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.

When Is a Cure Not a Cure?

Wouldn’t it be great if any serious disease had a treatment to cure it? Unfortunately, when politicians get involved, that has proven to be a dangerous goal. That’s because politicians tend to focus on short-term wins, such as taking credit for a new law or new policy that will please voters. If you ask patients what they want, it is a treatment that will give them hope in the short-term and better health and a better quality of life in the long-term. Sadly, many patient advocates have been misled by laws such as the 21st Century Cures Act (passed 5 years ago) which lowered scientific standards for FDA approval, jeopardizing patient safeguards. An updated version of the law was introduced in Congress in November 2021, and would expand previous efforts.

Cancer treatments and treatments for Alzheimer’s Disease or for rare diseases are perfect examples of how the short-term goals of politicians and the long-term needs of patients can conflict. For more than a decade, Congress has been pushing the Food and Drug Administration (FDA) to get treatments approved more quickly. FDA has responded to those demands by looking for quick successes – proudly telling the media about an “innovative” new treatment for cancer or Alzheimer’s, for example – often before there is clear evidence that the product is safe or effective. If it is later found that those new products are not safe or not effective, the FDA can take years to announce that or to get the ineffective drug off the market.

Since our founding in 1999, the National Center for Health Research and our Cancer Prevention and Treatment Fund have been fighting to make sure that new medical products are proven safe and proven effective before they can be sold in the U.S. All products have risks, but the likely benefits should outweigh the likely risks for most patients – as required by law. When the FDA fails in that mission, patients and consumers can be seriously harmed, the cost of health insurance skyrockets, and Medicare faces possible bankruptcy. Sound familiar? Here are 2 examples:

Aduhelm Vs. Alzheimer’s Disease in 2021

When the FDA approved Aduhelm for the treatment of all patients with Alzheimer’s Disease in June 2021, many families thought their prayers had been answered. It didn’t take long for reality to set in, unfortunately. What have we learned as a result? Will 2022 bring better news for millions of families affected by Alzheimer’s Disease, or just more dashed hopes? Will the FDA continue to ignore its own scientific advisors in an effort to please lobbyists paid directly and indirectly by the companies who make those products?

The Ongoing Saga of Cancer Treatments That Don’t Work

The same rush to get treatments on the market as quickly as possible that resulted in FDA’s approval of Aduhelm has caused the FDA to approve many cancer drugs for many different types of cancer, sometimes based on very questionable evidence.

For many years, the FDA required evidence that cancer drugs helped patients live longer. But in recent years, FDA rarely requires that gold standard, instead giving most cancer drugs “accelerated approval” based on short-term studies that measure changes in tumor size. This standard is called “Progression Free Survival,” or PFS. PFS refers to the fact that the cancerous tumor is not getting larger and that the patient is still alive. The accelerated approved drugs are often enormously expensive, even though FDA requires the company to continue their studies to see if the patients actually live longer, a standard referred to as “Overall Survival.”
Have you ever wondered why U.S. agencies such as FDA, CDC, and NIH sometimes disagree about important health issues? In newspapers across the country, NCHR President Dr. Diana Zuckerman explained to *Kaiser Health News* why government experts’ perspectives vary: “It’s no secret that FDA doesn’t have the disease experts in the way that the NIH does... And it’s no secret that the NIH doesn’t have the experts in analyzing industry data.”

In November 2021, President Biden finally nominated Dr. Robert Califf to again serve as FDA commissioner. Dr. Zuckerman was quoted in numerous news outlets including *The New York Times*, *AP*, *Yahoo News*, *Washington Post*, *Roll Call*, *Axios*, and *Bloomberg Business*. She told reporters that Dr. Califf is a political compromise; He has conflicts of interest with Pharma but is someone who has usually avoided the controversy that happens when FDA ignores scientific evidence.

Confusing statements mislead customers trying to avoid buying cookware containing harmful chemicals. Even when cookware is advertised as free of PFAS (“forever chemicals” linked to cancer and other health problems), cookware can also contain similarly harmful chemicals called PTFE. Dr. Diana Zuckerman told *E&E News* that she, like many customers, unknowingly purchased cookware containing these harmful substances before switching to less toxic ceramic coating instead, and that nobody should need a Ph.D. to buy safe cookware.
What Is “Long COVID” and What Helps These “Long Haulers” Recover?

We’ve all heard about people who had COVID months ago – even those who became sick almost 2 years ago – and are still not recovered. The stories can be mystifying. Much has been written about people who lost their sense of smell and taste, but those aren’t the most common and certainly not the most devastating symptoms of what is called Long COVID. Some young healthy people who barely had any symptoms of COVID are now suffering so severely from disabilities that they have lost their jobs, can’t do most of the things they used to do, and are losing hope of getting better. Perhaps most frustrating, many are finding it difficult to find health professionals who are available to help them.

As we learned more about this condition, we became determined to do something about it. Thanks to a Patient-Centered Outcomes Research Institute (PCORI) Eugene Washington PCORI Engagement Award, we started a project in September that is focused on bringing all kinds of patients, health professionals, and disability experts together to share knowledge, ideas, and information about what works and what doesn’t to help these patients.

With so much of the U.S. healthcare system focused on preventing and treating COVID, and reducing hospitalizations and deaths, there have been much fewer resources dedicated to the less urgent needs of Long COVID patients. But as their numbers have grown – and are expected to grow to several million in the U.S. alone – it is essential to find ways to prevent Long COVID and to help patients cope with their symptoms and recover.

We started our project by talking to patients and to health professionals who were in charge of some of the 44 Long COVID clinics in the U.S. We learned that major studies of Long COVID treatments and outcomes were barely underway and that many of the health professionals most focused on helping Long COVID patients had never met each other in person, and they were finding it difficult to find time to share information with each other.

Bringing People Together

Our project is designed to do just that – bring people together virtually and in-person – so that approximately 50 health professionals, patients, caregivers, disability experts, payors, and employers from across the country will have the opportunity to work together to help improve the lives of Long COVID patients. We created a “Stakeholders Steering Committee,” chaired by Dr. Monica Verduzco-Gutierrez of the UT Health Sciences Center in San Antonio. The committee is comprised of 11 health professionals, patient advocates, and disability experts, to help us plan the project. We held our first of six one-hour teleconferences in November, plan to hold our second one in January, and hope to hold our all-day in-person conference in Washington, D.C. in the spring. All of these activities will provide opportunities to share information, learn from each other, and start to plan the kinds of patient-centered research that is needed to improve outcomes for patients.

We have quickly realized that six teleconferences, two webinars, and one in-person conference would not be enough to achieve our goals, so we are encouraging participants to create smaller, informal Special Interest Groups, comprised of 5-10 people each, who will plan their own meetings to focus on specific topics such as specific types of treatments, symptoms or issues of particular importance to patients (such as Physical Therapy, coping with depression, managing chronic fatigue, how to successfully apply for disability benefits, or the unmet needs of caretakers.) After these Special Interest Groups have shared information and set goals, they will be encouraged to present their findings and ideas to the larger group during the one-hour teleconferences or the in-person conference.

Our first teleconference was a great success. We had hoped to attract 20 participants, and instead 44 attended. The topic was focused on the most common symptoms of Long COVID as well as information that is less well known. Most importantly, it gave everyone time to listen to others and find new colleagues that they would like to work with.

Would You Like to Join Us?

Would you like to learn more, attend our next teleconference, and perhaps even be actively involved in our Long COVID project? If so, please contact Dr. Nina Zeldes at nz@center4research.org.

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!
We’re Speaking Out!

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

Medical Devices

Medical implants often contain materials that patients are not warned about. In August 2021, we urged the FDA to make information about the materials in medical devices understandable and available to patients. For example, materials should not be listed using their scientific names, but rather described using common names. For example, the label for a device might include the chemical term “Au,” instead of “gold.” This is not acceptable, since patients deserve to know what materials are going into their bodies, as well as all of the potential risks of those materials because of allergies or other reasons. We stressed that patients must be given this information before scheduling a surgery.

In April 2021, we provided recommendations to the Agency for Healthcare Research and Quality (AHRQ) regarding their draft report on breast reconstruction following mastectomy. We noted several shortcomings of the report; for example, the report did not mention most complications caused by breast implants, and barely mentioned the risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL), and referred to it as “extremely rare.” In fact, BIA-ALCL occurs in 1 out of every 354 mastectomy patients reconstructed with textured implants. We were pleased to see that AHRQ revised the final draft of their report in order to reflect several of our concerns. Their final version discussed the overall limitations of data on breast reconstruction, adding that “very long-term benefit and harm outcomes of the various reconstruction options is largely unknown.”

Alzheimer’s Disease

You may have heard about Biogen’s drug Aduhelm (aducanumab), which is intended to slow cognitive damage caused by Alzheimer’s Disease. In July 2021, shortly after FDA approved the drug, NCHR wrote a letter to the Secretary of Health and Human Services (HHS), the Administrator of Centers for Medicare & Medicaid Services (CMS), and key members of Congress about the lack of evidence that the drug was safe or effective. We pointed out that the FDA’s approval of this drug sets a dangerous precedent, making it difficult to trust FDA decisions. We recommended 3 steps of action:

1. FDA should revise the drug indication to only be for mild Alzheimer’s patients, since the scientific evidence was limited to mild Alzheimer’s patients and require well-designed confirmatory scientific studies within two years rather than nine years.
2. Medicare should use appropriate scientific standards for its coverage decisions, even if FDA’s standards were not appropriately scientific.
3. The HHS Inspector General should investigate whether the Aduhelm approval decision was consistent with FDA’s scientific policies and other agency standards, and determine whether policy changes are necessary to ensure that future drugs are not approved when studies of meaningful patient outcomes do not show benefit.

Following our letter, the FDA announced that the drug’s indication would be revised to only those with mild Alzheimer’s, in line with the population that was studied.

COVID-19

In September 2021, NCHR Senior Fellow Dr. Meg Seymour testified at the FDA’s Vaccine Advisory Committee meeting about the safety and effectiveness of boosters for Pfizer’s COVID-19 vaccine. She expressed our concern about the small number of patients in the safety study and the fact that very few of the patients were over 65 and none were ages 16 and 17. Dr. Seymour expressed our view that medical products should only be authorized or approved for the types of patients that were studied, not for patients of other ages. In November 2021, Dr. Seymour testified at an FDA Advisory Committee meeting about a potential new treatment for COVID-19, molnupiravir, emphasizing why it is so important to carefully and scientifically evaluate the safety and effectiveness of COVID-19 medications for all types of patients who may take those medications.

In November 2021, Dr. Seymour spoke before the EPA’s Children’s Health Protection Advisory Committee about chemicals in the environment that can harm children’s health. She praised EPA’s recent decision to regulate levels of the toxic “forever chemical” PFAS in drinking water, and she urged the EPA to ensure that all communities are protected when the agency develops new rules about PFAS. She urged the EPA to pay more attention to the health risks of rubber playground surfaces and artificial turf fields to protect the health of children who play on them. We also urged the EPA to conduct research on which materials used for artificial turf and playgrounds contain toxic or hormone-disrupting chemicals, and to develop standards to require the safety of these materials.
Welcoming Dr. Thomas Eagen, Our New Health Policy Director

Despite our small size, NCHR has a disproportionate impact on public policy because of the expertise and dedication of its amazing staff. Thanks to our new Health Policy Director, Dr. Thomas Eagen, we’re able to reach out to Congress to share information and provide insights on public health issues. He works to inform Congress on a very wide range of health issues, with particular focus on the quality and affordability of medical treatments and their impact on the U.S. healthcare system.

Thomas’ expertise is a terrific complement to the expertise of other staff, who are trained in epidemiology, public health, psychology, health communications, bioethics, and nutrition. Prior to joining NCHR, he served as a Congressional Fellow in the office of Senator Casey (D-PA) on the Senate Special Committee on Aging through the American Political Science Association. He focused on disability policy, working on legislation to address accessibility throughout the COVID-19 public health emergency and improve access to home and community-based services for older adults and people with disabilities. Following his post-doctoral fellowship, he worked as the health Legislative Assistant for Senator Cantwell (D-WA), who is a senior member of the Senate Finance Committee and Chair of the Commerce Committee. His portfolio of work covered a broad range of health issues which included Medicare, Medicaid, Social Security, the Affordable Care Act, mental and behavioral health, and drug pricing. He was also actively engaged in the federal response to COVID-19, monitoring in-state trends and ensuring equitable distribution of testing, treatments and vaccines to underserved communities.

Thomas received his Ph.D. in Rehabilitation Science and Master’s in Public Health from the University of Washington, where his research focused on the effectiveness of evidence-based programs supported by federal funding that are for older adults and people with disabilities living in the community.

He can be reached at te@center4research.org.

Get Ready for the David vs. Goliath Battle for Patients and Consumers!

While corporations spend billions of dollars to lobby against safe and affordable medical products, we’re proud to announce that the Patient, Consumer, and Public Health Coalition is ready to fight! NCHR has been a leader of this coalition for two decades, which consists of experts and nonprofit organizations that are united to 1) Ensure access to safe, effective and affordable drugs and medical devices and 2) To protect adults and children against unsafe exposures from medications, personal care products, and toxic chemicals in our daily environment.

This is a David vs. Goliath battle, but by working together, our informal, dues-free Coalition sometimes wins against all odds! Our principal objectives are to:

- Advocate for the timely approval of safe and effective prescription drugs and medical devices supported by a thorough, unbiased review of the evidence.
- Enhance the funding and enforcement ability of the federal agencies responsible for research, regulation, and oversight of medications, medical devices, and other consumer products.
- Serve as a voice for patients, consumers, and public health to advocate for federal policies that will increase the availability and appropriate prescribing of safe, effective, and affordable drugs and medical devices.
- Promote education and greater awareness of drug and medical device safety and effectiveness issues on the part of the general public, patients, and those who care for them.
- Advocate for better public access to information about medical products and the basis for FDA decisions.
- Provide opinion leaders and decision-makers with timely analyses and recommendations on federal policies that affect our health every day.
- Ensure that government researchers are free to do their work and analyses based on the best available science, free from corporate and political interference.

Our more than 2 dozen member organizations include the USA Patient Network, Breast Cancer Action, National Consumers League, National Women’s Health Network, Jacobs Institute for Women’s Health, Our Bodies Ourselves, Washington Advocates for Patient Safety, TMJ Association, American Medical Student Association, the American Medical Women’s Association and many other nonprofit organizations dedicated to improving the health of all Americans.

If you are active in a patient, consumer, or public health nonprofit organization, we hope you will contact Thomas Eagen at te@center4research.org to find out how to join our coalition.
An Unproven Alzheimer’s Drug (Cont’d)

Here is a brief summary to explain why the FDA made the decision to approve Aduhelm for all Alzheimer’s Disease, then immediately changed the approval to be limited to mild Alzheimer’s Disease, and why the reactions of experts in Alzheimer’s and experts in FDA standards were so scathing.

First, it is important to know that past efforts to find an effective treatment focused on the plaque that was found in the brains of Alzheimer’s patients. Some treatments were found to help dissolve some of that plaque. But that didn’t help improve the patient’s memories or ability to function, and in some cases made them worse. For that reason, the FDA always required that studies show that Alzheimer’s treatments delay or improve memory and other cognitive abilities - until last June. That’s when the FDA approved Aduhelm for all Alzheimer’s patients based on preliminary, “promising” evidence that it could slightly delay the development of plaque for people with mild Alzheimer’s, even though other studies showed it had no benefits for their memory, thinking, or other cognitive measures.

And the drug had serious risks. The company’s studies showed that Aduhelm caused many patients to have swelling in their brains. Expensive brain scans were necessary to try to prevent the swelling from seriously harming patients. Although the initial studies excluded patients with moderate or severe Alzheimer’s, swelling tended to be worse for patients who were somewhat more impaired when they started the study. That’s why so many experts were so outraged when the FDA approved Aduhelm for all Alzheimer’s patients, not just ones with very mild cognitive impairment. In response to scathing criticisms, someone at the company or the FDA rather quickly decided to change the approval to only include mild Alzheimer’s, not moderate or severe disease. Meanwhile, an article published in a journal of the American Medical Association in November 2021 reported that more than 41% of the patients taking Aduhelm in the two studies experienced brain swelling or other serious adverse reactions.

High Drug Costs Hurt Everyone

For a common disease like Alzheimer’s, treatment cost is important not just for individual patients and their families, but also for all of us. Biogen, the company that makes Aduhelm, decided to charge $56,000 per patient per year, an outrageous cost for an unproven treatment that is not intended to be a cure, is approved for a very common disease, and that patients would expect to take for many years. Unfortunately, the frequent MRIs that would be needed would add thousands of dollars to the annual cost. Together, this would be a huge expense for health insurance companies, and a big enough expense to bankrupt Medicare.

Typically, when the FDA approves a drug, Medicare and health insurance companies agree to cover it. By law, the Medicaid program must cover drugs approved by FDA, including accelerated approval drugs. Because of the enormous publicity about the lack of evidence that Aduhelm works, several major medical centers (Mount Sinai, Cleveland Clinic) and experts in the field have refused to administer it and many insurance companies are not automatically paying for it. Medicare has not yet decided whether to cover these costs and for which patients, and meanwhile the drug failed to be approved in the UK. Will the U.S. be the only country to bankrupt its healthcare system to pay for Aduhelm? Only time will tell.

Ineffective Cancer Drugs (Cont’d)

Progression Free Survival sounds good, but it isn’t proof that the treatment is effective. When tumors stop growing, or even shrink, patients and their physicians tend to be optimistic. But in reality, cancer treatments often shrink tumors in the short term, but after a few months the tumors can start growing again, even faster than before. Or, the toxicity of the cancer treatment can cause the patient to get sicker or die from the toxicity, not the cancer.

That’s why Overall Survival is the treatment outcome that really matters – how long the patient survives. But with accelerated approval, patients pay for cancer treatments that are not proven to help them live longer (and that may cause frequent vomiting and other debilitating side effects), and by the time the longer-term studies are conducted years later, many of those patients have died, some families have gone into debt to pay for the ineffective cancer treatment, and in many cases the studies can’t be completed. Why? Because once a cancer drug gets FDA approval, most patients do not want to be in a double-blind clinical trial where they might get the placebo instead of the new drug that is widely advertised as “A CHANCE TO LIVE LONGER” or other vague promises.

Getting Unproven Cancer Drugs off the Market

After years of criticisms by experts in the field, including our Center, the FDA finally admitted last April that “confirmatory” studies had found that numerous cancer drugs did not help patients live longer. The result of that meeting and the threat of subsequent meetings for other cancer drugs resulted in several companies “voluntarily” withdrawing their widely used cancer treatments – but not before Medicare had spent at least $569 million on 10 treatments that were recently shown to not work, according to a study by Harvard researchers reported in a October 2021 article in an American Medical Association (AMA) journal. That didn’t include the millions of dollars that patients and private insurance companies spent on those cancer drugs or that Medicare spent on other cancer drugs that were recently found to be ineffective. Some cancer drugs that have been found to be ineffective for several types of cancer include drugs you’ve seen advertised on TV, such as Keytruda and Opdivo.

Fortunately, researchers are starting to bring attention to how FDA standards for cancer drugs are hurting patients and our healthcare system. In November 2021, researchers from the London School of Economics and Political Science published a study in the same AMA journal, criticizing the fact that FDA-approved labels on cancer drugs often did not include information on whether the drugs improved overall survival. Since FDA-approved labels are the main way that physicians and patients can access objective information about medications, the failure to include that information, the authors recommended that “labeling should routinely contain clear, nontechnical statements of whether or not clinical trials show statistically significant OS benefit... and the magnitude of OS benefit.”

Cancer drugs are very expensive. A study of the 46 cancer drugs approved in 2018 and published in the same AMA journal in February 2021 concluded that they would cost $39.5 billion per year. If even one in four of those drugs is later found to be ineffective, the cost to the healthcare system – and that means all of us – would be almost $10 billion per year.

For several examples, take the quiz on page 7.
Test Your Knowledge!

Side effects for drugs and devices are on the label, but where is the label? If the label isn’t included with your pills or device, you can find it online on the drug company’s website or by using the search box on the FDA website (www.fda.gov). Or you can ask for product safety information sheets (medication guides) or labels that your doctor or pharmacy can give to you. If the information seems too long or technical, just focus on the information about what you shouldn’t eat or drink while taking the drug, complications, the types of patients who should not take the product (“contraindications”), and other risk information. After reading those warnings, talk to your doctor or pharmacist to be better informed.

1. Keytruda, an immunotherapy approved for several types of cancer, including metastatic small cell lung cancer in 2019
2. Tecentriq, an immunotherapy approved for several types of cancer, including Metastatic Triple Negative
3. Opdivo, an immunotherapy approved for several types of cancer, including small cell lung cancer in 2018, advertised as “A chance to live longer”
4. Endologix AFX, a graft system for the treatment of abdominal aortic aneurysms
5. Penumbra, a medical device used to remove blood clots on thousands of patients since 2007
6. Molnupiravir, for the treatment of mild-to-moderate COVID-19 in adults who are at high risk for severe COVID-19
7. Spinal cord stimulators, implants that use electrical currents that are designed to block pain signals, as an alternative to opioids.

A. Accelerated approval was withdrawn in September 2021 when better research showed it is not beneficial for this treatment
B. Revised several times, this product was never studied in well-designed clinical trials and was recalled due to patient deaths in 2021
C. FDA never required clinical trials to prove safety or effectiveness, and has received more than 150,000 reports of injuries, including paralysis, and more than 1250 patient deaths
D. Withdrawn in March 2021 because later studies indicate it does not help patients live longer
E. FDA required better studies, and 2 years after those studies showed it did not save lives, it was withdrawn for that treatment in 2021
F. This product was only tested on the highest risk patients, and they were only 3% less likely to be hospitalized or die compared to patients taking placebo.
G. Because of serious risks, this product has been revised several times by the manufacturer, but FDA has not required the company to prove that the newer versions are safer.


Leaving a Legacy

We are proud to announce our 2022 Omega Logan Silva Fellow, Ms. Avni Patel. Avni is finishing her MPH at Cornell after completing her Bachelor’s degree in Public Health and Communications at St. Louis University. She was an intern for the Cornell Center for Health Equity this fall, where she reviewed research and literature regarding racial health equity and transformed it into a visual training tool to be taken by staff and faculty of Cornell Weill School of Medicine.

We’re excited to have Avni join us and she truly appreciates being an Omega Logan Silva intern. “Dr. Silva has such an inspiring story, and her legacy as an African American woman in this field cannot be understated. This will be a meaningful experience for me, not only as a woman of color, but also as a public health practitioner who is committed to improving healthcare in the United States.

We’re proud to again offer 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.”
Cancer took a devastating toll on her family. She lost two sisters and two brothers to cancer — all different types of cancers, but all with the same outcome. “Mom also died from cancer. I am glad to have the opportunity to have an internship named in honor of my Mom that will help train a young professional to help others to prevent cancer. I believe wholeheartedly that prevention is the only sure way to save lives and prevent the type of pain my Mom felt, and in losing her the type of pain we feel everyday.”

Is there someone you would like to honor? Internships and fellowships provide training that can result in a lifetime of good work. Honor a loved one through a donation of $3,000 or more in 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.
To: 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.

Donate online at www.stopcancerfund.org
Or CFC #11967

We’re here for you so you can be there for them. Let’s fight cancer.