Experts Discuss Societal Burden of Migraine Research at Congressional Briefing

Removing the stigma of migraine and encouraging more scientists to research the condition could help advance the treatment and prevention of migraine. Experts across the research and public health spectrum discussed potential solutions at a congressional briefing hosted by Research!America titled “The Value of Research and Prevention in Addressing the Societal Burden of Migraine” on June 15. The briefing focused on interventions and the necessity of research for a disease that is severely underfunded relative to its burden on society.

Walter Koroshetz, M.D., director of the National Institute of Neurological Disorders and Stroke (NINDS) emphasized that there have been developments in effective treatments to combat migraine, but “we still don’t have a really good sense of what causes the migraine,” he added.

Migraine sufferers miss twice as many workdays as those who do not suffer from migraines, said Brian Gifford, Ph.D., director of research and measurement, Integrated Benefit Institute. He discussed the implications of workforce productivity of migraine sufferers. “If [employers] are able to help people manage their conditions better…they really can have a business advantage,” he noted.

Innovation Intersection – Advances in Clinical Research

New technologies will challenge the current drug development paradigm, and regulations will have to innovate and keep pace. Such innovation will require support from Congress and federal funding, said Research!America board member Sudip Parikh, Ph.D., senior vice president and managing director of DIA Americas, at the congressional briefing “Innovation Intersection” hosted by Research!America on June 12, 2017.

Parikh joined experts in basic science, clinical and translational research, and patient advocacy who also discussed innovations that are improving clinical research.

“Many clinical trials from 30 years ago had few minorities and few women,” Parikh said. “Now [diversity] is incorporated into how clinical trials are run.”

Research!America board member Victor Dzau, M.D., president of the National Academy of Medicine, said researchers must also begin focusing on segments of the population, rather than the entire population, when developing treatments.  

continued on page 3
We go to press with cautious optimism about the success of relentless advocacy for research and innovation, at least as that pertains to actions taken in the last few days by the House of Representatives to assure that achieving medical progress remains a high national priority. While we are deeply grateful that the National Institutes of Health is slated for an increase in support, other agencies critical to achieving better health and maintaining global competitiveness are being cut. (Read more elsewhere in this newsletter.)

Meanwhile, states are taking counterproductive actions to push science out of schools. Our Chair Emeritus, former Congressman John Edward Porter, provides some straight talk on this matter in a July 13 letter to the editor in The Washington Post. To quote in part: “What is taught as science in classrooms is important. If we expect to compete globally, students must be able to differentiate science from issues cloaked in the mantle of science.” As stakeholders in a healthy, prosperous future for our children and grandchildren, we can’t afford to avert our gaze or outsource advocacy right now. It’s up to every one of us to speak out. Your congressional representatives will be in their home districts in just a few weeks, providing the perfect opportunity for you to make a visit and let them know what your priorities are!
Migraine Briefing continued from page 1

Amaa Starling, M.D., a neurologist and migraine specialist at the Mayo Clinic, said just two-percent of migraine sufferers are currently receiving effective treatments. Lack of research funding has led to gaps in treatment, she concluded. Jaime Sanders, a migraine patient advocate, echoed Dr. Starling's comments and stated her goal is “to put migraine and other headache disorders on the forefront to gain access to treatment, research and support.” Panel moderator Mary Franklin, executive director of the National Headache Foundation, said she hopes more young investigators will research the causes of migraine.

For photos from the event, visit http://bit.ly/2tiIPXk.

Innovation Intersection continued from page 1

Patty Fritz, M.S., vice president of U.S. Corporate Affairs at UCB, echoed Dzau’s statement. “There’s no such thing as an average patient,” she said. “We need to solve for [each patient’s] unique challenges in order to provide targeted, personalized solutions.”

John Hubbard, Ph.D., FCP, chairman of the Association of Clinical Research Organizations, and president and CEO of Bioclinica, stressed that the high cost of clinical trials must also be addressed. “It’s about $2.5 billion to bring a drug to market,” he said. “We need to begin moving the needle to bring the cost down or [a] generation of new drugs is at risk.”

For photos from the event, visit http://bit.ly/2sHCTBE.

Federal Policy Update

Congress and the Administration have had a busy May and June. President Trump released his budget on May 23. The budget would cut $54 billion from non-defense discretionary (NDD) spending and increase defense spending by the same amount. Neither the House nor Senate has shown any willingness to follow suit: a draft House budget resolution reportedly would reduce NDD by $5 billion, $8 billion below the topline FY17 number. While the Senate has not released a budget resolution, it is likely to mirror the House resolution or be slightly more favorable to NDD.

While NIH continues to receive bipartisan support, absent another bipartisan budget deal to raise the sequestration caps imposed by the 2011 Budget Control Act (BCA), the Labor-H Subcommittees in the House and Senate will face some tough choices. The recently released House LHHS appropriations bill includes a $1.1 billion increase for NIH (inclusive of $496 million in Cures funding), a $200 million cut for CDC and a $24 million cut for AHRQ. Full committee consideration of several bills is also underway in the House. The Agriculture bill provides flat funding for FDA and the Commerce, Justice, Science (CJS) bill includes a 1.78% cut to NSF.

One positive sign: a group of moderate House Republicans recently sent a letter to House Speaker Paul Ryan advocating for a deal that raises the FY18 budget caps. Research!America sent a letter with nearly 210 organizational signatories to House Speaker Paul Ryan advocating for a deal that raises the FY18 budget caps. Continued advocacy will be essential as federal budget battles rage on.

It appears Congress is on track to pass the FDA Reauthorization Act (FDARA), which establishes new user fee agreements, with time to spare before FDA is forced to send reduction in force (RIF) notices at the end of July. Also in FDA news, FDA Commissioner Scott Gottlieb recently discussed bold plans to speed approval of treatments for rare diseases and increase competition in the pharmaceutical marketplace, especially for off-patent drugs with no generic counterpart.

As of this writing, the Affordable Care Act (ACA) is still in place. The House passed its version of replacement legislation and sent it to the Senate, but the Senate version is on hold. Both bills would eliminate the Prevention and Public Health Fund (PPHF) and repeal the medical device excise tax. Research!America continues to urge Congress to sustain the PPHF, which plays a crucial role in CDC’s ability to protect the public’s health.
Congressman Tom Cole to Speak at Rally for Medical Research

Congressman Tom Cole (R-OK), Chairman of the House Labor-Health and Human Services-Education Appropriations Subcommittee, will speak at the Rally for Medical Research Hill Day breakfast. Cole will kick-off day two of the September 13-14 event, which attracts a broad coalition of scientists, patients, and other advocates in Washington, D.C.

The goal of the Rally for Medical Research is to increase support among policymakers of the urgent need for continued investment in the National Institutes of Health to advance medical progress. It began in 2013 after sequestration imposed a $1.5 billion budget cut to the NIH. The Trump Administration’s FY18 budget proposal calls for a $7.2 million cut, heightening the importance of advocacy to protect research funding.

The event is coordinated by the American Association for Cancer Research and partners, with support from Research!America and other scientific organizations. It begins September 13 with a Capitol Hill Day training session. Rep. Cole will speak September 14, before advocates proceed to the Hill to meet with members of Congress and staff.

Participants and supporters are encouraged to increase awareness through social media by using the hashtag #RallyMedRes and posting photos with #IRallyFor cards.

Registration and social media materials are available at rallyformedicalresearch.org.

Research!America’s 2017 National Health Research Forum

Leaders in government, industry, patient advocacy and academia will be among the panelists for Research!America’s 2017 National Health Research Forum on Thursday, September 7 at the Newseum in Washington, D.C.

Confirmed panelists include: Francis Collins, M.D., Ph.D., director, National Institutes of Health; Anne Schuchat, M.D., principal deputy director, Centers for Disease Control and Prevention; Joe Selby, M.D., MPH, director, Patient Centered Outcomes Research Institute; Gary Reedy, chief executive officer, American Cancer Society, and Research!America board member; Mathai Mammen, M.D., Ph.D., global head, science and development, Janssen Research & Development, LLC, one of the Janssen Pharmaceutical Companies of Johnson & Johnson; Lucinda Maine, Ph.D., R.Ph., executive vice president and CEO and Research!America board member, American Association of Colleges of Pharmacy; David Neal, CBE, FMedSci, FRCS, senior vice president of global academic research, Elsevier; and Iris Loew-Friedrich, M.D., Ph.D., chief medical officer, UCB.

The current political and budgetary climate has raised uncertainty regarding the future of our nation’s scientific enterprise. The Forum will bring together thought-leaders and diverse stakeholders to discuss potential solutions to challenges that could slow the pace of scientific progress. Panelists will have an opportunity to discuss topics such as gauging our progress toward actually ending disease, exploring what it will take to overcome the opioid crisis and other urgent community health threats, and untapped opportunities for faster medical progress.

Moderated by high-profile journalists, the Forum is the only event of its kind that convenes the directors of federal agencies and other leaders within the research ecosystem in a setting where a distinguished audience may hear from, ask questions of and interact with those who are advancing medical innovation and public health.

Lead sponsor for the 2017 Forum is Pfizer Inc. Panel sponsors include Amgen, Celgene Corporation, Elsevier, Janssen Pharmaceutical Companies of Johnson & Johnson, PCORI, and UCB. To register, visit http://bit.ly/2sQRV3Z.

Eradicating Disease: Can We Get an App for That?

Disease prevention and early diagnostics in health care could advance with the use of technology. “Everybody has [a cellphone] and they are on it all the time. You can capture all kinds of [health] data,” said Luke Timmerman, founder of the Timmerman Report.

Timmerman moderated an interactive panel discussion coordinated by Research!America titled, “A World Without Disease, Can We Get There?,” at the BIO International Conference on June 20 in San Diego, CA.

The panel included Donna Cryer, president and CEO, Global Liver Institute and Research!America board members William Hait, M.D., Ph.D., global head, Janssen Research and Development and Mark McClellan, M.D., Ph.D., MPA, director, Duke-Robert J. Margolis Center for Health Policy.

“If we knew [what diseases we are incubating], we could stop the process before we get a disease,” said Hait.

We could “create personalized plans for people in the early stages of diseases to help coach them and steer them to the right paths,” Cryer suggested.

“There is a lot we can do with information and tools in preventive ways,” McClellan said. To spur innovation he suggested, “Shifting to a payment system that incentivizes identifying risk factors, diagnosing patients, and getting treatments early.”

Federal Research Budget

<table>
<thead>
<tr>
<th>AGENCY</th>
<th>FY16</th>
<th>FY17 Omnibus</th>
<th>$ CHANGE FY16-17</th>
<th>% CHANGE FY17-16</th>
<th>RESEARCH!AMERICA’S FY18 ASKS</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIH*</td>
<td>$32.08 billion</td>
<td>$34.08 billion</td>
<td>$2.00 billion</td>
<td>5.9%</td>
<td>$36.58 billion</td>
</tr>
<tr>
<td>CDC*</td>
<td>$7.18 billion</td>
<td>$7.17 billion</td>
<td>-$0.01 billion</td>
<td>-0.1%</td>
<td>$7.85 billion</td>
</tr>
<tr>
<td>FDA**</td>
<td>$2.73 billion</td>
<td>$2.76 billion</td>
<td>$0.03 billion</td>
<td>1.1%</td>
<td>$2.80 billion</td>
</tr>
<tr>
<td>NSF*</td>
<td>$7.46 billion</td>
<td>$7.47 billion</td>
<td>$0.01 billion</td>
<td>0.1%</td>
<td>$8.00 billion</td>
</tr>
<tr>
<td>AHRQ**</td>
<td>$0.33 billion</td>
<td>$0.32 billion</td>
<td>-$0.01 billion</td>
<td>-3.1%</td>
<td>$0.36 billion</td>
</tr>
</tbody>
</table>

* indicates that program level is reported in this chart
** indicates that budget authority is reported in this chart
Disputing Scientific Facts

Research!America Chair Emeritus The Honorable John Edward Porter said scientific facts cannot be disputed in a letter to the editor published in The Washington Post in response to an article about a new Florida law that allows residents to challenge what is taught in science classes. “Instructional science materials must continue to reflect the evidence and rigorous data supported by scientists and scientific organizations that generate, test and evaluate ideas that contribute to our knowledge base.”

President Trump’s Proposed FY18 Research Budget

Research!America president and CEO Mary Woolley was quoted in The Washington Post, POLITICO Pro, The Scientist, The Hill, and Chemistry World regarding President Trump’s FY18 budget proposal. Woolley penned a letter in the Journal Gazette (Fort Wayne IN) opposing the proposed cuts to research. Research!America VP of Communications Suzanne Ffolkes was also quoted in STAT about the consequences of President Trump’s budget cuts to research.

In a Modern Healthcare article, Research!America board member Georges Benjamin, M.D., executive director of the American Public Health Association, discussed the impact of the President’s proposed budget cuts to public health programs. Research!America board members Rush Holt, Ph.D., CEO of the American Association for the Advancement of Science and and Elias Zerhouni, M.D., president of global research & development at Sanofi wrote an op-ed in The Hill urging Congress to protect R&D investments.

Health Policy

Research!America board member Sudip Parikh, Ph.D., senior vice president and managing director for DIA Americas, was quoted in a BloombergBNA article about the impact of the health care debate on the public health and prevention fund, NIH and opioid prevention and treatment programs. Research!America VP of Policy and Advocacy Ellie Dehoney was also quoted about FDA user fee legislation.

Federal Health Agency Leaders

Keith R. Yamamoto, Ph.D., Research!America board member and executive vice dean of the school of medicine at University of California, San Francisco, was quoted in Science magazine about Dr. Francis Collins continuing his role as director of the NIH.

TIME magazine quoted Georges Benjamin, M.D., about the new CDC director, Dr. Brenda Fitzgerald. Woolley was quoted in a Lancet article in support of Dr. Collins as NIH director and Dehoney was quoted in a Modern Healthcare article about the new director for the Agency for Healthcare Research and Quality, Mr. Gopal Khanna.

Pharmacy Education

Research!America board member Lucinda Maine, Ph.D., R.Ph., executive vice president and CEO of the American Association of Colleges of Pharmacy, penned a Drug Topics editorial about contemporary pharmacy education.

Smoking and Health

In a Men’s Health magazine article, E. Albert Reece, M.D., Ph.D., MBA, dean of the University of Maryland School of Medicine and Research!America board member, discussed results of a recent UMD research study which confirmed the serious health risks associated with secondhand smoke.

IN BRIEF

- Research!America board member Keith Yamamoto, Ph.D., vice chancellor for science policy and strategy, and director of precision medicine, University of California, San Francisco, received the 2017 Luminary Award.


- Research!America board member Larry Shapiro, M.D., the former dean of the Washington University School of Medicine, has been named the CEO of the University Health Partners of Hawaii.


- Former commissioner of the Georgia Department of Public Health Brenda Fitzgerald, M.D., has been named as director of the Centers for Disease Control and Prevention (CDC).

  http://bit.ly/2tMuV9i

- The National Academies published a report, Preventing Cognitive Decline and Dementia: A Way Forward, led by Research!America board member Alan Leshner, Ph.D., CEO Emeritus of AAAS.

Medical Innovation and the Role of Government

Federal investments in research have had numerous payoffs in finding solutions to what ails us, says Mary Woolley, CEO and president of Research!America speaking at the American Enterprise Institute (AEI) event on the role of government in medical innovation on June 29 in Washington, D.C. Thomas Peter Stossel, M.D., an AEI visiting scholar and Harvard Medical School professor moderated the program which focused on issues ranging from education and science training to research funding and the 21st Century Cures Act.

Other panelists included Jeffrey Flier, M.D., former dean of Harvard Medical School, Daniel Sarewitz, Ph.D., professor of science and society at Arizona State University, and Frances Visco, president of the National Breast Cancer Coalition. Dr. Flier credited government-funded research as the foundation for drug discovery by pharmaceutical companies, adding “That’s where a lot of their ideas come from.” Dr. Stossel agreed that the ecosystem for research has fueled major advances in fighting disease but questioned the importance of publicly-funded research in driving innovation.

Advocating for Science: Your Role in Changing Hearts and Minds

If they hope to raise research and innovation as a higher national priority, scientists must communicate with the public, media and policymakers on how science contributes to the economy, national security and better health. Research!America president and CEO Mary Woolley explained why scientists should be actively engaged as advocates during a session at the American Society for Microbiology (ASM) Microbe 2017 conference on Friday, June 2.

Woolley joined Bill Novelli, distinguished professor, Georgetown University and formerly CEO of AARP, as well as a former Research!America board member, and ASM CEO Stefano Bertuzzi, Ph.D., MPH, to discuss the important role that scientists play in raising public awareness and generating support for science with the general public and policymakers. With steep cuts for non-defense discretionary programs in President Trump’s FY18 budget, there is a palpable sense of urgency. It is important that every member of the science community reach out to their member of Congress and Senators.

Novelli noted that almost half of Americans erroneously believe that cuts to government funding would have no impact on scientific progress. He shared survey data drawn from a recent ScienceCounts study on public perceptions of science, pointing to most effective words and concepts to achieve effective communication to engage a non-science audience. He discussed effective social movements in other sectors, finishing on an optimistic note about his conviction that scientists can and will have the impact we all wish to achieve.

Effectively Communicating the Value of Nursing Research

Nursing researchers contribute to life-saving health interventions, meeting the needs of local communities and improving the lives of individuals and families. What is the best way to articulate the value of nursing research to the general public? Participants at a Research!America science communications workshop held at Johns Hopkins University School of Nursing (JHU SON) on June 8, learned about strategies such as the “three-minute thesis,” a concise storytelling technique to connect with non-scientists.

Research!America Vice President of Communications Suzanne Ffolkes shared insights about the essential components of a well-crafted elevator speech to set the stage for a thoughtful conversation with those unfamiliar with nursing research. Research!America Senior Communications Manager Anna Briseño encouraged participants to customize messages with specific information that will resonate with different audiences.

“[Thinking about] why your audience or whoever you are speaking with be interested in your research and what impact it could have on them personally or someone they know or the society as a whole…that has been the most helpful to me,” added Yvonne Commodore-Mensah, assistant professor, JHU SON. For more information about Research!America science communication workshops contact info@researchamerica.org.
The Society for Women's Health Research (SWHR) is a national nonprofit based in Washington, D.C. A pioneer in promoting research on biological differences in disease, SWHR is dedicated to transforming women's health through science, advocacy, and education. Founded in 1990 by a group of physicians, medical researchers and health advocates, SWHR aims to bring attention to the variety of diseases and conditions that disproportionately or predominately affect women. Thanks to SWHR's efforts, women are now routinely included in most major medical research studies, and scientists are considering sex as a variable in research.

MEMBER SPOTLIGHT

The Society for Women's Health Research (SWHR) is transforming women's health through the study of sex differences and diseases that disproportionately or predominately impact women. SWHR believes it is crucial for medical research to reflect the diversity of the population, and works to ensure that women are adequately included in clinical trials. SWHR is unique as the leading science-based advocate for advancing women's health interests.

In 2017, SWHR welcomed new president and CEO, Amy M. Miller, Ph.D., to write new chapters not just in SWHR's history, but in promoting greater health by eliminating imbalances in care for women by advancing science, advocacy, and education. “Differences in the ways that women and men experience diseases have been dangerously understudied,” said Dr. Miller. “We believe progress in the science of sex differences will benefit the health and longevity of both women and men.”

SWHR's success has been based on gathering the broadest and most diverse set of scientific disciplines and experienced thought leaders to discuss and research the implications of sex differences on certain conditions, diseases, and disorders. SWHR's current work includes the creation of interdisciplinary scientific networks dedicated to Alzheimer's disease, urological health, and sleep health as well as migraines.

SWHR established the Organization for the Study of Sex Differences (OSSD), the only scientific membership society in North America dedicated to promoting interdisciplinary research on biological sex differences. OSSD publishes the Biology of Sex Differences, an open-access, peer-reviewed online journal. Additionally, SWHR created the Recognizing the Achievements of Women in Sciences and Engineering (RAISE) Project, a campaign to elevate the status of professional women through recognition of their scientific and medical achievements.

A major concern of SWHR is the impact of federal spending cuts on scientific research and the jobs they provide. “Proper support of scientific research is necessary for targeting major public health risks and improving the health and well-being of Americans. Without enough support for medical research, the American people will be denied new, potentially life-saving treatments,” said Dr. Miller.

SWHR’s mission to promote women's health and sex differences research spans the halls of Congress, the White House, and federal health agencies. In the last three decades, SWHR has successfully advocated for increased federal funding for biologically-based research, and won the passage of notable legislation that impacts women's health, such as the National Institutes of Health Revitalization Act.

“Research!America’s” commitment to making health research a higher national priority is directly aligned with SWHR's mission to champion the study of sex differences that affect disease and treatment, as well as increased funding for women's health research and parallel funding increases for federal health agencies,” said Dr. Miller.

For more information, visit www.swhr.org.
Urge Congress to Lift Sequestration Caps

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.