Take Action Now
Urge Congress to #RaisetheCaps for FY18.
Learn more on page 8.

Research Institutions Provide Support in Wake of Hurricane Harvey

For every tragedy, communities come together to aid those in need. Many research institutions and health organizations are in full response mode as they offer resources to those affected by the storm.

The American Diabetes Association, JDRF and Insulin for Life have shipped more than 3,750 pounds of donated diabetes supplies to people with diabetes affected by the hurricane.

Georges Benjamin, M.D., executive director, American Public Health Association and Research!America board member has encouraged health centers to use the National Academies of Science and Medicine report, Strengthening the Disaster Resilience of the Academic Biomedical Research Community, as a road map for recovery and future planning.

Academic institutions, such as Baylor University, the University of Texas Health Science Center, Louisiana State University, and the University of Alabama at Birmingham are reaching out to affected students and providing links to resources on their websites.

The National Medical Association is coordinating donations, in-kind services, and relocation job opportunities. Healthcare Ready, a non-profit created by PhRMA to ensure health care access during times of disaster has activated RxOpen map, a free interactive map showing open and closed pharmacies in affected regions.

Experts and Agency Heads will Discuss a World Without Disease

Major health threats ranging from the opioid epidemic to Alzheimer’s disease are impacting the pace of medical progress. How can we overcome these challenges to achieve a longer, healthier lifespan? Research!America’s National Health Research Forum will focus on potential solutions in panel discussions Thursday, September 7, 11:00 a.m. – 3:00 p.m. ET, at the Newseum in Washington, D.C. Experts representing academia, patient groups, government, industry and scientific societies will discuss what it will take to make dramatic strides against deadly and debilitating health threats.

Mikael Dolsten, M.D., Ph.D., president of worldwide research & development, Pfizer, will provide keynote remarks. Scott Gottlieb, M.D., commissioner of the Food and Drug Administration, will discuss the agency’s current priorities to advance research and innovation.

The first panel, moderated by Marilyn Serafini, health care policy consultant and former award-winning journalist, will explore the role of research in understanding and addressing the opioid epidemic and other community health threats. Panelists include Governor Charlie Baker (R-MA); Seth Ginsberg, co-founder and president, Global Healthy Living Foundation; The Hon. Patrick Kennedy, U.S. Representative, 1995-2011; Gopal Khanna, director, Agency for Healthcare Research and Quality; Lucinda Maine, Ph.D., R.Ph., executive vice president and CEO, American Association of Colleges of Pharmacy; and Anne Schuchat, M.D., principal deputy director, Centers for Disease Control and Prevention.

VIsta us on the web
www.researchamerica.org
Hurricane Harvey has proven to be a major game changer. First and foremost, for the lives and property lost and damaged in Texas and beyond. The outpouring of assistance, from national, state and local government entities to individual acts of kindness and bravery, is nothing short of inspirational. As recovery moves into the next stages, health risks will be more and more apparent. CDC and NIH, local institutions and their national and international support networks are at the ready; indeed they are already at work. We at Research!America are proud to be advocates for the research and researchers who make prevention, early intervention and delivery of treatment life-saving and cost-effective.

There is another way that Hurricane Harvey is a game changer, and that’s here in Washington, as it influences decision-makers’ agenda this month. Bipartisan support for recovery in Houston is a given; this spirit is likely to extend to challenges that too often have seemed intractable, including those that directly impact the conduct of research in both the public and private sector. That’s a reason for optimism, but not a reason for complacency. September is crunch time for all the stakeholders in research for health to speak up as part of our campaign to #RaisetheCaps to assure that bipartisan congressional support for science has every chance to succeed. Read more on this and other topics elsewhere in this newsletter.
Federal Policy Update

As members of Congress return to D.C. this month, they face formidable budget challenges. There are only 12 days in September when both chambers are in session; yet, by September 30, 2017 they must: 1) pass and secure the president's signature on an FY18 budget bill; 2) increase the debt limit; and 3) potentially pass supplemental spending to assist Texas in the wake of Hurricane Harvey. Congress will also be under significant pressure to stabilize the individual insurance market by shoring up the Affordable Care Act. It is likely that Congress will limit its consideration of ACA-related matters to this aspect of reform, and will not address repeal of the medical device tax in September.

One of the first items on the Senate Appropriations agenda is marking up the FY18 LHHS bill. One troubling rumor is that the Senate bill may not only include restrictions on fetal tissue research, similar to the House bill, but that it will also place new restrictions on embryonic stem cell research.

The House plans to unveil a 12-bill omnibus when they return in early September that incorporates the four-bill, security-focused minibus that passed the House in July, along with the other eight appropriations bills that have passed their respective appropriations subcommittees. However, it is unlikely that the House and Senate will coalesce around a final FY18 spending package by September 30. The most likely budget scenario is that Congress will pass a short-term Continuing Resolution temporarily sustaining FY17 funding levels.

It remains critically important to make the case for a bipartisan budget deal that raises FY18 “sequestration” caps on discretionary spending. On August 30, Research!America hosted an alliance members call to set the stage for a two-day digital #RaiseTheCaps initiative on September 11 and 12.

Research!America also hosted an in-person alliance members meeting on August 29 with Majority and Minority staff of the Senate HELP Committee. The Committee staffers shared their FDA and NIH priorities for the remainder of 2017 and fielded questions about 21st Century Cures implementation, indirect costs, a standing fund for public health emergencies, hearings on the topic of drug pricing, the possibility of a hearing exploring AHRQ’s role in advancing health and health care, and other salient issues.
**Scientists as Effective Global Health Advocates**

“The public wants to hear from you,” Mary Woolley, CEO and president of Research!America, explained during a videoconference on August 28 with student advocates at the University of California Global Health Institute.

“The best way to connect with someone is through the heart, not the mind,” she said, encouraging students to share their story, not just their data with the public and policymakers. Researchers and lawmakers can find common ground on global health issues, she noted. “Our troops are at risk all around the world, including from diseases that aren’t endemic to the U.S. Everyone benefits from research to eliminate those disease threats.”

Using advocacy tools, Woolley said scientists can connect with lawmakers and their communities, through writing op-eds, hosting community engagement events, and publically acknowledging the congressional champions who have fought to increase funds for research and preserve the work of the Fogarty International Center. “The most important four words a researcher can say to the public: I work for you,” she concluded.


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**Public Perception of Clinical Trials Appears to Shift Favorably**

More Americans say they would ‘very likely’ participate in a clinical trial if recommended by a doctor, an 11% increase from 2013, according to a new national public opinion survey commissioned by Research!America; and 46% say they admire people who volunteer for clinical trials ‘a great deal’, a 9% increase.

“The research community is committed to conducting safe, ethical, and high-quality clinical trials and we are gratified that the public’s perception of clinical trials has moved in a positive direction,” said Doug Peddicord, executive director of the Association of Clinical Research Organizations (ACRO).

An overwhelming majority of respondents (86%) say discussions about clinical trials should be a part of standard of care even as participation rates remain low. While 80% of respondents say they have heard of a clinical trial, only 18% say they or someone in their family has ever participated in one.

More than half (55%) of Americans say individuals do not participate because of lack of awareness and information. In fact, only 19% say their doctor or other health care professional has ever talked to them about medical research.

“Development of incentives to drive more discussions between patients and health care professionals about the importance of participating in trials could encourage both ill and healthy individuals to view this as a routine health behavior,” said Mary Woolley, President and CEO of Research!America.

Many Americans are also embracing technology for data sharing. A majority (72%) say they are likely to use technology such as apps, phones and monitoring devices to share their personal health data for clinical research; and nearly half (47%) say they like having clinical trial information/data/results delivered through their phone.


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**Federal Research Budget**

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<th>FY16</th>
<th>FY17 Omnibus</th>
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* indicates that budget level is reported in this chart
** indicates that budget authority is reported in this chart
Sequestration Budget Caps

Research!America President and CEO Mary Woolley said the Budget Control Act of 2011 has a damaging effect on the nation’s scientific enterprise in a letter-to-the-editor in The Wall Street Journal. “Under the arbitrary rules of that bill, federal research agencies like the National Institutes of Health are severely underpowered.”

Opioid Crisis

Research!America board member Harold L. Paz, M.D., M.S., EVP and CMO, Aetna, was quoted in a WFPL (NPR) article about Aetna’s naloxone donation to first responder agencies in Kentucky to curb opioid-related deaths in the state.

Health Disparities

In a Modern Healthcare article, Research!America board member Georges Benjamin, M.D., executive director of the American Public Health Association, discussed the stress-induced health effects caused by racial discrimination, urging clinicians to help alleviate social inequities that have contributed to disparities in health outcomes. “You can call for your medical society to support things that you know will improve the health of the population in which you serve.”

Mental Health

In a Business Insider article, Research!America board member Herbert Pardes, M.D., executive vice chairman, Board of Trustees, NewYork-Presbyterian Hospital, commended Doctors Without Borders/Médecins Sans Frontières for providing mental health services and humanitarian efforts for people living in volatile areas around the world.

Federal Funding for Science

Research!America’s Vice President of Communications Suzanne Ffolkes was quoted in a Bloomberg BNA article regarding the need for increased federal funding to support science priorities outlined by the White House.

Science and Society

Research!America board member Rush D. Holt, Ph.D., CEO, American Association for the Advancement of Science (AAAS), was quoted in the Laboratory Equipment magazine about the Administration’s decision to disband the Federal Advisory Committee for the Sustained National Climate Assessment. “The capacity to understand and effectively address important policy issues depends on access to relevant scientific and technical expertise.”

Clinical Trials

In a Clinical Leader article, Research!America board member Sudip Parikh, Ph.D., senior vice president and managing director of DIA Americas, highlighted trends in clinical trials. “As a whole, remarkable progress is being made in all parts of our ecosystem.”

Medicaid

In an Associated Press article, Research!America board member Mark McClellan, M.D., Ph.D., director, Duke-Robert J. Margolis, MD, Center for Health Policy, Duke University, discussed the implications of an overhaul of Medicaid.

IN BRIEF

• Research!America board member and APHA Executive Director Georges Benjamin, M.D., received the National Medical Association Meritorious Service Award


• The National Academies will convene leaders of business and industry, federal and state government, and other sectors for “Revitalizing the University-Industry-Government Partnership” on November 15.


• Modern Healthcare named the “100 Most Influential People in Healthcare,” including Research!America board members James Madara, M.D., and Georges C. Benjamin, M.D.

http://bit.ly/2wTHOMA

• FasterCures will be hosting Partnering for Cures in San Francisco, CA on November 14, bringing together 250 innovators from across medical research.

http://bit.ly/2eI8UR1

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First In Human Documentary Highlights Bench to Bedside Patient Care

The National Institutes of Health (NIH) Clinical Center has opened its doors to give the public unprecedented access to ongoing research for the three-part documentary, First in Human, aired on the Discovery Channel throughout August.

Known as Building 10, the nation's largest dedicated clinical research hospital has treated over half a million patients. The series provides an in-depth look into clinical trials taking place inside the Bethesda, MD, campus, trials that not only inform science but provide hope to families with loved ones suffering from terminal illnesses.

Narrated by actor Jim Parsons, First in Human has highlighted what "bench-to-beside" research is capable of achieving for patients with complex diseases.

"The NIH Clinical Center's more than 60-year history has resulted in remarkable medical advances, from the first use of chemotherapy to treat cancer, to the development of the technique to keep the blood supply clean and safe from viruses," NIH Director Francis S. Collins, M.D., Ph.D., said in a press release. "For millions of patients around the world, it is known as the National Institutes of Hope."

For more information, visit http://bit.ly/2gq44LG.

Research in the Public Context

Serving the public interest is a shared responsibility between policymakers and scientists, said Mary Woolley, CEO and president of Research!America during a forum at the Stanley Manne Children's Research Institute. Experts gathered August 10 in Chicago to discuss a broad range of topics on the current state of medical research including emerging trends and generational differences between scientists, public-private partnerships, and harnessing the power of technology for health care informatics.

Woolley discussed the research enterprise in the context of policy decisions, highlighting the necessity of scientists and advocates for scientists to speak up for their research to the public and policymakers to ensure robust support for medical research.

Other panelists included Alan Schwartz M.D. Ph.D., professor of pediatrics at Washington University School of Medicine; Jeffrey Sherman M.D., FACP, chief medical officer and executive vice president of Horizon Pharma; and Robert Schmit, customer engineer at Google Cloud. "As we think about our transformative imperative of advancing pediatric medicine and research, this is the context in which [we] are trying to move forward in," said Thomas Shanley M.D., chief research officer of the Manne Children's Institute.

Safeguarding Biomedical Research Facilities from Natural Disasters and Attacks

Many biomedical research facilities are ill-equipped to withstand natural disasters, such as Hurricane Harvey, putting years of research and millions of dollars at risk, according to a recent report by the National Academies of Sciences, Engineering, and Medicine.

The exact scope of Harvey's damage remains unclear, but past disasters indicate that it could be far-reaching. In 2012, Hurricane Sandy destroyed more than $20 million worth of scientific equipment at New York University's Langone Medical Center, according to Nature, and Tropical Storm Allison caused such severe damage to the University of Texas Health Science Center at Houston that some were forced to restart their research from scratch.

In the report, Strengthening the Disaster Resilience of the Academic Biomedical Research Community: Protecting the Nation's Investment, the National Academies urges institutions to put in place comprehensive and integrative disaster resilience plans; create partnerships with local, state, and national emergency organizations; and implement mandatory disaster resilience education and training programs. To learn more, visit http://bit.ly/2wFUVpa.

Congressional Visits to Research Facilities During August Recess

Several congressional champions for research toured research facilities in their districts during the August congressional recess to reinforce the importance of robust federal support for research. Senator Roy Blunt (R-MO) met with researchers at Washington University School of Medicine in St. Louis on August 8 to discuss efforts to increase funding for medical research.

"Exciting health research is being done right here in Missouri at Washington University in St. Louis," Senator Blunt shared in a Facebook post. "I have visited campus with National Center for Advancing Translational Sciences Director Dr. Austin to discuss the impact federal investment is having on the groundbreaking research that's underway in our state."

Representative James McGovern (D-MA) visited University of Massachusetts Medical School officials in Worcester on August 16 and called proposed budget cuts to the National Institutes of Health (NIH) "a threat to this city's and this state's ability to thrive in the face of global competition." Rep. McGovern highlighted the fact that Massachusetts ranks first in per-capita research funding from the NIH.

In Gainesville, Florida, Representative Ted Yoho (R-FL) toured the University of Florida Health Cancer Center on August 3. "Our purpose is to find out about the research and development that they're doing," he said. "These guys are on the cutting edge." Rep. Yoho toured labs and spoke with researchers who conduct clinical trials for difficult to treat cancers.
As a global biopharmaceutical research company, UCB is committed to making an impact on the lives of patients and those who care for them, particularly in the areas of neurology, immunology, and bone. UCB is inspired by patients and driven by science. At UCB, everything starts with a simple question: “how will this deliver value to patients living with severe diseases?” The world’s fifth largest biopharmaceutical company, UCB has two sites in the U.S. – a U.S. corporate headquarters in Atlanta, Georgia and clinical development in Research Triangle Park in North Carolina.

As a global biopharmaceutical research company committed to delivering value to patients, research and innovation are critical to UCB’s success. To do this, UCB engages with patients, their families, and health care professionals.

“We listen and we work collaboratively to address patients’ unmet needs,” said Patty Fritz, vice president, corporate affairs at UCB. “At UCB we want to enhance our understanding of disease and the real-life experiences of patients so our teams can deliver the right medicine and the right care to the right patient at the right time.”

UCB has more than 7,000 employees around the world working to deliver value to patients. As a company, UCB invests more than a quarter of its revenue back into research and development.

For UCB, creating value for patients means finding unique outcomes that help patients achieve their goals. To do this, and support patients and caregivers on their journey to have the best individual experience, their aim is to address outcomes that matter to people where UCB’s medicines are likely to be most effective. UCB is continuously working to advance science and embrace new knowledge, leveraging scientific advances and skills in areas such as genetics, biomarkers, and human biology.

Recognizing there is no such thing as an average patient, UCB uses all the tools, channels, and scientific and technological advances available to develop a better understanding of the expressions of disease and embed the real needs of specific patient populations in the science and innovation process. UCB’s unique patient value model starts with patient needs to inform scientific discovery to develop innovative solutions to deliver to patients.

Open innovation is a key component of UCB’s success. By engaging through a model of open innovation, sharing knowledge among experts, they can more rapidly grow scientific understanding.

As one example, UCB is partnering with scientists and leading universities, including Harvard, Baylor, and Cornell, to uncover the therapeutic tools needed to create new medicines. Instead of one-off partnerships that end, these are ongoing collaborations for the long haul with the original investigators.

“To be successful, partnership and collaboration are critical. Our scientists collaborate with leading researchers from academia and industry to advance science,” Fritz continued. She reiterated the importance of working together across the private and public sectors to have the greatest impact for patients. Fritz concluded, “That’s why organizations like Research!America championing the importance of research in the health care ecosystem and the development and delivery of new medicines for patients is so important. We are proud to support Research!America’s work advocating for and advancing health research.”

For more information, visit www.ucb-usa.com.

Clinical Trial Participation is as Valuable as Giving Blood

Please tell me if you agree with the following statement — Taking part in clinical trials is as valuable to our health care system as giving blood.

- 4% Strongly disagree
- 19% Somewhat disagree
- 27% Not sure
- 11% Somewhat agree
- 9% Strongly agree

Source: A Research!America survey of U.S. adults conducted in partnership with Synovia Analytics in July 2017. Due to rounding, the total may not add to 100.

Patty Fritz

UCB

• Founded: 1928
• Location: Atlanta, Georgia
• Mission: Delivering value to patients.
Urge Congress to #RaisetheCaps

As Congress begins to negotiate the federal budget for fiscal year 2018 (FY18), the austerity level “sequestration” budget caps established under the 2011 Budget Control Act are once again in force after a partial, two year reprieve. Unless Congress negotiates another agreement to lift these draconian caps, the FY18 budget for non-defense agencies and programs will be constrained to a level even lower than in FY17. Under that kind of stifling spending limit, Congress simply cannot fulfill its responsibility for advancing the health and wellbeing of the American people, including continuing to rebuild the long-neglected budget of the NIH, equipping the CDC to combat deadly infectious health threats and ensuring our other health and research agencies meet their respective missions.