

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.

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Cancer Patient Fights an Unsafe Medical Device

Dr. Amy Reed was a physician at Harvard Medical School's Beth Israel Deaconess Medical Center and the mother of six when she started to feel light-headed in April of 2013. She was treating some of the most famous patients in the country – the victims of the Boston Marathon bombs as well as the bomber himself, Dzhokhar Tsarnaev. Like any working mom, feeling less than perfectly healthy was not surprising, but as a physician, Dr. Reed suspected something was wrong.

Tests showed she had a fibroid tumor in her uterus, but a gynecological oncologist at Harvard's Brigham and Women's Hospital, Dr. Michael Muto, assured her it was just a fibroid, "clearly a benign process," not cancer. As Harvard physicians themselves, Amy and her husband, Dr. Hooman Norchashm, trusted his judgment.

The tumor was removed during a minimally invasive laparoscopic surgery in October, and a week later Amy and Hooman, a cardiac surgeon, learned that the fibroid contained cancer. The worse news was that a power morcellator, a medical device used to mince up fibroids to facilitate laparoscopic surgery, had spread the cancer throughout Amy's abdomen – thus "upstaging" it to a stage 4 cancer. Her life was now in danger.

The Brigham doctors apologized for this "rare event," but did not offer much hope.

Amy and Hooman were in shock, but they wanted to know more. The more they learned, the more they realized that this was a completely preventable tragedy. They wanted to make sure it would not happen to anyone else.

They demanded that the hospital stop using power morcellators for surgery to remove uterine fibroids, since Amy was not their first patient to get metastatic uterine cancer as a result of power morcellation. The hospital leadership refused. As Hooman tried to see what he could do to change this medical policy at Harvard and elsewhere, medical school officials told him to stop using his work email for that purpose and suggested that he might be "under stress."



Dr. Amy Reed and Dr. Hooman Norchashm are recipients of our Health Policy Hero Award

Hooman sat down with his neighbor, an editor of the *Wall Street Journal*, and explained what had happened and its implications. Then two *Wall Street Journal* reporters, Jennifer Levitz and Jon Kamp, started looking into it and wrote a series of articles. They were later recognized for these articles as Pulitzer finalists in the Public Service category.

While at Amy's bedside after she underwent surgery in Washington, D.C. in hopes of killing the cancer cells, Hooman started reaching out

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We're in the Headlines!

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Bill to Speed Approvals to Drugs Is Cut Back

The New York Times
May 1, 2015

Candidate to Lead FDA Has Close Ties to Big Pharma

Time
Feb. 19, 2015

Congress Is Up to Something

The Huffington Post
Jan. 9, 2015

Specialists Split Over HPV Test's Role in Cancer Screening

NPR
Jan. 8, 2015

Letter to the Editor: Keep the Medical Device Tax

ABC15 Essure Investigation: Is Essure birth control safe?

ABC15
Feb. 25, 2015

The New York Times
Feb. 13, 2015

A medical device used to diagnose and treat cancer and other conditions was responsible for spreading a drug-resistant bacterial superbug. In the **LA Times**, **Medical Express**, **CNN** and **CBS**, NCHR President Diana Zuckerman questioned why the FDA allowed an unapproved medical device that can't be adequately cleaned to be used in hospitals.

The FDA never approved a medical device used in knee replacements that has harmed many patients. NCHR president told the **New York Times** that the FDA needs to improve its surveillance to keep patients safer.

Our Government Relations Manager Paul Brown published a **Letter to the Editor** in the **New York Times** supporting their editorial in favor of the medical device tax: "Repealing the tax is indeed 'a terrible idea' that solves a nonexistent problem. It could result in cutting health care programs that patients rely on."

On the same topic, Dr. Zuckerman wrote an article in the **Huffington Post** and **Rodale.com** that advised "If you think Americans deserve good health care and successful companies should pay taxes," let Congress know. See our report on www.center4research.org showing the success of device companies since the tax went into effect.

Two medical groups want to replace Pap smears with HPV tests to screen for cervical cancer, but other medical groups disagree. NCHR president told **NPR**, **Vox**, **Contra Costa Times**, and other media that "so many women get HPV who will never, ever get cancer." She cautioned that using HPV tests would increase the number of unneeded, expensive and possibly harmful follow-up tests.

The company that makes **Essure** permanent birth control says it is 99.8% effective and very safe, but hundreds of patients say otherwise. "When you see data that looks so great and you talk to women who have used the product whose experience is completely different, you have to question the studies," Dr. Zuckerman told **ABC15** and **WJLA**.

When FDA commissioner Margaret Hamburg announced her resignation, Dr. Zuckerman told the **Wall Street Journal**, "Dr. Hamburg has been a strong voice for public health and this is a major loss at a dangerous time for the FDA." She told **Time** that a candidate with close ties to pharmaceutical companies "should be of great concern."

Several pharmaceutical companies have announced they would make their clinical trial data available to outside researchers. Dr. Zuckerman told the **New York Times**, **Wall Street Journal**, **Modern Healthcare**, and other media that we're enthusiastic but "the devil is in the details." What will they actually make available, and to whom?

Understanding the Debate on Campus Rape

Have you ever wondered what it would be like for the President of the United States to quote your research and then talk about the need to respond with new policies to help women across the country? As some researchers have learned, turning research into action is exciting, but it also presents challenges.

When he first published a study of sexual assaults on college campuses in 2009, Chris Krebs never dreamed it would be widely quoted by President Obama and others, and become a flash point in the debate about how to reduce violence against college women.

“We conducted a study at two large public universities and never claimed that it was representative of all colleges in the U.S.,” Dr. Krebs tells us. But, studies at colleges and universities across the country have shown similar statistics, supporting the finding that “1 in 5 women are sexually assaulted during their college years.”

Critics have pointed out that the definition of sexual assault includes unwanted kissing and sexual touching, and there is a debate about whether those are serious or just “boys will be boys” behaviors. But the statistics speak for themselves: most of the women who reported experiencing unwanted or “nonconsensual” sexual contact in an anonymous survey experienced rape—oral, vaginal, or anal penetration—not just other types of unwanted touching.

“Whether the most accurate statistics of rape are 1 in 5 or 1 in 7, or even if they were 1 in 20, campus rape and other types of sexual assault are a huge problem.”

How many women out of the over 5,000 who participated in Dr. Krebs much discussed study were raped? **About 1 in 7 (15%) seniors reported being raped since entering college.** These rapes happened because the women were physically forced or threatened, or because they were “incapacitated” and unable to give consent. The two large public universities where this survey was done were in the Midwest and the South, so these findings do not necessarily represent a national average. But a 2004 study by Harvard faculty at 119 colleges nationwide found a somewhat similar statistic: **1 in 20 of the 24,000 women who responded had been raped during that school year** (in the previous seven months). Over the course of 4 years, that would



likely be similar to 1 in 7, since the likelihood of getting raped tends to be higher for younger college women.

Dr. Krebs first became interested in studying campus sexual assault a decade ago when two students in his class privately told him that they had been in the ER after having been given date rape drugs. “I was surprised to hear this from two women, especially in one semester, so I looked to see what research had been done. I saw there were no data, so I applied to the National Institute of Justice to get a grant to look at the bigger picture.”

The White House Calls

The White House didn’t just quote Dr. Krebs’s research – White House staff talked to him to make sure they understood how the study was done and how it should be interpreted. “We all realize that more research is needed,” he tells us. “I’m in the process of working on a larger study funded by the Office of Violence Against Women and the Bureau of Justice Statistics, but the first step is to make sure that we are asking the right questions, and asking them in the right way. We want to make sure that the data we collect are valid and that the students are as representative as possible. So, we’re going to be surveying about 20,000 undergraduates (12,000 women and 8,000 men) at 10 schools that differ in terms of size and geography, whether they are public or private, and 2-year or 4-year schools.”

“Whether the most accurate statistics of rape are 1 in 5 or 1 in 7, or even if they were 1 in 20, campus rape and other types of sexual assault are a huge problem,” says NCHR’s Brandel France de Bravo. The colleges have not done a good job of preventing it or ensuring justice for the students involved. The media likes to focus on individual victims, but their “he said/she said journalism” is missing the point. That has to change. ♦

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Profiles

Interns and Senior Fellows Make the Difference!

Ever wonder how our small organization accomplishes so much? Over the years, we've had some of the best interns and fellows in the country! Let us (humbly, of course) brag here about some—all now members of our Young Professionals Advisory Committee.

Leaving a Legacy: Internships and fellowships provide training that can result in a lifetime of good work. If you're interested in funding one in someone's name—to honor them, their memory, or their work—contact Diana at dz@center4research.org.

Or, if you just want to send your tax-deductible contribution to us to create a named internship (or fellowship position for a young professional), let us know if there's a particular health issue you want the intern to focus on!

Jessica Cote



Ros Brannigan Intern, 2012.
B.S. Neuroscience, Trinity College, Hartford, CT

Where I am now: I am currently pursuing a PhD in Neuroscience at the University of Michigan in Ann Arbor.

What I'm doing: I am designing experiments to answer questions about our metabolism and how it

relates to fertility. Are there "energy sensors" in the brain that sense changes in fat and energy and ultimately lead to changes in fertility? In the coming months, I plan to team up with other scientists and journalists at the University of Michigan to organize writing workshops for undergraduate and graduate student scientists. The goal of the workshops is to enhance scientific communication skills, especially in dialogue with policy groups and fields outside of research science.

I'm excited to report that I was awarded a Graduate Research Fellowship from the National Science Foundation in March. The grant will fully fund my dissertation research for three years and greatly expand my research and teaching opportunities.

What I gained from my internship: The skills and ideas that I developed while interning at NCHR greatly bolstered my fellowship application to the National Science Foundation. As I work toward my graduate degree, I see the immense value in the communication skills I learned at NCHR. Nearly every day I use the techniques I learned at NCHR to articulate complex concepts in simple ways—in grant applications, research articles and presentations.

"I use the techniques I learned at NCHR to articulate complex concepts in simple ways—in grant applications, research articles and presentations."

Stephanie Portes-Antoine



Joy Simonson Intern, 2009.
MD, Boston University School of Medicine, MPH, Boston University School of Public Health

Where I am now: I am an Internal Medicine Resident at Mount Auburn Hospital Cambridge, MA

What I'm doing: This past year, I completed a proposal addressed to the Haitian Ministry of Health on eliminating malaria and

stopping drug resistance in Haiti.

What I gained from my internship: NCHR gave me my first glance into healthcare policy. As a physician in training, we tend to focus on the individual and the disease, but it is just as important to focus on population medicine, and how policy can either positively or negatively affect my medical practice.

Aaron Litz



Intern in 2013. B.S. Behavioral and Community Health, University of Maryland, College Park, MD

Where I am now: Engagement & Retention Coordinator with BUILD Metro DC, Washington, DC

What I'm doing: I am working for BUILD to help high school students start their own

businesses. The Parent Connect Team is an initiative I started this year to strengthen the communication between all of our parents, since family engagement is crucial to student attendance, enjoyment, and success.

What I gained from my internship: Exposure to social media management, data analysis, and coalition building at NCHR helped me feel confident in my next steps.

Megan Cole



Intern in 2010. MPH, Health Policy and Administration, Yale University, New Haven, CT

Where I am now: PhD Candidate in Health Services Research and Policy at Brown University; Research Fellow at Brown and consultant at the Lewin Group.

What I'm doing: For one of my current projects, I am looking at

how a state's decision to expand or not to expand Medicaid affects health centers.

What I gained from my internship: At NCHR, I learned how to better translate research into accessible language and to always question the strength and objectivity of evidence when evaluating health research, which has helped to make me a better health policy researcher.

Laura Covarrubias



Marcy Gross Intern, 2012. MSPH, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD

Where I am now: Health Education Specialist, The University of Texas MD Anderson Cancer Center, Houston, TX

What I'm doing: Currently I am working on creating a decision aid for women whose cancer

treatments may affect their fertility and who might want to pursue fertility preservation. In my work I have to communicate with patients from a wide variety of backgrounds, and this means that I often have to change the way I write or speak to communicate technical health information most effectively.

What I gained from my internship: Interning with NCHR gave me many opportunities to strengthen my communications skills, particularly writing articles for the websites.

Jennifer Wernimont



Intern in 2014. B.S. Health Communication, B.A. Dance, James Madison University, Harrisonburg, VA

Where I am now: I'm a Project Manager in Implementation Services at Epic Systems Corporation, Madison, Wisconsin

What I'm doing: Epic is an electronic health record company

that makes software for medical groups, hospitals, and integrated healthcare organizations, and we try to understand how the software can enhance their processes. I'm currently working with Greenville Health System in South Carolina to implement an Epic Health Information Management product. Internally, I coordinate the creation of system workflow materials and the training of Epic end-users.

What I gained from my internship: While working with NCHR, I was encouraged to seek out events that interested me and enhanced my experience, including conferences, roundtables, and other health nonprofit meetings. This has served me well at Epic because I've approached my new position with the same "seeking attitude."

Jen Yttri



Senior Fellow, 2012-2013. PhD in Immunology, Washington University in St Louis

Where I am now: Science & Technology Policy Fellow, American Association for the Advancement of Science (AAAS)

What I'm doing: As a AAAS fellow, I am helping to manage a grant program at the National

Science Foundation (Arlington, VA) that supports research on health information technology—the novel computer science and engineering ideas that are transforming healthcare today. I have spent the past year recruiting new scientists, designing workshops to support new collaborations, writing articles on the future of health IT and the research NSF is funding, and helping scientists better describe how their research benefits the general public. In addition to these day-to-day goals, I spent 4 months at the Department of Commerce in the Office of Health and Information Technology writing a report on international commercial opportunities for US health information technology companies.

What I gained from my fellowship: I got my first foray into the world of health policy while a Senior Fellow at NCHR. In fact, I was selected for an AAAS Science and Technology Policy Fellowship partly based on my experience there, where I helped with sign-on letters to legislators and health agencies on behalf of NCHR or the Patient, Consumer, and Public Health Coalition (NCHR plays a leading role in the Coalition), and met with Senate and Congressional staff on a variety of health issues, including problems with compounding pharmacies. My work with NCHR gave me the confidence to draft Federal strategies on Health Information Technology as I'm doing now. And it was thanks to my work with NCHR on safe and effective antibiotics that I became interested in health information technology, the policies around sharing health information, and how this technology can be used for research and improved drug development. Now I'm turning that interest into a career! ♦

Will 20th Century Patient Safeguards be Reversed in the 21st?

Most physicians and patients assume that the medications they take and prescribe are proven both safe and effective. Those standards from the U.S. Food and Drug Administration (FDA) were born out of a series of 20th century tragedies that included the deaths of 107 Americans in 1937 from an elixir containing a chemical used in antifreeze, and 10,000 babies born worldwide with deformities in 1961 because their pregnant mothers took thalidomide for morning sickness. Thanks to the first woman scientist of FDA, Frances Oldham Kelsey, thalidomide was never approved in the U.S. By 1962 it was banned from sale in nearly every country where it had been in use. The thalidomide tragedy resulted in stronger laws in the U.S. to protect patients against unsafe and ineffective treatments.

The first effective challenge to those laws and to the FDA's growing authority came in the 1980s, as people with AIDS faced certain death and demanded that the FDA's drug approval process be more responsive to their needs. AIDS activists pressed for faster drug approval and for making experimental therapies widely available, and their successes helped shape FDA reforms.

AIDS activists soon realized, however, that speeding up the approval process had risks as well as benefits. The first generation of AIDS drugs (AZT) was found to have no long-term benefits. Fortunately, a newer generation of AIDS drugs, protease inhibitors, were used in combination with the older medicines, and this resulted in dramatic reductions in illness and death.

Patient Safeguards Start to Erode

Starting in the early 1990s, drug industry lobbyists sought to further weaken FDA standards, often citing the legacy of AIDS activists. Gregg Gonsalves, who has been HIV-positive for 20 years, worked with others to oppose those efforts, but Congress responded to industry pressure by gradually eroding drug approval and safeguards for patients. They voted to reduce the number of studies required to get new drugs on the market from at least two to only one, and to make it easier for drugs to be approved on the basis of very preliminary data.

This erosion has continued in the 21st century. The FDA now offers four pathways to speed the approval process for many

drugs and biologics as well as an easier approval pathway for drugs for orphan diseases (defined as affecting fewer than 200,000 patients in the U.S.). The lower standards for most drugs approved through expedited pathways include smaller and shorter term studies. One study found that new drugs

approved through these faster pathways were tested on an average of about 100 patients, compared with almost 600 for standard FDA approvals.

As a result, patients today are relying on many new medications that are not clearly proven to be safe or effective. Although additional research is often required after approval, it takes an average of 11 years after a drug is on the market for the FDA to finalize new warnings, rescind approval, or require new risk information or contraindications be made public.

Medical devices are allowed to be sold based on even weaker standards. Only 1% of devices are reviewed through a process that requires clinical trials. With those lower standards, 90% of the thousands of new medical devices are cleared by the FDA for market within 90 days. Even so, FDA has responded to political pressure by proposing a new, faster approval process for devices.



Frances Oldham Kelsey, FDA scientist who refused to approve thalidomide, a medication that caused birth deformities, during the Kennedy Administration

21st Century Cures Vs. Safety

Congressional efforts to reverse patient safeguards continue. In April, members of the House health committee introduced draft legislation called *21st Century Cures* which would dismantle some major components of the drug approval process that have been in place for the last 50 years. "Supporters of those sections of the proposed law are ignoring the fact that all patients need better and more complete answers about the drugs and devices they put in their bodies, not just access to new ones," explains NCHR government relations manager Paul Brown.

We are working closely with other public health think tanks, consumer groups, and AIDS organizations to educate members of Congress about the riskiest elements of the legislation. As Gregg Gonsalves, now co-director of Yale University's Global Health Justice Partnership, tells us, "We need to reject any legislative proposals that would leave an FDA that looks more like the one in the mid-20th century, not one worthy of the 21st."



Letters to Annie

If you like crime stories and want to make sure that the medications you take are safe, you will want to check out our new blog serial, "Letters to Annie," which investigates the sudden, unexplained death of a vibrant and healthy young woman. In the form of letters written to Annie by her mother after Annie's mysterious death, the story of what happened to Annie is gradually revealed.

Annie died suddenly in her sleep, and as a result of Letters to Annie, thousands of young women and their parents across the country will want to know why.

Our goal is to make sure that what happened to Annie doesn't happen to anyone else. You can help by spreading the word about the website (www.letterstoannie.org), the Letters to Annie Facebook page, and the @NC4HR twitter account. And you can enjoy an original song that her friends wrote just for her. Visit. Look. Listen. If you want to take action or contribute in any way, contact us at info@LetterstoAnnie.org



Cancer Patient Fights an Unsafe Medical Device

Continued from page 1

to the medical community via email. He assumed that the OB/GYNs who treat uterine fibroids would want to stop the use of morcellators. "I got nowhere with them," Hooman tells us. "And the more vocal I became, the more they treated me as if I'd gone off the deep end. Ultimately, the Brigham administration tried to demote me, and I was shut out of cardiac surgery for a few months."

Even as Brigham officials admitted that the chance of morcellators spreading cancer was close to 1 in 400 instead of the official estimate of 1 in 10,000, they continued to resist changing their policies.

"The hospital was covered with banners saying 'First do no harm,'" Hooman explains. "That was what really got to me. And then I heard from a man whose wife had just died of a morcellated uterine cancer, and realized that another patient at the same hospital had the same experience as Amy a year earlier, and yet the hospital had done nothing to warn patients."

Asking the Right Questions

The couple began to wonder why this medical device was approved by the FDA. They learned that it was not required to be studied in clinical trials – a loophole called the 510(k) review that is used for 95% of medical devices. They also learned that despite laws requiring hospitals to report serious complications from medical devices, no morcellation reports had been made to the FDA prior to the one that Hooman (not the hospital) made to the FDA in December 2013.

The FDA responded to Hooman's efforts by putting out a strongly worded warning about using morcellation devices for uterine fibroids, but did not ban them. The media

responded by covering the story. Many in the medical community and several morcellator manufacturers responded by defending the devices.

Fortunately, several hospitals and insurance companies changed their policies to provide much better warnings to patients about power morcellators and/or to restrict their use for most patients.

In January 2015, Amy was well enough to start her new job at the Hospital of the University of Pennsylvania. But a month later, a recurrence of the cancer was diagnosed. She had surgery to remove a metastatic tumor from her lumbar spine, and underwent radiation treatment.

Hooman and Amy are now studying her tumor in the laboratory in hopes of finding a cure. Meanwhile, they are trying to change the way devices are approved by the FDA.

Amy Reed is optimistic. She credits her husband for his tenacity in the face of opposition at the Brigham. "Although we did not get morcellators off the market, every OB/GYN will now think twice before using them, and patients will get some justice if physicians use them without very clear informed consent. I'm thankful that we've won that war, and stopped most of these tragedies from happening."

She is hopeful that their continued efforts will be successful as they point out the enormous weaknesses in the FDA's review of most devices. "I think we're being heard. We're up against a big force – industry. At an FDA meeting we attended in April, the entire focus was on FDA working more closely with industry. I disagree. Patient safety should be first and foremost for the FDA." ♦

Hooman and Amy were honored as Health Policy Heroes at NCHR's awards luncheon in May 2015.

National Center for Health Research

Cancer Prevention and Treatment Fund (our largest program)

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Inside the issue:

*Who is this former Foremother, and
why is she important today?*

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