with obesity or weight-related health conditions, and Mounjaro in 2022 for diabetes, their popularity exploded in 2023 and Zepbound was also approved that year for weight loss.

In August 2023, Wegovy's maker, claimed in a press release that the drug reduced the chances of having a heart attack, stroke, or death by 20% compared to placebo. We pointed out that this statistic is misleading because 8% of the people in the placebo group had had a nonfatal stroke or heart attack or died due to cardiovascular causes, compared to 6.5% in the Wegovy group.

That decrease from 8% to 6.5% is a 20% decrease, but the difference is only 1.5% for patients considering whether it is a meaningful difference for them. Similarly misleading claims have been made about Ozempic. Equally important, the studies were based on patients who took the drugs for two years, but most people who take these drugs stop within a year. That's because the most common side effects of these GLP-1 medications include stomach issues such as nausea and diarrhea, with some patients experiencing persistent vomiting or severe gastroparesis (stomach paralysis). Hair loss is also a possible side effect for women. Another possible side effect for long-term use is the chances of developing thyroid cancer. When patients stop taking the drugs, they gain some or most of the weight back. Although some patients are happy with the way these drugs have reduced their appetite, the

drugs are very expensive, the benefits tend to be temporary, and the long-term risks are still unknown. Many of us want a magic pill to lose weight, but at this point in time, exercise and a healthier diet remain the safest option for weight loss.

Environmental Health

We continue to be a major voice fighting to ban dangerous chemicals, especially those that can cause obesity, cognitive damage, asthma, and cancer. Our current work to ban hormone-disrupting chemicals such as phthalates and BPA builds on our successful fight in Congress in 2008 to get many phthalates banned from children's toys and products.

Phthalates are hormone-disrupting chemicals used to soften plastic, and have been linked to birth defects in baby boys, including abnormal genitals, testicular cancer, and liver problems. We have fought well-funded, repeated efforts by industry to overturn the law since it passed in 2008, and are glad to report that those dangerous chemicals are still banned from children's products.

BPA was originally developed as a synthetic estrogen that was replaced by an even more dangerous one (DES). BPA is currently used in hard plastic products and is also commonly found in the lining of food and beverage cans. BPA leaches out of the plastic and the CDC reports that it is in the bodies of more than 93% of Americans.

PFAS (pronounced P-Fass) is the short name for a class of human-made chemicals known as per- and polyfluoroalkyl substances. PFAS chemicals are often called "forever chemicals" because they do not easily degrade in the environment or in the body, so they accumulate in both over time. There are thousands of types of PFAS chemicals, and they disrupt hormones, just as phthalates do.

PFAS chemicals are used to make products stain- and grease-resistant, so they are found in many products in your home, such as clothes, carpeting, upholstery, food packaging, non-stick cookware. They are also found in many cosmetics, as well as firefighting foam, and in any factories that make these products or uses the chemicals. The chemicals travel easily in water and do not easily break down, so they can enter the water supply and soil around these factories or anywhere that the factories dump the chemicals. In 2023, a study found that 30% of U.S. tap water contains PFAS. Another source of PFAS exposure is through fish or animals that have the chemicals in their bodies. For example, if a person eats fish from water with high PFAS concentrations, the PFAS can enter that person's body. For that reason, some lakes have banned or limited fishing due to high levels of PFAS found in the fish.

People can also become exposed to PFAS from their home gardens. A study examining nine brands of fertilizer that are marketed as "eco" or "natural" fertilizers found that eight of them had levels of PFAS chemicals that were higher than the levels that are recognized as safe by some experts.

PFAS are in so many products that it is impossible to entirely avoid PFAS exposure. Our work is focusing on urging EPA to ensure lower levels in water, working with the Consumer Products Safety Commission to ban these chemicals from common household products and artificial turf, and educating communities about the harm of PFAS in artificial turf and rubber playground surfaces.

Keeping Families Safe

Too many chemicals used in our homes and communities can increase the risk of serious diseases including cancer. We explain to families and policymakers how research proves why the cancer-causing chemicals in flame retardants used in drapes and furniture have risks that are much higher than benefits – for families and for firefighters.

Unnecessary Radiation

Whether from cell phones, unnecessary CT scans, or mammography that is done too frequently, radiation can increase the risk of cancer even as radiological devices can contribute to easy communication or better medical diagnosis. We are fighting to reduce unnecessary radiation exposure, especially for vulnerable populations such as young children, adults at high risk of cancer, and others.

We know that most people are not going to stop using cell phones, but you can lower your exposure and your risks by limiting the length of your calls; using hands-free devices, "speaker phone," or holding the phone away from your ear; limiting your cell phone use in rural areas or anywhere reception is poor; text instead of talking; and do not keep your cell phone in your pocket, bra, or any-where close to your body while it is turned on.

Risks of Vaping

In recent years, vaping became popular as an alternative to smoking, and the public was told that vaping and other smoke-free tobacco products were much safer than traditional cigarettes. Independently funded research soon showed that this was a major public relations campaign, rather than reality, It will take years to determine the impact of vaping on lung cancer, but our review of the research made it clear that vaping can cause serious and potentially deadly heart disease and lung damage. We have been outspoken in educating the public about the risks of vaping, which can result in even greater dependence on nicotine than smoking. Equally important, vaping is rarely an effective way to quit smoking. Instead, most people who "switched" from smoking to vaping continue to do both, and many children and young adults who had never smoked but started vaping are now smoking and vaping -- a particularly unsafe combination.

Remember – We're Always Here for You!

We assist individuals from across the country through our online and tele-phone helplines. In some cases, we spend hours on the phone talking to a patient or family member, and hours more providing useful information via email. In other cases, we provided one or more email responses to questions pat-ients, family members, consumers, or health professionals have about prevent-ing or treating specific types of cancer or other diseases, or provided free patient booklets or other materials that we had developed or adapted from the NIH or other credible websites.

We provide policy makers, health profes-sionals, and other opinion leaders with an unbiased explanation of scientific data so that they can make educated decisions that affect everyone in our nation. Our research and advocacy work represents the interests of ordinary patients and families, who are often left out of policy debates. We educate leaders in our nation's capital and across the country.

The National Center for Health Research is one of the most active organizations ensuring that FDA helps patients by approving medical treatments that are proven safe and effective. We also work closely with the CMS, the agency that runs Medicare, to make sure that Medicare pays for drugs and devices that are proven to have benefits that outweigh the risks for Medicare patients, and requires additional evidence of being safe and effective for patients 65 and older when that evidence is lacking.

We also work with other federal agencies to ensure that essential research is conducted and that toxic chemicals and other products are removed from our homes and communities.

In 2023 and 2024, NCHR staff testified at more than 30 FDA Advisory Committee meetings and other national or international meetings about the safety and effectiveness of new medical products being considered for approval. A few examples of these testimonies include:

- April 14, 2023: NCHR President Dr. Diana Zuckerman testified at FDA meeting about the risks of Rexulti antipsychotic medication for agitation in Alzheimer's patients.
- April 19, 2023: Dr. Diana Zuckerman testified at FDA meeting questioning the long-term safety and efficacy of opioids
- May 9, 2023: NCHR Policy Associate Sophia Phillips testified at FDA meeting on Opill (norgestrel) as an OTC birth control pill
- May 2024: Dr. Zuckerman testified at the U.S. House of Representatives Small Business Committee. Her invited testimony explained that it is important to all of us that the FDA requires evidence that medical products are safe and effective, and that does not stifle innovation, as some companies claim.
- June 9, 2023: Dr. Diana Zuckerman testified at FDA meeting on Leqembi (lecanemab) for the treatment of early Alzheimer's disease.
- June 16, 2023: Sophia Phillips testified at FDA meeting on improving dosage for pediatric cancers.
- June 22, 2023: Dr. Diana Zuckerman spoke on a panel hosted by the Alzheimer International Society discussion on upcoming FDA approval of Leqembi.
- July 2023: Dr. Diana Zuckerman told the Massachusetts legislators about our support of Bill H. 3948 to prohibit state municipal contracts to install artificial turf fields.
- August 1, 2023: Dr. Diana Zuckerman testified at the Center for Medicare and Medicaid Services meeting regarding transitional coverage for emerging technologies
- September 11, 2023: Sophia Phillips testified at the FDA meeting on oral Phenylephrine (PE) as a nasal decongestant
- September 27, 2023: Dr. Diana Zuckerman's testified at the FDA Advisory Committee on NurOwn for ALS treatment
- November 7, 2023:Dr. Diana Zuckerman testified at the FDA advisory panel on blood irradiators
- November 16, 2023: Sophia Phillips testified at the FDA meeting on accelerated approval cancer drugs that are not proven to work but still are sold in the U.S.
- December 5, 2023: Dr. Diana Zuckerman was a keynote speaker at the CDC Childhood Lead Poisoning Prevention Program Annual Meeting
- April 15, 2024: Dr. Diana Zuckerman introduced the FDA speakers and served as the moderator for an Alliance for a Stronger FDA webinar featuring the FDA's Chief Medical Officer Hilary Marston, Acting Chief Scientist David Strauss, and CFO Benjamin Moncarz, discussing their roles regarding FDA premarket and post-market scientific reviews and monitoring.

- April 23, 2024: Dr. Diana Zuckerman presented a webinar hosted by the Patient Safety Action Network and attended by other Patient, Consumer, and Public Health Coalition members, explaining FDA's approval pathway for breakthrough devices and the controversies about CMS coverage of these devices.
- April 29, 2024: Dr. Diana Zuckerman testified at FDA meeting on final rule on regulation of lab developed tests
- February 22, 2024: NCHR Post-doctoral fellow Dr. Jessica Copeland testified at the Presidential Advisory Council Meeting on Combatting Antimicrobial Resistance
- May 2024: Dr. Diana Zuckerman testified at the Consumer Product Safety Commission about the risks of lead and chemicals in children's playgrounds and urged them to investigate these risks.
- May 22, 2024: Dr. Jessica Copeland testified at FDA meeting on pediatric cancer drugs
- May 23, 2024: Dr. Jessica Copeland testified at FDA meeting on the Shield blood test for colorectal cancer.

In addition to our oral testimony, NCHR staff provided written recommendations to various government agencies through more than 75 comments and letters in 2023 and 2024. Some examples include:

- 2023: We wrote to government officials in Montclair and Essex County, N.J and Kingston, NY to urge them to reduce dangerous exposures from artificial turf and rubber playground surfaces by using grass, engineered wood fiber, and other safe, natural products.

Congressional Testimony, Briefings, College Lectures, and Speeches

"I'd like to send my appreciation for the information you presented at the FDA Advisory Committee...I have been feeling overwhelmed and disheartened about the lack of dialogue and transparency in the last year and a half, and am grateful to you for acknowledging the importance of further investigation about benefits over risk/side effects, especially in that forum." -M.C.

- March 20, 2023: We provided recommendations to FDA on using medical device user fees to improve safety and effectiveness
- April 2023: We provided recommendations to FDA on review on cannabis for pain
- April 2023: We supported CPSC additional standards to improve the safety of cribs that are not full size, and also urged them to ensure that any mattresses used with these products meet all safety standards, since soft mattresses can cause suffocation.
- May 2023: We provided recommendations to FDA on a petition to remove food dyes.
- May 2023: We provided recommendations to FDA on guidance on clinical trials for cancer drugs
- June 2023: We provided recommendations to FDA on their survey on quantitative claims in direct-to-consumer prescription advertising
- July 2023: We provided recommendations to FDA on their bioequivalency guidance to ensure effectiveness of generic drugs
- July 2023: We provided recommendations to Health and Human Services on plans to support smoking cessation
- August 2023: We provided recommendations to FDA on their guidance on decentralized clinical trials for drugs and devices
- August 2023: We provided recommendations to FDA on guidance for evidence needed for Medicare coverage document
- August 2023: We provided recommendations to FDA on guidance for in-home disposal systems for opioid analgesics
- August 2023: We provided recommendations to CMS on their notice on transitional coverage for emerging technologies
- October 2023: We urged the CPSC to improve their proposed study of toys for children ages 2-4 to ensure that the toys are safe for all children in that age group.
- November 2023: We provided recommendations to FDA on "Medication Guides: Patient Medication Information"
- November 2023: We provided recommendations to FDA on guidance for medical devices for weight loss
- December 2023: We supported the CPSC guidelines on safety standards for infant and toddler rockers, but urged them to add a minimum age of use of at least 4 months old and more strongly discouraged the use of rockers for sleeping
- December 2023: We provided recommendations to FDA on their guidance for "Stimulant Use Disorders: Developing Drugs for Treatment"
- December 2023: We provided recommendations to FDA on communications from firms to healthcare providers regarding scientific information on unapproved uses of approved medical products
- December 2023: We provided recommendations to FDA on development of novel drugs for diabetic foot infections
- December 2023: We provided recommendations to FDA on confirmatory evidence needed to demonstrate a drug's effectiveness

- 2024: We wrote to government officials in Tucson, Arizona, Wethersfield, CT, Philadelphia, PA, and Los Angeles and Sunnyvale, California to urge them to reduce dangerous exposures from artificial turf and rubber playground surfaces by using grass, engineered wood fiber, and other safe, natural products.
- January 2024: We urged the CPSC to study a large number of children who are representative of the U.S. population when they are determining young children's use of smart toys
- January 2024: We provided guidance to United States Preventive Services Task Force (USPSTF) on screening for adolescents with high BMI
- February 2024: We provided recommendations to USPSTF on their research plan for BRCA-related cancer counseling and treatment
- April 2024 : We provided recommendations to FDA on ads for beverages with alcohol content
- April 2024: We provided recommendation to CMS on their rule to prevent conflict of interests
- April 2024: We provided recommendations on race and ethnicity data in clinical trials of medical treatments
- June 2024: We provided recommendations to FDA on treatments for early Alzheimer's disease
- November 2024: We provided recommendations to Medicare on coverage for IPAPS for heart failure management

Internet and Social Media

Our websites, www.center4research.org and www.stopcancerfund.org, provide free information on a wide range of topics important to anyone who wants to improve their health or increase their chances of getting effective treatment. We also reach a broad virtual audience through social media on our Facebook pages *www.facebook.com/nationalresearchcenter* and *www.facebook.com/CancerPreventionandTreatmentFund*; Twitter accounts: @NC4HR and @cancer_fund; and Instagram accounts: @safe.to.play and @healthresearch4u; Threads: @healthresearch4u; and Bluesky: @nc4hr.bsky.social. We have thousands of Twitter and Facebook followers.

Our online hotlines enable anyone to obtain free information about their own personal health concerns by contacting info@center4research.org info@stopcancerfund.org. We help individuals all over the country with their questions regarding prevention and treatment options.

Community Meetings and Forums

Parents who had read our articles about the dangers of artificial turf playing fields and playgrounds have asked for our help. We've provided free help to families across the country.

People were shocked when we told them that the same kinds of toxic chemicals that have been banned for more than a decade from children's toys are allowed in children's artificial turf playing fields and playgrounds. These same chemicals

are also in indoor tiles used on the floors of daycare centers and home playrooms. But many of these families hit a bureaucratic brick wall when they tried to convince officials from schools and city agencies to use safer, natural products.

We were surprised at how difficult it was to get these officials to listen to scientific evidence or even to common sense, and even more surprised to learn that families were installing artificial turf in their yards as well! These products are widely advertised online and sold on popular websites such as Amazon, Home Depot, and Lowes. As discussed on pages 9-10, we testified and sent information to officials in Arizona, California, Connecticut, Maryland, Massachusetts, New York, New Jersey, Washington, D.C., and many others about the risks of these products Our goal is to stop the installation of these fields and playgrounds before children are permanently harmed by frequent exposure to phthalates, volatile organic compounds (VOCs), lead, and other toxic materials.

Training Journalists to Provide Accurate Medical Information

The news media and social media are major sources of information regarding health issues, whether it is the 24/7 news cycle on hot topics such as fluoride and vaccines or new research on cancer, heart disease, pain management, diabetes, or other serious health issues. With partial support from the Patient Centered Outcomes Research Institute (PCORI), we hosted free workshops, teleconferences, and webinars for reporters in 2019-2023. The in-person workshops and several teleconferences and webinars were aimed at improving journalists' understanding of important new research results on a wide range of health topics.

We are proud that this work was enthusiastically appreciated by almost 200 journalists across the country, who used the information we provided as they disseminated life-saving information via TV news, newspaper and magazine articles, websites, and other media.

Patient Advocacy Training

Companies that make medical products financially support many patient organizations, encouraging them to urge Congress and the FDA to approve treatments more quickly. However, those patient groups have rarely focused on safety issues, or on other outcomes important to patients.

After hosting free workshops in 2015, 2016, and 2017 to train patient advocates about research on the safety and effectiveness of drugs and medical devices, our workshop participants formed the **USA Patient Network**, which now consists of patients, caregivers, and their friends and family members that are united by a common goal: to make sure that medical treatments are as safe and effective as possible. The **USA Patient Network** includes patients concerned about cancer and other serious diseases.

After being trained by us, many of these patient advocates have testified at public meetings with the FDA and other government agencies to improve the safety and effectiveness of medical products, and to improve the safety information available to patients and their family members. Several have served for years on the FDA Advisory Committees that help the FDA decide whether new drugs and devices should be approved. We continue to work with those patients and NCHR president Diana Zuckerman is an x-officio member of the **USA Patient Network** Board.

To find out more about the **USA Patient Network**, visit their website at **www.USAPatientNetwork.org**.

In Unity, there is Clout

The National Center for Health Research has a primary role in coordinating the Patient, Consumer, and Public Health Coalition, which includes dozens of well-respected nonprofit organizations, including:

American Medical Student Association, American Medical Women's Association, Annie Appleseed Project, ASHES (Advocating Safety in Healthcare E-Sisters), Association for Medical Ethics (AME), Breast Cancer Action, Breast Cancer Consortium, Center for Medical Consumers, Connecticut Center for Patient Safety, Consumer Federation of America, Consumers Union, DES Action USA, Government Accountability Project, Institute for Ethics and Emerging Technology, Jacob's Institute of Women's Health, MedShadow.org, MISSD, National Consumers League, National Women's Health Network, Our Bodies Ourselves, The Society for Patient Centered Orthopedics, The TMJ Association, Union of Concerned Scientists, US PIRG, Washington Advocates for Patient Safety , and WoodyMatters.

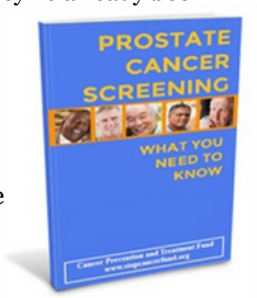
Through this coalition, we host numerous coalition meetings, strategy sessions, and nationwide efforts to help consumers understand new health information. The coalition also presents oral testimony and written comments to federal agencies.

For example, in July 2023, the Coalition wrote to FDA Commissioner Califf to express concerns that FDA Center Directors overruled the decisions of their own scientists when approving drugs that were not proven to work. In August 2023, the Coalition wrote to CMS to encourage the agency to make registry data on Alzheimer's treatments available to the public.

Free Patient Booklets

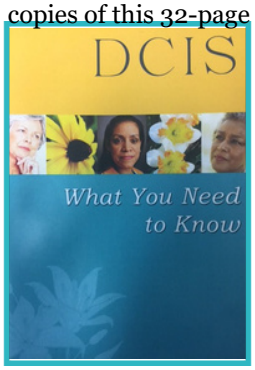
We continued to distribute electronic and hard copies of the following patient booklets, which have been updated as important new research results are made available:

Prostate Cancer Screening: What You Need to Know. This 10-page booklet provides the information that men need to know to make informed decisions about if and when they should be screened for prostate cancer. If they've already been screened for cancer, the booklet explains what it means if their test showed they had prostate cancer. It is available for free on the National Center for Health Research website and our Cancer Prevention and Treatment Fund website.



Surgery Choices for Women with Early Stage Breast Cancer. We worked with NIH to develop this 24-page booklet gives women the information they need when confronted with an early stage breast cancer diagnosis. It is also available for free on our Cancer Prevention and Treatment Fund website.

DCIS: What You Need to Know. This patient booklet explains DCIS in everyday language and enables women who have been diagnosed with it to make informed treatment decisions. To date, we have distributed more than 1,500 free hard copies of this 32-page booklet to other breast cancer patients, physicians, and individuals. It is also available for free on the on the National Center for Health Research website and our Cancer Prevention and Treatment Fund website.



Public Service Announcement with Actress Elisabeth Rohm

We were thrilled when Elisabeth Rohm enthusiastically agreed to film a public service announcement for us in 2016. She's been in TV shows such as Law and Order, Hawaii Five-O, The Last Ship, Jane the Virgin, and in many films, including starring alongside Jennifer Lawrence in American Hustle and Joy.

She is particularly interested in our unique work to prevent cancer and to keep cancer-causing chemicals out of children's products as well as our neighborhoods, food, and homes. As a devoted mother, she shares our concerns that her daughter might be exposed to these chemicals on playgrounds and in toys, soda cans, and even pizza. You can find a link to this video at the bottom of our homepage at www.stopcancerfund.org, or visit www.stopcancerfund.org/in-the-news/press-releases/actress-elisabeth-rohm-urges-give-back-join-fight-cancer.

Internships

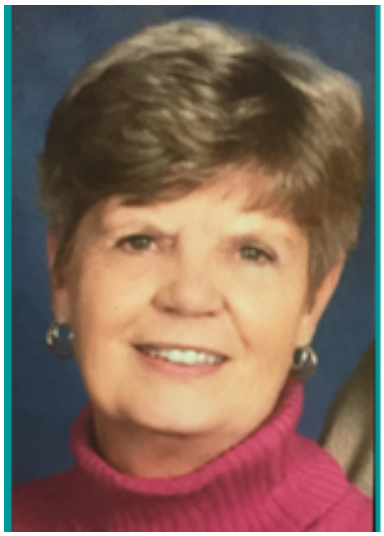
The National Center for Health Research was assisted by 7 impressive interns in 2023 and 2024, including graduate and undergraduate students from University of California Santa Barbara, UCLA, University of Texas Houston, Dartmouth, University of Rochester, University of Pennsylvania, and Georgetown University.

Interns can focus on health communication or policy and gain a wide range of experiences working with Capitol Hill.

Interns learn about the Washington, D.C. policy scene while helping to communicate with the public about a range of health issues.

Interns gain experience writing and editing articles, reports, and press releases, and using the internet to influence people and policies. They also develop their research skills and learn how to communicate effectively with patients and consumers.

Janice Bilden Cancer Prevention Internship



Janice Bilden

The Janice Bilden Cancer Prevention Interns are responsible for writing and updating web articles as well spreading the word about cancer prevention on social media.

They also assist with research and policy issues of importance to cancer prevention, including nutrition, exercise, other health habits, and avoiding dangerous exposures.

The Janice Bilden Cancer Prevention Internship is an annual internship that was started in 2018 thanks to a generous donation from Janice's daughter, Holly Bilden-Stehling.

Jack Mitchell Health Policy Internship

Jack Mitchell

We were devastated when our Director of Health Policy, Jack Mitchell, died from non-Hodgkin's lymphoma in December 2019. Jack started his career as a muck-raking journalist working for columnist Jack Anderson, became a Washington correspondent for CNN, and became a federal investigator for the Senate and the FDA, where he was a special assistant to Commissioner David A. Kessler.

Their crusading effort to regulate tobacco companies culminated in a 2000 Supreme Court case and the subsequent regulation of tobacco products by the FDA. We are honored to offer the Jack Mitchell Policy Internship, which is generously supported by his family, friends, and colleagues.

Omega Logan Silva

Omega Logan Silva Internship

Dr. Omega Logan Silva was one of our long-time Board members and we have honored her legacy with this internship. Dr. Silva was professor emeritus of medicine at the George Washington University in Washington, D.C. She was a long-standing advocate for universal health care and a committed supporter of NCHR and of the advancement of women in medicine. In 1963, she returned to Howard University to train as a physician, earning her medical degree in 1967. She served as president of the American Medical Women's Association, served on 6 different advisory groups for the NIH, and received numerous awards as well as letters of commendation from President Reagan and President Clinton.

The Omega Logan Silva internship has been generously supported by her friends and family, and focuses on women's health and training women in medicine.

MEDIA AND COMMUNICATIONS

In 2023 and 2024,the media turned to the National Center for Health Research for timely, health and medical information from a credible source. We responded to frequent requests from reporters and producers across the country for information, comments, and interviews. The following is just a small sample of news stories that quoted us in 2023 and 2024. In addition, we publish and distribute issues of our own printed newsletter, *The Voice*, and emailed monthly issues of our e-news Digests. Contact us at info@center4research.org if you want to be added to these mailing lists.

Medicare outlines plan to expand coverage for costly new Alzheimer's drugs
The Washington Post, *June 1 2023*

FDA's new plan to study opioids' effectiveness faces resistance
STAT News, *April 19, 2023.*

F.D.A names a new chief of medical devices
The New York Times, *October 22 2024*

Vivek Ramaswamy's crusade to change FDA could boost biotech, and himself
The Washington Post, *November 25, 2024*

Americans Are Paying Billions to Take Drugs That Don't Work
Bloomberg News, *April 15, 2024*

We were quoted over 65 times by 10+ media outlets!

Scientists urge FDA to rescind approval of test for opioid addiction risk
The Washington Post, *April 5, 2024*

10 doctors on FDA panel for Abbott hear device had financial ties to the company. The FDA didn't disclose the payments.
NBC News and Kaiser Health News, *April 6, 2024*

He Regulated Medical Devices. His Wife Represented Their Makers.
The New York Times*, August 20, 2024.*

Accelerated Approval Withdrawal Offers Hints On New FDA Approach
Inside Health Policy, *March 4, 2024*

What Trump's election win could mean for AI, climate, and health
Nature, *November 8 2024*

After Drug Trial Fizzles, Sarepta Still Seeks Broad Approval
Bloomberg News, *November 1, 2023*

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