Lead in drinking water is not a rare event, and when the problem is exposed, it rarely gets attention beyond the local news. The disaster in Flint, Michigan is different. Lead in the water has threatened the health of many families, and the reasons for the disaster have threatened the political future of Michigan’s governor, embarrassed the Environmental Protection Agency (EPA), and attracted the attention of candidates for president. More importantly, it has raised awareness of the problem in many other communities. For that reason, the heroes of Flint are being honored as our Health Policy Heroes for 2016.

LeeAnne Walters is the Flint, Mich., stay-at-home mother who was getting nowhere convincing state and local officials that there was something seriously wrong with their water. Her family’s hair was falling out and her son’s skin was irritated. Officials reassured her that the water was safe.

Walters called the EPA to tell them about the high levels of lead in her water, and she reached EPA’s Miguel Del Toral, who contacted Michigan’s Department of Environmental Quality (DEQ). In February 2015, DEQ staff told Del Toral that Flint had a corrosion control program that was keeping the water safe, and he shared that information with Walters.

Walters scrutinized city reports and discovered that Flint was not using any corrosion control treatment. Walters called Del Toral to let him know, and Del Toral continued to investigate the problems in Flint that eventually led to a June EPA memo highlighting the peril to Flint’s children.

After Del Toral was silenced by EPA, and then discredited by the state, Walters looked online for help and called Marc Edwards, an environmental engineering professor from Virginia Tech and MacArthur “Genius award” winner. He had taken on the powers that be in Washington D.C. about the safety of their water supply more than a decade earlier. Edwards explained to Walters over the phone how to take her own water samples, which she sent to Edwards to test. Her samples had the highest lead levels he had seen in 25 years of testing in consumers’ homes.

State and local officials responded to the results by calling them an isolated problem, suggesting that her family use a hose to get water from their next door neighbor.

State and local officials responded to the results by calling them an isolated problem, suggesting that her family use a hose to get water from their next door neighbor.

Marc Edwards has spent hundreds of thousands of dollars of his own money to investigate the lead disaster in Flint’s water.
**We’re in the Headlines!**

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**Could This Opioid Implant Really End the Opioid Epidemic?**

**Senate committee approves legislation to speed approval of medical devices**

**F.D.A. Faulted for Problems With Drug Tracking**

**Cancer moonshot misses the target**

**Abortion clinics vs. cosmetic surgery centers: which are safer for women?**

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A study last year showed new cancer drugs were no more effective than cheaper drugs already on the market, which is “huge news,” we told the Portland Tribune.

Safety is “not currently a priority at the FDA or Congress,” Dr. Diana Zuckerman told Medscape. Dr. Tracy Rupp told Inside Health Policy that too few new medical products are examined to make sure they are safe and effective for women, men, people of color, and patients over 65.

Lobbyists are influencing state laws to make it harder for patients to access less expensive drugs. We told The Center for Public Integrity that this would benefit the brand-name drugs, not patients.

The Government Accountability Office (GAO) reported that FDA isn’t tracking the safety of many new medications. “We are shortcutting an important part of the approval process in the hope that we get the information later, but now we’re finding out that’s not happening,” we told the New York Times and LegalReader. We explained to CQ Roll Call and Stat that FDA needs to make sure drugs actually benefit patients, and we told Medscape that FDA also needs to keep better track of drugs that it finds have serious risks.

Dr. Zuckerman told HealthLeaders Media what she would like to see in the Vice President’s Cancer Moonshot Initiative: “more FDA scrutiny, both before and after approval, of marginally effective cancer drugs.” When drugs are developed with NIH research funds, drug companies should have to lower their prices for those medicines.

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In March and April, the Senate approved bills to speed up the approval of new medical devices. “The focus of these bills is on getting medical products to market more quickly, instead of making sure that they are safe and effective,” Dr. Zuckerman explained in the Wall Street Journal, Medical Design Technology, Politico, and Dotmed.com.

Probuphine is a new matchstick-sized upper arm implant that slowly releases an opioid. NCHR’s Dr. Tracy Rupp told Maine public radio, Buzzfeed, the Daily Beast, and USA Today that better studies are needed to make sure the implant is safe and effective. “Many of these patients will require [addiction] treatment for years. We need long-term safety data from diverse populations.”

We told Modern Healthcare and U.S. News and World Report that Bayer’s Essure contraceptive needs a black box warning. Bayer’s own studies led to misinformation of the dangerous side effects, we explained to QMED. We encouraged FDA to conduct its own post-market studies instead of Bayer, we told Buzzfeed News and Forbes.

While states are requiring more stringent standards for abortion clinics, they are ignoring the fact that death rates are higher at cosmetic surgery clinics, Dr. Zuckerman explained, blogging on the Our Bodies Ourselves website.
Are Breast Implants Contributing to U.S. Suicides?

The suicide rate for women in the U.S. is higher than ever before. Is it possible that the popularity of breast implants is one of the reasons?

When women are diagnosed with breast cancer, they have many treatment decisions to make. One main decision is what kind of surgery to undergo: mastectomy (removing the entire breast) or lumpectomy (removing just the cancer and a small amount of healthy tissue around it). For women undergoing mastectomy, a related decision is whether to undergo reconstruction with breast implants. But a study of women with early-stage breast cancer shows that mastectomy patients who get breast implants are 10 times more likely to commit suicide than mastectomy patients who did not get breast implants.

Breast Implants and Suicide

Suicide rates are surprisingly high for all women with breast implants, not just mastectomy patients. There are 6 studies showing that women who got breast implants to increase the size of their healthy breasts are also more likely to kill themselves than other women of the same age, demographic background, and health habits. In fact, women with cosmetic breast implants are more likely to kill themselves than women of the same age who undergo other types of cosmetic surgery. While the suicide risk is higher for mastectomy patients with implants than most augmentation patients, age also makes a difference: postmenopausal women with cosmetic implants were 12 times more likely to kill themselves than other women of the same age and demographic traits.

Suicide Among Mastectomy Patients

For the 15 years after diagnosis, breast cancer patients are more likely to kill themselves than other women. But that does not explain why women who get breast implants after mastectomy are committing suicide at such a higher rate than other breast cancer patients. In fact, it raises the surprising question of whether the suicide rate is so high among breast cancer patients because of breast implants, not because of the cancer.

Reconstruction with implants immediately after mastectomy is often encouraged by health professionals and advocates as the best way to make the surgery less traumatic and help women feel “whole” again. A federal law, the Women’s Health and Cancer Rights Act of 1998, requires insurance companies to pay for post-mastectomy reconstruction with implants. For many women, the availability of free breast implants helps them decide to undergo mastectomy instead of lumpectomy. Although the goal of choosing mastectomy is usually to prevent breast cancer from returning, the latest research indicates that the opposite is true: women with early-stage breast cancer who undergo lumpectomy live longer on average than those who undergo mastectomy.

Breast cancer patients deserve treatment options, but they should always be adequately warned about the risks of undergoing mastectomy or of getting breast implants.

Mastectomy patients who get breast implants are 10 times more likely to commit suicide than mastectomy patients who did not get breast implants.

Are Implants to Blame for Suicides?

One theory is that women who decide to get breast implants are more depressed or have lower self-esteem than other women. However, scientific evidence does not support that theory. Is there evidence that breast implants actually increase the risk of suicide? There are no well-designed studies to answer that question, but when implant companies were required to study the self-esteem and quality of life of women before compared to two years after getting breast implants, they found that women tended to have less positive feelings about themselves and their lives after getting breast implants than they had before. Not surprisingly, the companies did not publish those research results.

Implications for Women and for Doctors

Millions of women have breast implants, and in the U.S. at least 75% got implants to increase the size of their healthy breasts, not because of breast cancer. Many of these women expect that implants will make them more self-confident and happier. The suicide study results, however, suggest that mental health screening should be conducted before implant surgery to identify women who may be vulnerable to depression or suicide. The high suicide rate clearly indicates that breast implant surgery should never be considered a solution for low self-esteem or depression.

The suicide rate for women with breast implants in the seven studies ranges from about 2 in 1,000 women with implants to 7 in 1,000. That is much higher than it is for women without implants. Research is needed to understand why the rate is higher, and whether women over 40 are especially at risk whether they are cancer patients or not.

For more information, see our article in Women’s Health Issues or www.center4research.org.
Our Current Research

Our Center conducts many different types of research. Here’s information about several of our research projects, all of which are focused on helping patients and improving health care.

What happens when software glitches affect medical care?

Most of us have our medical information stored in electronic health records, and many of us depend on physicians who rely on information provided by various health information technologies. That software helps physicians calculate the appropriate dose for medications, warns them about possible drug interactions that could be harmful, and reminds them when we need screening tests or vaccines. In other words, our lives may depend on medical software.

Some Members of Congress are proposing laws that would prevent the FDA or any other federal watchdogs from making sure all software programs are safe to use. So, we are studying how often software glitches have occurred and became dangerous for patients.

Our results show a disconcerting problem: sometimes electronic health records incorrectly substitute information about the wrong patient. When a physician makes decisions using that inaccurate information, it can put patients at risk.

There have also been reports of software that incorrectly calculated the dose of medication or intravenous nutrition needed, also putting patients’ lives at risk.

We are completing our analysis of these important data to submit to a medical journal, and we’re making the information available to Congress as they consider changing the law to eliminate the safety net that currently allows recalls of potentially dangerous software technology.

Why so many new cancer drugs don’t work

New cancer drugs are being made available to patients more quickly than ever, because the FDA is no longer requiring evidence that they help patients live longer. Most cancer drugs now only have to prove that they shrink tumors or have other effects that might—or might not—help patients have a better quality of life, live longer, or spend less time in the hospital.

It is not until years after these cancer drugs have been on the market that the companies are required to complete additional research providing evidence of the exact benefit to patients in terms of health, survival, or quality of life.

Much to our surprise, researchers from the National Cancer Institute and the Oregon Health Sciences University reported in December 2015 that many years later there is still no evidence that most of those cancer drugs actually work. We decided to take a look for ourselves.

We found that there are numerous cancer drugs that are still being prescribed by doctors and used by patients even after research showed they were no better than placebo (sugar pills). And, many of those drugs cost more than $100,000 per patient per year!

We’re continuing to analyze the data to see which of these cancer drugs have any benefits at all. We’re also estimating how much money is wasted on cancer drugs that don’t work. When our study is completed, we’ll be publishing it in a medical journal and sharing our findings with the FDA leadership, the U.S. Congress, and the Vice President’s “Cancer Moonshot.”

How can we find a cure for Alzheimer’s Disease?

Researchers have been looking for a cure for Alzheimer’s Disease for decades, but so far, the only Alzheimer’s drugs on the market provide small improvements for a few months, at best.

Some people think that a bill called 21st Century Cures will help find a cure sooner by allowing Alzheimer’s drugs on the market based on promising data that are preliminary rather than conclusive.

Our research examined that question.

We scrutinized all the studies conducted on drugs submitted to the FDA for the treatment of Alzheimer’s in the last 5 years. We only looked at treatments for which information about the research is publicly available.

There were 3 drugs: Semagacestat, Bapineuzumab, and Dimebon. All were found to be very promising in “phase 2 clinical trials,” which are studies with relatively few patients studied for a short period of time. The New York Times and other major media quoted experts predicting these would be blockbuster drugs.

What happened? None of the three drugs ever went on the market in the U.S., because when better studies were required as part of the FDA approval process, the results showed none of the drugs worked. In fact, one of the drugs made patients’ memory worse, and increased the risk of skin cancer. In other words, these drugs would have been either worthless or dangerous to Alzheimer’s patients.

Then we evaluated the cost. Our conservative estimate was that a quarter of a million of the 5 million U.S. Alzheimer’s patients would have taken any one of these drugs if the FDA had approved them based on their promising preliminary results. Even if these drugs cost only as much as current Alzheimer’s drugs, such as Aricept, that would still have cost at least $7 billion before later studies proved that the drugs didn’t work. The bottom line—don’t rush the science if you want to cure Alzheimer’s.
Are medical treatments studied on women, men, people of color, and older patients?

A hot new topic in medicine is “precision medicine.” The idea that we should not rely on “one size fits all” medical treatments is not new to us. For more than a decade, we have been urging Congress and the FDA to require that medical treatments be proven safe and effective for women, men, major racial and ethnic groups, and people over and under 65. It is well known that these demographic differences can affect how people metabolize drugs or are affected by medical devices.

Congress passed a law in 2012, that required the FDA to do a better job studying demographic differences. We are conducting two studies to see how well the agency is doing. We evaluated the publicly available research findings that the FDA evaluated for medical products considered for FDA approval in 2014. Here’s what we found:

<table>
<thead>
<tr>
<th>Medical Devices</th>
<th>Medications</th>
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<tbody>
<tr>
<td>Most medical devices that were intended to be used by men and women, did not provide studies ensuring they were safe and effective for both men and women.</td>
<td>The results were a little better for drugs. Even so, 23% of drugs were not separately analyzed to determine if the drug was safe for women and for men. One-third of the studies did not include at least 30 Black patients – some didn’t even include 10! It is impossible to determine safety or effectiveness based on so few patients. For example, Blacks were not separately analyzed in a study of the asthma drug Singulair, despite previous evidence that the drug did not work for Blacks. One third of the drug companies did not even tell FDA how many patients in their studies were 65 and older. And of those that did specify ages, some had too few patients over 65 to draw any conclusions about safety or effectiveness.</td>
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<tr>
<td>Blacks and Hispanics are the largest minorities in the U.S. but most devices were not evaluated for safety and effectiveness for Hispanics, Blacks, or even for all non-White patients.</td>
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<tr>
<td><strong>Patients 65 and older</strong> are eligible for Medicare, but none of the devices were specifically studied for patients who are 65 and older. Should Medicare cover the cost of devices that might not be safe or effective for older patients?</td>
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Studying how doctors can explain confusing pre-cancer results

Not all cancers are equal. Some “lesions” that have been called cancer, aren’t really cancer. Some cancers grow so slowly that they do no harm. How can we prevent patients from getting unnecessarily traumatic treatments that they don’t need and won’t help them?

To find out, we are partnering with faculty at the University of Maryland Medical Center to test new ways for doctors to communicate with patients about mammography results that are diagnosed as ductal carcinoma in situ (DCIS). DCIS used to be called “very early breast cancer” but is now considered a “pre-cancer” or “marker” for increased risk of developing breast cancer. The goal of our study is to find ways to provide accurate, understandable information to patients that will help them to choose the medical treatment they need, rather than overly aggressive treatment that can do more harm than good.

**The results will help us better understand why so many patients get unnecessarily aggressive treatment for conditions like DCIS.**

While a diagnosis of DCIS might be new to them, these women already have a lot of information about DCIS or cancer, and some of that information is inaccurate or frightening. Regardless of what doctors tell them about their own condition, their perceptions of good treatment decisions are heavily influenced by any friends and relatives who have had breast cancer or breast surgery.

The same is probably true for men who are diagnosed with a high PSA on their prostate screening test or with very early prostate cancer. Even if the doctor tells them that they don’t need to worry, they will be influenced by other friends and family members who have had prostate cancer or other types of cancer.

Our challenge is to help health professionals provide medical information to patients that is so powerful that it overcomes the fears or misunderstanding that many people have developed because loved ones have died from cancer.

Leaving a Legacy

Is there someone you would like to honor?

Internships and fellowships provide training that can result in a lifetime of good work. Honor a loved one through a donation of cash or stock, a distribution from a retirement plan or life insurance policy, or a will.

*For more information, contact info@center4research.org*
Prescription Drug Abuse of Opioids: Is There a Solution?

While millions of Americans wonder what opioids are or why they are in the news so often, millions of others have learned the hard way that opioid addiction and overdose have reached epidemic proportions and are affecting all kinds of families all across the country.

In the United States, the annual number of deaths from opioid overdoses (more than 35,000) is greater than the number of deaths caused by motor vehicle accidents (almost 34,000).

How did this happen, who is to blame, and what can be done about it?

A major cause of the problem is wide-spread availability. Opioids are commonly prescribed when they are not needed. For example, many patients are prescribed OxyContin before undergoing surgical procedures in case they need it afterwards. Similarly, dentists and periodontists frequently prescribe Tylenol with codeine and other addictive painkillers in case they are needed after painful procedures.

Patients are often told to fill the prescriptions before surgery or immediately afterwards, so that the pills will be easily available if needed. Some patients start taking the drugs without waiting to see if non-addictive painkillers such as ibuprofen are sufficient. Other patients fill the prescriptions but then decide not to use them, keeping them in their medicine cabinet “just in case” or because they are not sure how to safely dispose of them. That is potentially risky, because teenagers or other family members may be curious enough to try them, or realize that they can easily sell them. Any of these scenarios can contribute to the epidemic of addiction and abuse.

Possible Solutions

In response to political pressure, the Centers for Disease Control and Prevention (CDC) issued guidelines in March for physicians, aimed at improving the use of prescription opioids for chronic pain. At the same time, the Food and Drug Administration (FDA) announced that it is now requiring a boxed warning about “the serious risks of misuse, abuse, addiction, overdose and death” on the labels of all short-acting opioid pain medications.

The CDC’s new guidelines resulted in a firestorm of criticism, with some claiming that the guidelines will make it harder for patients who need pain medications to get relief, and others that the guidelines don’t go far enough to rein in overuse and abuse. Chronic pain is a significant public health problem, with one study estimating that 11% of U.S. adults suffer from daily pain. On the other hand, annual opioid prescriptions averaged one bottle of pills for every adult in the U.S. in 2012.

A major issue is how often opioids are not more effective than other, non-addictive treatments. For many people, painkillers that are easily available for little cost from your local drug store are just as effective as opioids, and with much less risk. That’s why the CDC guidelines recommend that patients first try non-opioid options like ibuprofen or aspirin to treat pain, and only get opioids if those non-addictive painkillers don’t work. Even then, the guidelines recommend that opioid treatment for short-term pain usually be prescribed for only three days, and rarely longer than seven.

CDC Guidelines for Prescribing Opioids for Chronic Pain

- Opioids are not first-line or routine therapy for chronic pain
- Discuss risks, benefits, alternatives to opioids, and establish and measure goals for pain and function
- Use immediate-release opioids when starting, not long-acting opioids
- Start with a low dosage and go slow; for acute pain, use no more than needed
- Follow-up and re-evaluate risks: consider reducing dose, tapering off, or discontinuing
- Clinicians should review state Prescription Drug Monitoring Program data to check if patients are receiving high doses or prescriptions from other providers
- Test urine to identify prescribed substances and undisclosed use
- Do not prescribe opioids if benzodiazepines are prescribed, and vice versa
- Arrange treatment for opioid abuse or addiction if needed

In the U.S., the annual number of deaths from opioid overdoses is greater than the number of deaths caused by motor vehicle accidents.
Continued from page 1

supply and elsewhere across the country.

Flint wasn’t his first investigation. For example, in 2004, Edwards proved that corrosion in Washington D.C.’s pipes had caused dangerously high levels of lead in the city’s drinking water. He then spent 6 years challenging the accuracy of the report of Centers for Disease Control and Prevention (CDC) regarding lead in DC water. In 2010, he was vindicated when it was proven that the CDC had falsified a key scientific report, which had claimed that no one had blood lead levels elevated above the CDC level of concern.

After being contacted by LeeAnne Walters, Edwards reached out to the EPA to share his findings. But when EPA officials refused to act on a memo authored by EPA employee Miguel Del Toral, Edwards enabled Flint residents to collect and test hundreds of water samples, set up a website to update the public (www.flintwaterstudy.org), expose corruption via Freedom of Information Act (FOIA) requests, and help hold local, state, and federal governments accountable.

LeeAnne Walters and Marc Edwards continue to work together in Flint. Walters is currently a part of the Grassroot Warriors and leads her own group called Community Development Organization. Edwards now has an official role to continue his efforts to make Flint’s water safe, and Time magazine has named him one of the 100 Most Influential People.
Several of our staff are welcoming spring:
From left to right: Nisa Hussain, Laura Gottschalk, Stephanie Fox-Rawlings, Amelia Murphy, Farzana Akkas, Tracy Rupp, Paul Brown

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