

National Center for Health Research

We are dedicated to improving the health and safety of adults and children by using research to develop more effective treatments and policies. The Cancer Prevention and Treatment Fund is our major program.

The Cancer Prevention and Treatment Fund

Our Cancer Prevention and Treatment Fund helps adults and children reduce their risk of getting cancer and helps everyone get the best possible treatment.

Cancer Helpline:

info@stopcancerfund.org

Websites:

www.center4research.org
www.stopcancerfund.org

Twitter:

@NC4HR
 @stopcancerfund
 @Implants101

Instagram

@safe.to.play
 @breastimplantinfo



WHAT'S INSIDE

We're in the Headlines...2

Does Online Therapy Work?...3

We Are Speaking Out!...4

Common COVID Misconceptions...5

Leaving a Legacy...6

Test Your Knowledge!...7

Important New Research on Breast Implants...7

Is a COVID-19 Vaccine a Good Idea for You? Will Your Life Go Back to Normal?

If you are at high risk of COVID-19 because you are older, have cancer or other serious diseases, or even if you're at average risk, you're probably wondering if you should get a vaccine as soon as possible. As we write this, there is not yet a COVID-19 vaccine that is widely available. But, we have preliminary data about some of the vaccines. The goal of this article is to give you the information you need to help you make an informed decision. We will also try to answer this key question: Will the vaccines be good enough so that life goes back to normal?

On October 22, the FDA held a public Advisory Committee meeting to discuss the scientific standards needed for a COVID-19 vaccine to be considered good enough to be sold. Food and Drug Administration (FDA) approval standards are higher than the standards for FDA's "Emergency Use Authorization" (EUA). That's why we would have more confidence in a vaccine that was approved by FDA, rather than authorized through an EUA.

At the meeting, we were impressed by how U.S. government agencies are working to prepare for a COVID-19 vaccine to be evaluated and disseminated. However, in her testimony before the Advisory Committee, NCHR president Dr. Diana Zuckerman expressed her concerns that the vaccine trials that FDA has required have serious design flaws. The standards set by the FDA and described in the companies' studies make it likely that at least some COVID vaccines won't achieve what the public expects. Instead, it is likely that some vaccines will only be proven to reduce the risk of mild infections, but won't be proven to reduce the risk of hospitalization, ICU use, or death.

In November, Pfizer and Moderna each announced that their preliminary research indicated that their COVID vaccine was approximately 95% effective. However, only 100-200 of the 30,000-40,000 participants in each trial had tested positive for the virus and had at least one mild symptom. Each company announced that 95% of those COVID patients were in the placebo group and only 5% had



gotten the vaccine. That sounds very impressive. However, these studies must continue and it could be many months before the studies can conclude whether the vaccines prevent hospitalizations or deaths of the people most at risk. And it could be much longer before we know if people taking either of these vaccines are immune from later COVID infections.

Meanwhile, we remain concerned about the major flaws that we described in our testimony:

- The FDA asked companies to measure effectiveness in terms of reducing "symptomatic COVID-19." They defined symptomatic COVID-19 as a patient who tested positive and has at least 1 symptom. However, the symptom could be very mild, such as a mild cough.
- The FDA requires the companies to study at least half of the participants for at least 2 months after they were vaccinated or given the placebo. That is too short to study how well a vaccine works. Some patients won't even be exposed to the virus within 2 months. For those that are exposed, we need a longer follow-up to know how long an effective vaccine remains effective. We can't rely on later studies for long-term effectiveness information, because once a vaccine becomes widely available, most people don't want to participate in a study where they might get the placebo instead of the vaccine.

WE'RE IN THE HEADLINES!

Board of Directors

Brandel France de Bravo, MPH
Consultant

Sarah Deutsch, JD

Daniel Fox, PhD
President Emeritus, Milbank Memorial Fund

Ben Gitterman, MD
Associate Clinical Professor
Pediatrics and Public Health
George Washington University

Nancy Hardt, MD
Professor Emerita of Pathology
and OB/GYN at University of
Florida College of Medicine

Judith L. Harris, JD
President, Matthew Harris
Ornstein Memorial Foundation

Alan Mendelson, LLD
Axion Venture Partners

Omega Logan Silva, MD
Former President, American
Medical Women's Association

Duchy Trachtenberg
Former Councilmember
Montgomery County, MD

Susanne Wilke, PhD, MBA
Venture Capitalist

Susan F. Wood, PhD
Research Professor
George Washington University

Diana Zuckerman, PhD
President
Nat'l Center for Health Research

We can't be bought.

Our Center doesn't accept funding from drug companies or device manufacturers, so we rely on the generosity of individual donors. You can donate online at stopcancerfund.org

FDA Panel to Lay Regulatory Groundwork for COVID-19 Vaccine
NPR, October 22, 2020.

Four ways Trump has meddled in pandemic science – and why it matters
Nature, November 3, 2020.

First, Their Breast Implants Made Them Sick. Then They Were Hit with the Bill.
Cosmopolitan, August 18, 2020

New Study Backs Breast Implant Illness Claims by Patients
International Consortium of Investigative Journalists, July 2, 2020

"We can't ever go to the doctor with our guard down": Why Black women are 40% more likely to die of breast cancer
Fortune Magazine: June 30, 2020

How the Coronavirus Pandemic May Affect Cancer Clinical Trials
Cancer Therapy Advisor, August 18, 2020

How MLB is Navigating the Coronavirus Pandemic to Play Ball
ESPN, May 19, 2020.

New FDA Virus-Test Policy Could Boost Availability, but Reduce Reliability
The Wall Street Journal, March 17, 2020.

Public Health Experts Want Rigorous FDA Review of COVID
Politico, August 7, 2020.

At an FDA Advisory Panel Meeting on COVID-19 vaccine safety in October, NCHR president Dr. Diana Zuckerman said that current vaccine trials "have serious design flaws" because they don't require that the vaccines save lives or prevent hospitalizations. She told *The Wall Street Journal* and *Bloomberg News* that the two-month follow-up the FDA asked for is too short to show how long the vaccines will work and whether they will prevent the most serious infections. Or will it only prevent mild symptoms for people at lower risk?

Many people are turning to telemedicine as a way to see their doctors during the pandemic. NCHR's president told *Drugwatch* that to make sure patients get the most out of their visits, they should prepare all of their questions and concerns in writing in advance.

As Major League Baseball and the National Hockey League tried to figure out how to continue professional sports during a pandemic, Dr. Zuckerman was interviewed for several articles in the *Washington Post* sports pages about the lax standards for baseball and the more credible safeguards for the NHL.

Allergan announced it had been unable to find and notify 52,000 women whose textured breast implants had been recalled due to cancer risks. NCHR's president told *Fortune* that Allergan needed a major ad campaign to notify women, instead of expecting patient groups to do all the work. And when FDA sent a warning letter to Allergan because they didn't complete required studies, Dr. Zuckerman told the *International Consortium of Investigative Journalists* that breast implant companies rarely comply with FDA requirements because FDA never penalizes them for not complying.

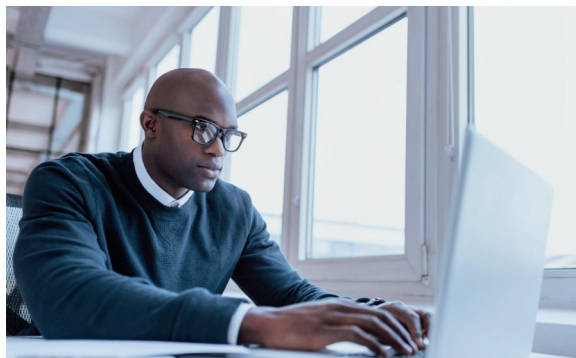
Does Online Therapy Work?

By Meg Seymour, PhD, NCHR Senior Fellow

It's been an unusually stressful year for many Americans. Financial problems and job insecurity, taking care of children while working from home, and worrying about contracting the coronavirus have made it a tough year. Many people feel socially isolated and lonely due to social distancing requirements and precautions. Adding to that, many were concerned about the election and policy issues that affect their lives every day.

There is research to back up what might seem obvious: In a July 2020 survey by the Kaiser Family Foundation, more than half of American adults reported that worry and stress over the pandemic had negatively affected their mental health. Rates of anxiety were more than 3 times as high as they were a year earlier, and rates of depression were close to 4 times as high. According to a June 2020 report published by the Centers for Disease Control and Prevention (CDC), adults were twice as likely to report seriously considering suicide in the past 30 days compared to the percentage of adults who reported seriously considering suicide in a 2018 survey.

But at the same time that stress is up, options for treatment have changed. To make therapy safer, most now takes place over online video chat programs, rather than a traditional in-person session. Is online therapy, also called teletherapy, as effective as meeting in-person?



What Does the Research Say?

A meta-analysis is a study that combines the results of numerous smaller studies to try to get more definitive information. In 2018, a meta-analysis compared the effectiveness of online and in-person therapy for **depression, social anxiety, and several other types of anxiety**. The study focused on a type of therapy called **Cognitive Behavioral Therapy (CBT)**, which helps patients learn to change their negative emotions by changing the way that they think about problems, fears, and experiences. The researchers combined the results from 20 studies, which included a total of more than 1,400 therapy patients. They found that online CBT was just as effective as in-person CBT for treating anxiety and depression.

Another meta-analysis, published in 2019, combined the results of 40 studies to look at the effectiveness of online CBT for treating **depression**. Most of the studies compared people receiving online therapy to

people not receiving therapy, to determine if online therapy makes a difference. It did. In addition, the one study that directly compared the effectiveness of the online CBT to in-person CBT found that the two methods of therapy were equally effective at reducing depression. The people who stayed in therapy the longest had the greatest benefit in reducing their depression.

A 2020 study looked at another type of therapy called **Solution-Focused Brief Therapy**, which focuses on setting goals and finding solutions to one's problems. The researchers randomly assigned college students with mild to moderate levels of **anxiety** to receive either online therapy or in-person therapy. Both methods of therapy were equally effective at reducing anxiety.

Some research has studied the effectiveness of online therapy for treating **PTSD**. A review of more than 40 studies found that both online and in-person therapy reduced PTSD symptoms. The therapies included CBT as well as a type of trauma therapy called **Cognitive Processing Therapy**. Not only did online therapy reduce PTSD symptoms, but patients were equally likely to stick with either method of therapy. And, those who had online therapy were just as satisfied with their experience as the in-person therapy patients.

What is Still Unknown?

CBT is considered an effective form of relatively short-term therapy, but it would be helpful to also study teletherapy using other types of therapy, and for issues other than anxiety, depression, and PTSD. Some researchers have cautioned against using online CBT to treat **schizophrenia** and other very serious types of mental illness. People with these very serious mental illnesses often delay beginning treatment or drop out of treatment. However a 2020 study found that when the coronavirus pandemic began, seriously mentally ill patients were just as likely as others to switch to online therapy, were just as likely as others to begin therapy for the first time using online therapy, and tended to use online therapy services more than others. Perhaps online therapy might make mental health services more accessible for patients who might otherwise delay or drop out of treatment.

The Bottom Line

Research has found that online therapy using CBT can be as effective as traditional in-person CBT at treating anxiety, depression, and PTSD. For more information, see this article on our website: <http://www.center4research.org/does-online-therapy-work/>

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.

Thank you to our wonderful

President's Circle Donors:

Dianne and Rick Ammons
Holly Bilden-Stehling
Diana Conway
Sarah Deutsch
Bill Gittler
Judith Harris
Janet Holt
Eldon Horst
Judy and Peter Kovler
Lisa Lopez
Alan Mendelson
Claudia Miller
Patricia Mitchell
Patricia and Jerry Olson
Renee Ridgeley
Susanne Wilke
Jennifer Yttri
Pam and Barry Zuckerman

National Advisory Board

The Honorable Rosa DeLauro (CT)

Mark Frankel, PhD
AAAS (retired)

Pat Hendel
Commission for Women

Phyllis Katz, PhD
Institute for Research on Social Problems

Rebecca Klemm, PhD
Klemm Analysis Group

Harriet Lerner, PhD
Psychologist and Author

Lisa Lopez, JD

Mary McDonough
Actress and Director

We're Speaking Up!

As a think tank, we frequently share our views with policymakers, government leaders, partner organizations, and health agencies, such as the Food and Drug Administration (FDA) and the Consumer Product Safety Commission (CPSC). 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 for patient safety and consumer needs. Here are a few examples:

Toxic Turf and Playgrounds

In April 2020, NCHR president Dr. Diana Zuckerman testified before the Consumer Product Safety Commission (CPSC) about the need to restrict unsafe chemicals and metals used in artificial turf and playgrounds. It should be a priority to require testing before artificial turf, playground surfaces, and the paint used for playground equipment can be sold, because children are exposed to these – and the lead and harmful chemicals they contain – day after day, year after year. For example, there are no federal restrictions on lead used in outdoor paint, even for products used exclusively by young children. CPSC should investigate this issue immediately.

The rubber and plastic that make up turf and playground surfaces contain chemicals with known health risks, which are released into the air and get onto skin and clothing. Crumb rubber – whether from recycled tires or “virgin rubber” – includes hormone disruptors that can affect early puberty, obesity, and asthma, as well as lead, zinc, and other carcinogens and skin irritants such as PAHs and VOCs. And, the plastic grass in artificial turf also has dangerous levels of lead, PFAS, and other toxic chemicals. PFAS are “forever chemicals” that get into the human body and are not metabolized, so they accumulate to dangerous levels over the years.

Medical Devices

Power morcellators are used to pulverize tumors, making it easier to surgically remove them, but can also spread cancerous tissue. In a written comment to the FDA in April 2020, we stated that the FDA’s newly proposed warnings are not strong enough. We urged that the black box warning should clarify that power morcellation can be dangerous for women under the age of 50 in addition to those over 50, and can also be dangerous for women undergoing hysterectomies as well as those treated for uterine fibroids. We pointed out that a warning specifying that older people are most at risk can be misinterpreted to mean that younger adults are not at risk. We also urged that the label should specify that patients undergoing a hysterectomy may have undiagnosed uterine cancer that could be spread if power morcellation is used; that all patients with presumed fibroids have a risk of hidden cancer; and that morcellators can also spread benign uterine tissue, requiring additional surgeries.

Mental Illness

In August 2020, NCHR Senior Fellow Dr. Meg Seymour testified before an FDA Advisory Committee about our concerns about a combination medication with Zyprexa (also known as Olanzapine) and Samidorphan (an opioid antagonist).

Zyprexa is used for psychosis and depression. The company claimed this combination medication would reduce the risk of patients having serious weight gain and possibly developing diabetes. However, the studies submitted to the FDA suggested that the risks were too high compared to the relatively small benefit of a few patients gaining less weight than if they took Zyprexa alone. In addition, most of the patients in the study were male, Black, adults 55 years old or younger, and were overweight before they started in the clinical trial. In the real world, many if not most patients who take these types of drugs are female, White, teenagers, or over 55 years of age. In addition, the Samidorphan increases the risk of opioid withdrawal problems, which is a great concern for patients with bipolar disorder, who are more likely to be abusing opioids than the general population.

Reproductive Health

In March 2020, we provided a written comment to the FDA on their Draft Guidance on hormonal IUD devices. We focused on the need for demographic diversity when IUDs are tested, in order to determine how safe and effective an IUD is for all the women likely to use it. For example, previous research has suggested that, compared to White women, Black women are more likely to discontinue use of an intrauterine device, for reasons that are not fully understood. We wrote that researchers should include more women in major racial/ethnic groups so they can determine how safe and effective these IUDs are for women in those groups. We also pointed out that an IUD’s effectiveness may be affected by a woman’s weight (BMI), making it important to study it on women with average, high, and very high BMI.

ADHD

ADHD medication is often misused as a “study drug” or for other stimulant purposes. In October 2020, Senior Fellow Dr. Meg Seymour spoke at an FDA Advisory Committee meeting that was considering a label of “abuse deterrent” for an ADHD medication. But the research did not demonstrate that the drug deterred the most common type of ADHD abuse, which is when people take pills that were not prescribed for them, or that it would deter abuse by snorting or IV use. And we agreed with FDA scientists that the high-dosage drug could increase rather than decrease abuse. We also pointed out that research shows that patients, family members, and providers often incorrectly assume that “abuse deterrent” means “less addictive.”

Common COVID Misconceptions

Confused about the conflicting info on face masks, testing, risks to children, and what you should and should not do? Wondering who to believe when experts – or politicians – disagree? Here's what you need to know.

Misconceptions	NCHR Response	Facts and Data
Masks are a personal choice and aren't really effective at preventing the spread of the virus.	Research now shows that masks protect the person wearing the mask as well as others nearby, because it blocks the spread of the virus when people breathe, talk, exercise, sing, etc.	Studies published in June and November found that when states had mandates to wear masks, or if a higher percentage of people in the state wore masks, it slowed down their daily COVID-19 rates. Studies comparing masks show that N95 masks are most effective, surgical masks are also very effective, and cotton masks that fit well are also effective. Bandanas/scarves tied around the mouth and nose are too loose to be effective, and so are stretchy "gators."
The U.S. is conducting a large number of tests, and that is why our virus statistics look worse than other countries.	It's important to measure testing and cases compared to population size. For months, other countries conducted more tests per million people and yet had fewer cases per million people. As of Nov. 15, Denmark and Iceland conducted more tests per million citizens than the U.S. but had fewer than half the number of cases and a small fraction of deaths per million.	According to <i>Worldometer</i> , as of Nov. 15, just over half a million tests have been conducted per million Americans – a much higher rate than earlier in 2020, which partly reflects daily and weekly tests on some of the same people. Compare this to Denmark, for example, which has conducted more than a million tests per million residents. In the U.S., there have been 33,994 cases and 758 deaths per million people, compared to 10,713 cases and 131 deaths per million in Denmark.
There are now drugs that are proven to prevent or treat COVID-19.	There are currently no drugs approved by the FDA for the prevention or general treatment of COVID-19. Remdesivir (Veklury) and steroids have reduced hospitalizations in one or more well-designed studies, and remdesivir is FDA-approved, but only for hospitalized patients. Studies on both are continuing. Convalescent plasma isn't proven to work.	A study in the <i>New England Journal of Medicine</i> found that remdesivir is better than placebo at shortening the recovery for hospitalized adults, but did not save lives. In November, WHO recommended against remdesivir. The National Institutes of Health has stated that there is not adequate data to suggest that convalescent plasma is safe and effective for treating COVID-19. Studies show that hydroxychloroquine is not effective for COVID-19 and the FDA states that "Hydroxychloroquine can cause abnormal heart rhythms such as ... a dangerously rapid heart rate."
President Trump claims that the U.S. has one of the lowest mortality rates from COVID-19.	The number of deaths from COVID-19 per million people in the U.S. is one of the worst in the world. Since early November, more than 1,000 Americans have died from COVID-19 every day, and the average exceeded 1,500/day as of mid-November.	703 out of every one million Americans have died from coronavirus thus far. This rate per million has been surpassed by Belgium, Spain, and Peru; is similar to the U.K., Mexico, and Italy; but is much higher than Canada, Germany, Switzerland, Israel, or Poland, for example.
Rooms and surfaces should be sterilized to reduce the spread of the virus.	The virus is rarely spread from contaminated surfaces. The virus stays in the air when people talk, breathe, sing, cough, etc., which is the main way that the virus is spread.	By Nov. 2020, experts agreed that sterilizing rooms and surfaces is rarely needed in homes, hotels, or offices. They urge the safeguards focus more attention to air filtration systems.
Older adults are the only ones at risk of getting coronavirus. Children are not at risk.	People of any age can become infected with the virus. Children and young adults can become very ill or die from the virus, although older adults are most likely to be hospitalized or die.	Over 1 million U.S. children have been diagnosed with COVID-19, resulting in 6,337 hospitalizations and 133 deaths, according to a November report from the American Academy of Pediatrics. However, children are unlikely to spread the virus to others.
Once you get COVID-19, you cannot get it again.	There are a few cases of patients who recovered and then were re-infected months later. There are no studies yet to determine how long immunity might last, or for whom.	One man in Nevada who became re-infected with COVID-19 became more ill the second time he was infected. It is unknown yet whether people who become re-infected can spread the virus the second time they are ill.
Only 6% of deaths reported from COVID-19 are actually due to COVID-19.	Death certificates are usually required to list all factors contributing to the death. That's why only 6% of people who died from COVID-19 had it listed as the <u>only</u> cause of death. Most people who die from COVID-19 have at least one other health condition, and COVID-19 is more deadly for people with health conditions such as obesity.	According to the CDC, people who died from COVID-19 had an average of 2.6 additional health conditions, such as pneumonia or hypertension. People with other health conditions are more likely to die of COVID-19, but COVID-19 is still the cause of death. Infectious disease expert Dr. William Schaffner has said "If it hadn't been for the COVID virus infection, these people would be living today...it's still the COVID virus that killed them."
Antibody tests can let you know if you are immune to COVID-19.	Antibody tests can tell you if you previously had the coronavirus. Unfortunately, we still don't know whether that provides immunity, or how long immunity would last.	According to the CDC, there are antibody tests and other serological tests that may show who has been infected with this novel coronavirus or other coronaviruses. There is no scientific evidence to prove whether or not these antibodies prevent future infections.
The COVID-19 pandemic will disappear soon.	As long as some people are infected and they are in contact with others, the virus will spread.	Most states have been surging to their highest levels of cases since October.

Is a COVID-19 Vaccine a Good Idea for You? (cont.)

- We don't know how diverse study participants will be in terms of age, race, or other illnesses. That's especially important for people who are exposed to the virus.
- The FDA requires that there be at least 5 serious COVID-19 cases in the placebo group. That's completely inadequate for 2 reasons.
 1. The definition of "serious COVID-19 cases" is not stringent. For example, it could include cases of mild COVID -19 if the patient has a blood oxygen saturation under 93%. But thousands of otherwise healthy Americans have levels below that.
 2. Even if the definition were more stringent, such as patients who were hospitalized or died, having only 5 such cases in the

placebo group is not enough. Even if there were zero serious cases in the vaccinated group, the difference between zero and 5 is a small difference that could happen by chance.

Unfortunately, the vaccines have known side effects that can be worse than mild cases of COVID-19, such as fatigue that lasts for weeks. Although the companies report that "serious side effects are rare," when a healthy person chooses to get a vaccine, they don't want the side effects to be worse than the disease is likely to be.

Bottom Line: There is a lot we don't know yet, and it is likely that vaccines will start to be made available to essential workers or high-risk patients before we have the answers to these essential questions. We suggest keeping an open mind, but be sure to read the fine print when it's time to make a decision. Or feel free to contact us at info@center4research.org for more information.

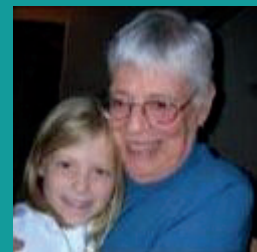
Leaving a Legacy



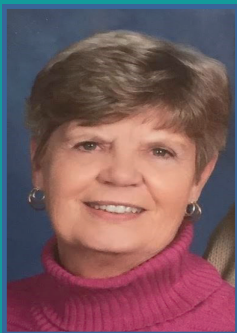
We were devastated when our Director of Health Policy, Jack Mitchell, died from non-Hodgkin's lymphoma last December. Jack started his career as a muckraking journalist working for columnist Jack Anderson, became a Washington correspondent for CNN, and became a federal investigator for the U.S. Senate 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. Prior to joining our staff, Jack was also a top adviser at the U.S. Dept. of Health and Human Services, the National Science Foundation, and the Office of the Special Inspector General for Afghanistan Reconstruction.

We are honored to name the Jack Mitchell Policy Internship in Jack's memory, supported by his family, friends, and colleagues.

It is with great sadness that we report the passing of Mary Hager, one of journalism's women pioneers, and one of our wonderful founding Board members. She was an outstanding investigative reporter on the major medical stories of our time. She began her career in the 1960s as a newspaper reporter before becoming an editor at *Life*, and a correspondent for *Newsweek* for 23 years. She covered the mysterious epidemic that came to be known as AIDS, tobacco company cover-ups of the risks of smoking, toxic waste at Love Canal and other SuperFund sites, and the lack of safety studies for implanted medical devices. In spite of her numerous national awards, Ms. Hager was always humble. "A reporter is only as good as her sources," she told us. Mary had a long and important life, and passed away in August at the age of 86.



It is our honor to name the Mary Hager Investigative Journalism Internship in her memory.



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. 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 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. Donations of \$3,000 or more can be designated for a named internship.

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.

Test Your Knowledge!

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

1

Vylessi, an injectable medication to increase women's libido

2

Jardiance, a drug for Type 1 diabetes to use in combination with insulin

3

Makena, a drug prescribed to reduce pre-term birth

4

Singulair, a medication for asthma and allergies

6

Evenity, to treat osteoporosis

5

Spravato, a nasal spray for treatment-resistant depression

7

Optimizer Smart System, implant connected to the heart with electric wires to treat chronic heart failure

8

Nicorette Quick Mist, mouth spray intended for smoking cessation. Approved in Canada and the UK.

A. Studied on only 7 non-Whites, making it impossible to determine safety or effectiveness for people of color

B. Side effects: hostility, anxiety, depression, disorientation, hallucinations, insomnia, suicide

C. Side effects: nausea, vomiting, high blood pressure

D. Benefit: reduces tiny spinal fractures that don't cause pain or disability, but "may raise the risk of heart attack, stroke, and death"

E. Warning: More people died than with placebo, half of those committed suicide

F. Studied in mostly White males, without a placebo control group, didn't work for most patients in the study

G. In October, FDA proposed that the company stop selling it because it is not effective. It is still being sold.

H. Some smokers use this in addition to smoking, becoming even more addicted.

Answer Key: 1:C, 2:A, 3:G, 4:B, 5:E, 6:D, 7:F, 8:H

Important New Research on Breast Implants 50+ Years Later

Breast implants have been sold in the U.S. since the 1960's, but at that time no safety studies had been conducted on women. New research on breast implants published in 2020 provide important information for women who have breast implants or are considering them for either augmentation of healthy breasts or reconstruction after mastectomy.

There are many well-documented concerns about the risks of both silicone gel or saline breast implants, such as leakage and breast pain, but in recent years the major focus has been on two especially serious risks:

1. A type of cancer of the immune system called "Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL), which is primarily caused by textured breast implants
2. A range of symptoms that seem to be related to autoimmune reactions or connective tissue diseases, which is referred to as "breast implant illness"

A 2020 published analysis of 49 women with BIA-ALCL, by De Boer and her colleagues, found that women with the breast cancer genes known as BRCA1 or BRCA2 were more likely to develop the lymphoma than women who did not have either gene but had the same type of textured breast implants. Of the 15 BIA-ALCL cases following breast cancer reconstruction, four (27%) had BRCA1/2 mutations, which is much higher than the 5% of BIA-ALCL cases with breast implants after breast cancer surgery that would be

expected. This was also much higher than the rate of BIA-ALCL for augmentation patients with textured implants.

A 2020 study conducted by plastic surgeons Dr. Corinne Wee, Dr. Lu Jean Feng, and their colleagues again proves that breast implants can cause the debilitating symptoms known as "breast implant illness." This study of 750 women compared their health before and after their breast implants were removed due to symptoms that specialists had not been able to explain after various tests. The study focused on 11 symptoms that women with implants frequently report: 1) numbness and tingling in the extremities; 2) joint and/or muscle pain; 3) hair loss; 4) memory loss/cognitive problems; 5) dry eyes and/or blurred vision; 6) chronic fatigue; 7) breast pain; 8) rashes and/or hives; 9) food sensitivity/intolerance; 10) flu-like symptoms; 11) difficulty breathing. After the women had their implants removed, most reported a statistically significant improvement in their health within 30 days, whether they had silicone gel implants or saline implants. Their improved health was maintained during the year after explant surgery.

These studies are important because of the seriousness of these two medical conditions. Many women with BRCA1 or BRCA2 genes undergo prophylactic mastectomy to prevent the development of breast cancer, often choosing reconstruction with breast implants. Would they choose differently if they knew about ALCL? The well-designed explant study confirms that breast implant illness is real and that explant surgery can reduce or even cure these symptoms.

National Center for Health Research

Cancer Prevention and Treatment Fund (our largest program)

1001 Connecticut Avenue NW, Suite 1100

Washington, DC 20036

Phone: (202) 223-4000

Website: www.center4research.org

Cancer Hotline: info@stopcancerfund.org



NONPROFIT
ORGANIZATION
US POSTAGE PAID
PERMIT NO. 2442

Address Service Requested

To:

The Voice Issue 36: Fall 2020/Winter 2021



How will you know if a COVID vaccine is a good idea for you?

Should you be concerned? See page 1 to find out.

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. Let's fight cancer together!