Featured Reports on Genetic Research

Caring for Our Family Caregivers

The Serious Problem of Bullying

Safety in Offshore Drilling

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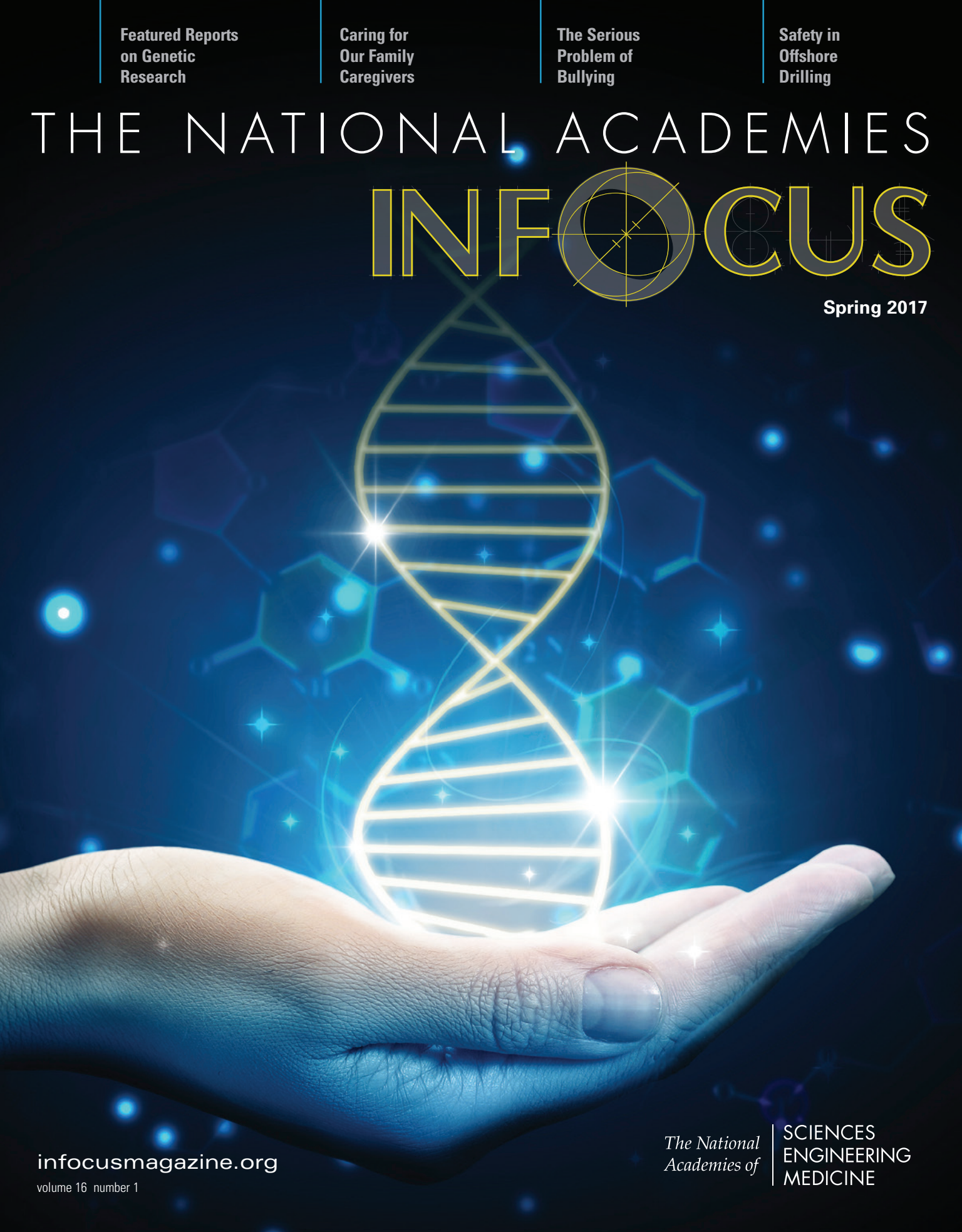

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The National Academies of SCIENCES ENGINEERING MEDICINE

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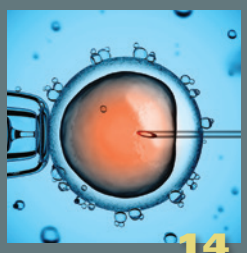

OTHER NEWS

THE NATIONAL ACADEMIES

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Bullying

A Serious Public Health Problem

Bullying has long been tolerated by many as a rite of passage among children and adolescents. Until recently, most bullying typically occurred at school or other places where children play or hang out, but the abundance of newer technologies in the hands of young people has led to cyberbullying through social media, texting, and other forms of digital communication. Although it is difficult to determine the extent of bullying due to inconsistencies in its definition and measurement, bullying likely affects between 18 percent and 31 percent of children and youths, and the prevalence of cyberbullying is estimated to range from 7 percent to 15 percent. Estimates are even higher for subgroups that are particularly vulnerable, such as individuals who have disabilities, are obese, or are LGBT. In addition, children with fewer same-ethnicity peers at school appear to be at greater risk for being targets of bullying.

Recognizing that bullying is a serious public health problem, a group of federal agencies and private foundations asked the National Academies of Sciences, Engineering, and Medicine to appoint a committee of experts to study what is

known about bullying and what we need still to learn to reduce such behavior and its consequences.

The committee's report outlines significant short- and long-term psychological consequences faced by both the targets and perpetrators of bullying. Children and adolescents who are bullied experience a range of physical problems, including sleep disturbances, gastrointestinal concerns, and headaches. Although the full consequences of bullying on the brain are not yet understood entirely, there are changes in the stress response systems and in the brain associated with increased risk of mental health, cognitive function, and self-regulation problems.

> "Bullying has lasting negative consequences and cannot simply be ignored."

Being bullied during childhood and adolescence has been linked to psychological effects such as depression, anxiety, and alcohol and drug abuse into adulthood. And children and youths who bully others are more likely to be depressed, engage in high-risk activities such as theft and vandalism, and have adverse outcomes later in life compared with those who do not bully, the report says. Moreover, individuals who bully others and are themselves bullied appear to be at greatest risk for poor psychological and social outcomes. Youth involved in bullying are also significantly more likely to contemplate or attempt suicide, though there is not enough evidence to conclude that bullying is a causal factor in youth suicides.

Assessing which prevention programs work best, the committee found the programs that appear most effective are those that promote a positive school environment and combine social and emotional skill-building for all students, with targeted interventions for those at greatest risk for being involved in bullying. These multicomponent programs include activities such as counselors or teachers presenting strategies for responding to bullying alongside teaching more intensive social-emotional skills or de-escalation approaches

to youths at risk of bullying or being bullied.

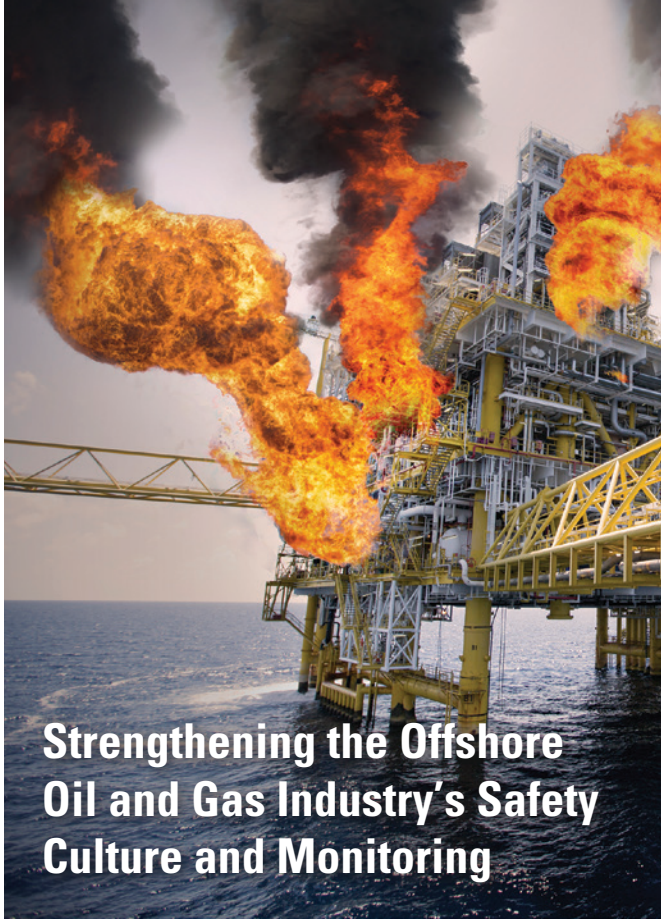
There is emerging research that widely used zero-tolerance policies — those that impose automatic suspension or expulsion of students from school after one bullying incident — are not effective at curbing bullying or making schools safer. This is because zero-tolerance policies may lead to underreporting of bullying incidents because the consequence is perceived as too harsh. The committee concluded that these policies should be discontinued, and resources should instead be directed to evidence-based policies and programs for bullying prevention in the United States.

"Bullying has lasting negative consequences and cannot simply be ignored," said committee chair Frederick Rivara, Seattle Children's Hospital Guild Endowed Chair in Pediatric Research and professor of pediatrics and epidemiology at the University of Washington. "This is a pivotal time for bullying prevention, and while there is not a quick fix or one-size-fits-all solution, the evidence clearly supports preventive and interventional policy and practice."

The committee also recommended federal agencies work with relevant stakeholders to sponsor the development, implementation, and evaluation of evidence-based programs to address bullying behavior and bullying prevention training for professionals and volunteers who work directly with children and adolescents on a regular basis. In addition, social media companies should partner with the Federal Partners in Bullying Prevention interagency group to adopt, implement, and evaluate on an ongoing basis policies and programs for preventing, identifying, and responding to bullying on their platforms and should publish their anti-bullying policies on their websites. — *Dana Korsen*

Preventing Bullying Through Science, Policy, and Practice (2016, 361 pp.; ISBN 978-0-309-44067-7) is available from the National Academies Press, tel. 1-800-624-6242; $79.00 plus $6.50 shipping for single copies; also on the Internet at <www.nap.edu/catalog/23482>. The study was sponsored by the Centers for Disease Control and Prevention, Eunice Kennedy Shriver National Institute of Child Health and Human Development, Health Resources and Services Administration of the U.S. Department of Health and Human Services, Highmark Foundation, National Institute of Justice of the U.S. Department of Justice, Robert Wood Johnson Foundation, Semi J. and Ruth W. Begun Foundation, and the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services.

Safety in Offshore Drilling



Strengthening the Offshore Oil and Gas Industry's Safety Culture and Monitoring

Mark Wahlberg's latest movie, *Deepwater Horizon,* showcased the importance of safety in offshore drilling on the big screen. It depicts the 2010 Macondo well blowout that led to an explosion and fire on the Deepwater Horizon drilling rig, which resulted in 11 deaths and 17 injuries and spilled an estimated 3.19 million barrels of oil into the Gulf of Mexico — the largest spill in U.S. history.

Along with immense marine and coastal environmental damage, the economic impact of the incident was estimated to reach $8.7 billion in lost revenue, profits, and wages in affected industries, as well as the loss of about 22,000 jobs. BP also had to pay at least $30 billion to cover fines, penalties, operational response, and liabilities. The blowout and spill also put the safety of offshore drilling and production under tremendous public scrutiny.

An Academies committee recently looked at the safety culture of the offshore oil and gas industry. About 75 operators, 17 drilling contractors, and more than 1,000 contractors/subcontractors varying in size and financial resources support offshore drilling, production, and construction activities in the Gulf of Mexico. Because of differing safety perspectives and economic interests, offshore oil and gas companies do not all belong to a single industry association that speaks with one voice regarding safety, the committee's report says. Several challenges exist in setting and implementing consistent goals for safety practices and culture, including the varied commitment among organization leaders to having a strong safety culture, variation in the types of organizations that may work on a single drilling site, inconsistency of practices such as supervision and training, and diversity of employees' safety attitudes and educational backgrounds.

The committee said that operators, contractors, subcontractors, associations representing these groups, and federal regulators should collaborate to foster a strong culture of safety throughout all levels of the offshore oil and gas industry and confront challenges collectively. The industry also should implement the recommendation of the National Commission on the BP

Deepwater Horizon Oil Spill and Offshore Drilling calling for an independent organization dedicated to safety and environmental protection, with no advocacy role. The Center for Offshore Safety, created by the American Petroleum Institute (API) immediately after the Deepwater Horizon blowout and oil spill, could be made independent of API to serve this purpose, with membership in the center required for all organizations working in the offshore oil and gas industry.

Another recent Academies report looks at how the Bureau of Safety and Environmental Enforcement (BSEE) of the U.S. Department of the Interior could apply remote real-time monitoring (RRTM) to improve the safety and reduce the environmental risks of offshore oil and gas operations, an issue that has become increasingly important with the move over the last 25 years into greater water depths and the drilling of deeper wells; such operations can experience higher pressures, increased temperatures, and greater uncertainty.

There are diverse RRTM technologies currently available, and their use varies across the industry. While no standard RRTM practice exists, the committee that conducted the study and wrote the report concluded that mandating a standard approach is not likely to work or be needed for every drilling company or well. Therefore, BSEE should pursue a performance-based regulatory framework that allows industry to determine relevant uses of RRTM based on assessed levels of risk and complexity.

In addition, BSEE should monitor RRTM technologies and best practices by using either an internal group, such as the agency's proposed Engineering Technology Assessment Center, or an external organization, such as the Ocean Energy Safety Institute. — *Dana Korsen*

Strengthening the Safety Culture of the Offshore Oil and Gas Industry (2016, 240 pp.; ISBN 978-0-309-36986-2) is available from the Transportation Research Board, tel. 202-334-3213; $48.00 plus $9.00 shipping for single copies; also on the Internet at <www.nap.edu/catalog/23524>. The committee was chaired by **Nancy T. Tippins,** principal consultant, CEB, Greenville, S.C. The study was supported with funds designated for the National Academy of Sciences as a community service payment arising out of a plea agreement entered into between the United States Attorney's Office for the Eastern District of Louisiana and Helmerich & Payne International Drilling Company.

Application of Remote Real-Time Monitoring to Offshore Oil and Gas Operations (2016, 117 pp.; ISBN 978-0-309-36978-7) is available from the Transportation Research Board, tel. 202-334-3213; $41.00 plus $9.00 shipping for single copies; also on the Internet at <www.nap.edu/catalog/23499>. The committee was chaired by **Richard A. Sears,** consulting professor, Department of Energy Resources Engineering, Stanford University, Stanford, Calif. The study was sponsored by the Bureau of Safety and Environmental Enforcement of the U.S. Department of the Interior.

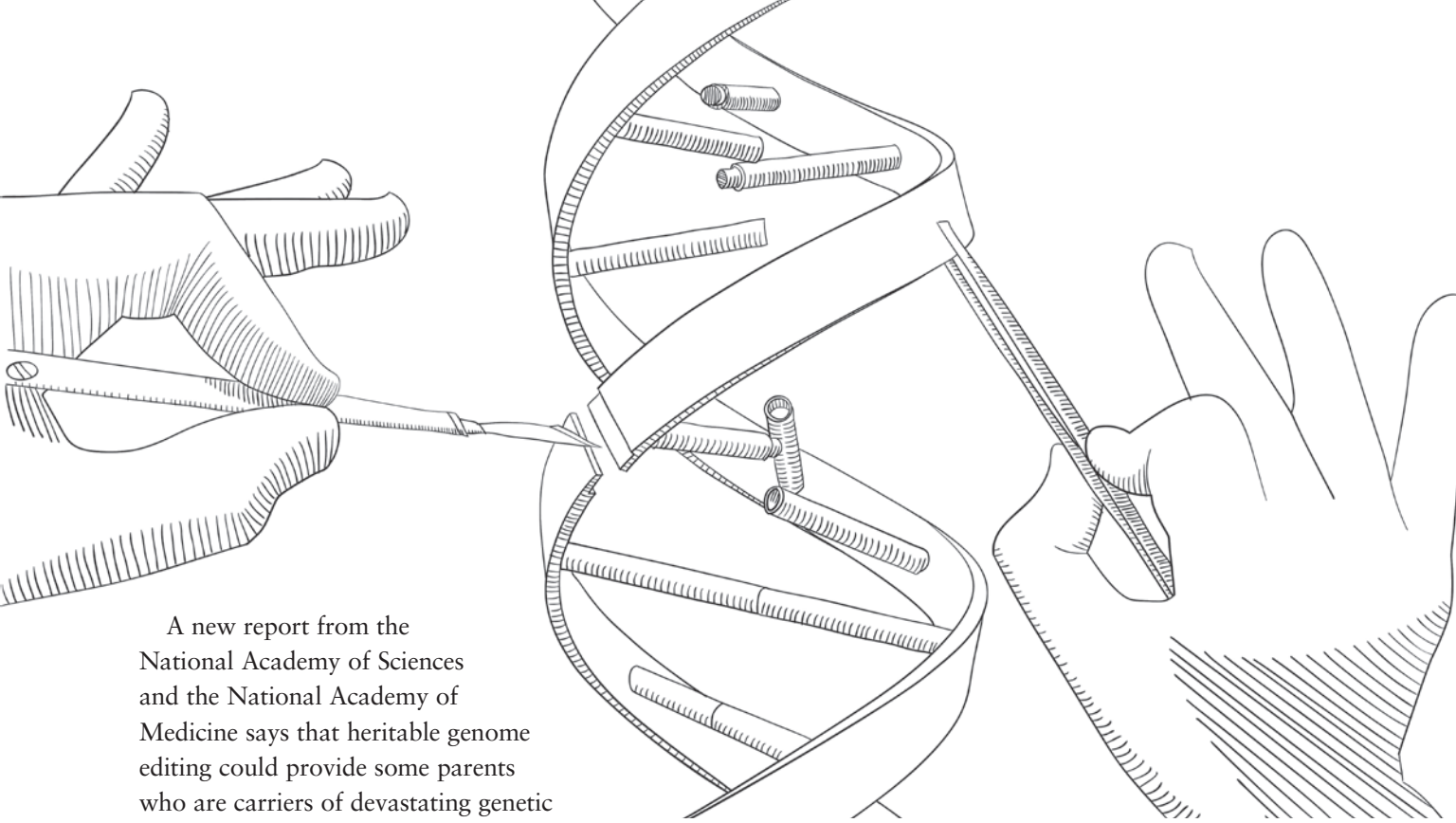
Focus on Genetic Research

The National Academies have a long history of providing leadership and evidence-based advice in controversial and provocative fields of science, such as rapidly developing areas of genetic research — human genome editing, mitochondrial replacement techniques, genetic engineering of foods, and gene-drive modified organisms. This issue of In Focus highlights a number of reports released in the past year on these topics.

HUMAN GENOME Editing

Guidance for Responsible Research and Clinical Applications

Powerful, precise, and less costly genome editing tools such as CRISPR/Cas9 have led to an explosion of research opportunities and potential clinical applications that could address a wide range of human health issues. But along with the excitement these new technologies have generated are various concerns. In particular, heritable genome editing — the adding, removing, or replacing of DNA base pairs in gametes or early embryos — has long been contentious because the resulting genetic changes could be inherited by future generations. Many view heritable genome editing as crossing an ethically inviolable line, raising difficult questions about "playing God" and interfering with human reproduction, influencing social attitudes toward people with disabilities, and risking the health and safety of future children, to name a few.



A new report from the National Academy of Sciences and the National Academy of Medicine says that heritable genome editing could provide some parents who are carriers of devastating genetic diseases with their best or most acceptable option for having genetically related children who are born free of these diseases. With stringent oversight, heritable editing clinical trials could be permitted in the future, but only for serious health conditions and only if the trials meet a number of strict criteria.

Human genome editing is already widely used in basic research and is in the early stages of development and trials for clinical applications that involve non-heritable cells. These therapies would affect only the patient, not any potential offspring. The development of such therapies should continue following the existing ethical norms and regulatory framework for development of gene therapy, and should be used only for treatment and prevention of disease or disability, the report says.

There is significant public concern these same techniques could be used for "enhancement" of human traits and capacities, such as physical strength. The report recommends that genome editing for enhancement should not be allowed at this time, and that broad public input and discussion should be solicited before allowing clinical trials for somatic — non-heritable — genome editing for any purpose other than treating or preventing disease or disability. "Genome editing to enhance traits or abilities beyond ordinary health raises concerns about whether the benefits can outweigh the risks, and about fairness if available only to some people," said Alta Charo, co-chair of the committee that wrote the report and Sheldon B. Lubar Distinguished Chair and Warren P. Knowles

With stringent oversight, heritable editing clinical trials could be permitted in the future, but only for serious health conditions and only if the trials meet a number of strict criteria.

Professor of Law and Bioethics, University of Wisconsin-Madison.

Heritable genome editing is not ready to be tried in humans, and much more research is needed before it could meet the appropriate risk and benefit standards for clinical trials. However, the technology is advancing rapidly, making heritable genome editing of early embryos, eggs, sperm, or precursor cells a "realistic possibility that deserves serious consideration," the report says.

Currently, heritable genome editing is not permitted in the United States due to an ongoing prohibition against the U.S. Food and Drug Administration using federal funds to review "research in which a human embryo is intentionally created or modified to include a heritable genetic modification." A number of other countries also have signed an international convention that prohibits heritable genome modification.

If current restrictions are removed, and for countries where heritable genome editing would already be permitted, the committee recommended that stringent criteria be met before going forward with clinical trials. They include the absence of reasonable alternatives; restriction to editing genes that have been convincingly demonstrated to cause or strongly predispose to a serious disease or condition; restriction to converting such genes to versions that are prevalent in the population and are known to be associated with ordinary health with little or no evidence of adverse effects; credible pre-clinical and/or clinical data on risks and potential health benefits; maximum transparency consistent with patient privacy; ongoing, rigorous oversight during clinical trials; comprehensive plans for long-term, multigenerational follow-up; continued reassessment of both health and societal benefits and risks, with wide-ranging, ongoing input from the public; and reliable oversight mechanisms to prevent extension to uses other than preventing a serious disease or condition.

The committee also recommended a set of overarching principles that should be used by any nation in governing human genome editing research or applications.

Promote well-being
Providing benefit and preventing harm to those affected

Transparency
Openness and sharing of information in ways that are accessible and understandable to patients, their families, and other stakeholders

Due care
Proceeding only when supported by sufficient and robust evidence

Responsible science
Adhering to the highest standards of research in accordance with international and professional norms

Respect for persons
Recognizing the personal dignity of all individuals and with respect for their decisions

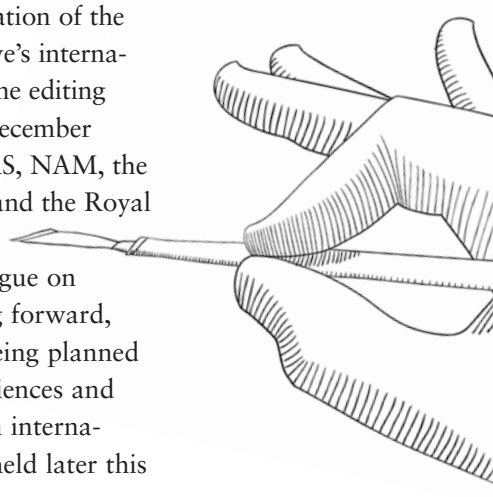
Fairness
Treating all cases alike, with an equitable distribution of risks and benefits

Transnational cooperation
Committing to collaborative approaches for research and governance while respecting different cultural contexts

"Genome editing research is very much an international endeavor, and all nations should ensure that any potential clinical applications reflect societal values and be subject to appropriate oversight and regulation," said committee co-chair Richard Hynes, Howard Hughes Medical Institute Investigator and Daniel K. Ludwig Professor for Cancer Research, Massachusetts Institute of Technology. "These overarching principles and the responsibilities that flow from them should be reflected in each nation's scientific community and regulatory processes. Such international coordination would enhance consistency of regulation."

The report is a major component of the NAS-NAM human gene-editing initiative, which was launched in 2015 to provide researchers, clinicians, policymakers, and societies around the world with a thorough understanding of these technologies in order to inform decisions about human genome editing research and clinical applications. Written by an international committee of experts, the report is a continuation of the dialogue sparked at the initiative's international summit on human genome editing held in Washington, D.C., in December 2015, and co-sponsored by NAS, NAM, the Chinese Academy of Sciences, and the Royal Society of the United Kingdom.

To keep the important dialogue on human genome editing moving forward, additional activities are also being planned by the Chinese Academy of Sciences and the Royal Society, including an international summit in China to be held later this year. — *Molly Galvin*



Human Genome Editing: Science, Ethics, and Governance (2017, approx. 300 pp.; ISBN 978-0-309-45288-5) is available from the National Academies Press, tel. 1-800-624-6242; $68.00 plus $6.50 shipping for single copies; also on the Internet at <www.nap.edu/catalog/24623>. The study was funded by the Defense Advanced Research Projects Agency, the Greenwall Foundation, the John D. and Catherine T. MacArthur Foundation, the U.S. Food and Drug Administration, and the Wellcome Trust, with additional support from the National Academies' Presidents' Circle Fund and the National Academy of Sciences W.K. Kellogg Foundation Fund.

A Path Forward for

Mitochondrial Replacement Techniques

Almost every cell of the human body contains mitochondria, the "powerhouses" that produce energy for our cells. Mitochondrial disease, sometimes caused by mutations in mitochondrial DNA (mtDNA), occurs when the mitochondria fail to produce enough energy for cells or organs to function properly. Mitochondrial DNA diseases are rare, yet they can be severely debilitating, progressive, and often fatal at a young age. Currently, there is no cure or approved treatment by the U.S. Food and Drug Administration for mtDNA disease.

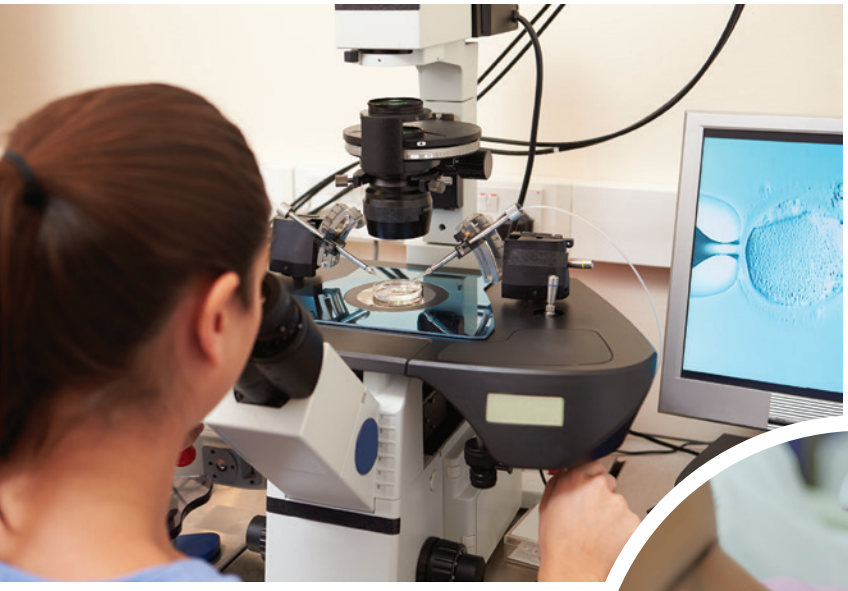
There exist, however, novel procedures that could enable intended mothers to have a child related to them by nuclear DNA but with a significantly reduced risk of inheriting pathogenic mtDNA. Known as mitochondrial replacement techniques (MRT), such procedures raise a series of complex ethical and social concerns. The techniques would remove nuclear DNA from the egg of a woman at risk for passing on mtDNA disease and transfer it to an egg provided by a woman with nonpathogenic mitochondrial DNA that has had its nuclear DNA removed. As mitochondria are inherited solely from the mother, this would, in theory, prevent transmission of mtDNA disease from the at-risk woman to her child. Children born as a result of MRT would have genetic material from three individuals: nuclear DNA from one man and one woman and mitochondrial DNA from another woman.

As the primary regulatory authority in this area, FDA would decide whether MRT can move forward into clinical investigations in the United States, and perhaps eventually into clinical use. While FDA does not have jurisdiction over the practice of medicine in general, it can regulate certain treatments or procedures, including the use of "human cells or tissues that are intended for implantation . . . into a human." Given the concerns about the perceived ethical, social, and policy implications of MRT, FDA asked the National Academies of Sciences, Engineering, and Medicine to examine these issues and whether the concerns raised preclude clinical investigation of MRT.

The committee that carried out the study determined that conducting clinical investigations of MRT in humans is ethically permissible as long as significant conditions and principles are met. One of the many conditions laid out in the committee's report is that initial MRT clinical studies should be limited to women who are at risk of transmitting a severe mtDNA disease that could lead to a child's early death or substantial impairment. Another is that in initial clinical

investigations, only male embryos should be allowed to be transferred to a woman for a possible pregnancy. This restriction is predicated on the need to proceed carefully and to mitigate potential adverse and uncertain consequences of MRT from being

Conducting clinical investigation of MRT in humans is ethically permissable as long as significant conditions and principles are met.



passed on to future generations — not on selection of one sex over another. The committee stressed that when balancing the benefits and risks of MRT clinical investigations, the primary consideration is minimizing the risk of harm to the child born as a result of the techniques.

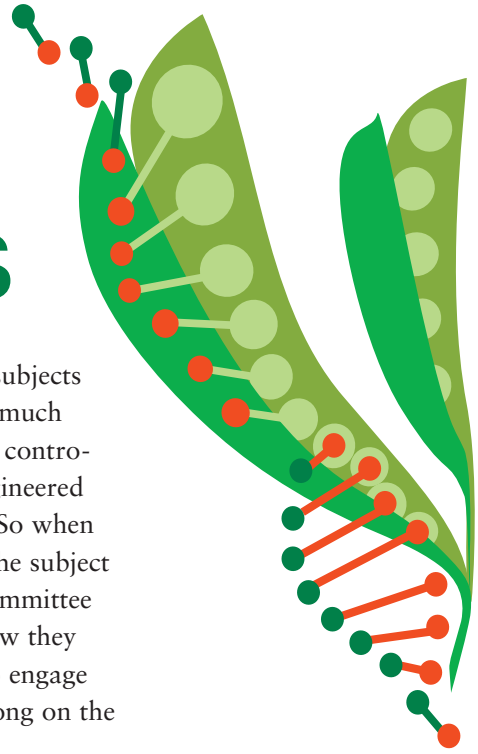
"In examining the ethical, social, and policy issues associated with mitochondrial replacement techniques, we concluded that the most germane issues could be avoided if the use of these techniques were restricted by certain conditions," said Jeffrey Kahn, chair of the study committee and the Andreas C. Dracopoulos Director and Levi Professor of Bioethics and Public Policy at the Johns Hopkins Berman Institute of Bioethics in Baltimore. "Although MRT would not treat a person with a mitochondrial disease, its pursuit could satisfy prospective parents' desire to bear genetically related offspring with a significantly reduced risk of passing on mitochondrial disease. The limitations on MRT that we propose focus on protecting the health and well-being of children born as a result of the techniques."

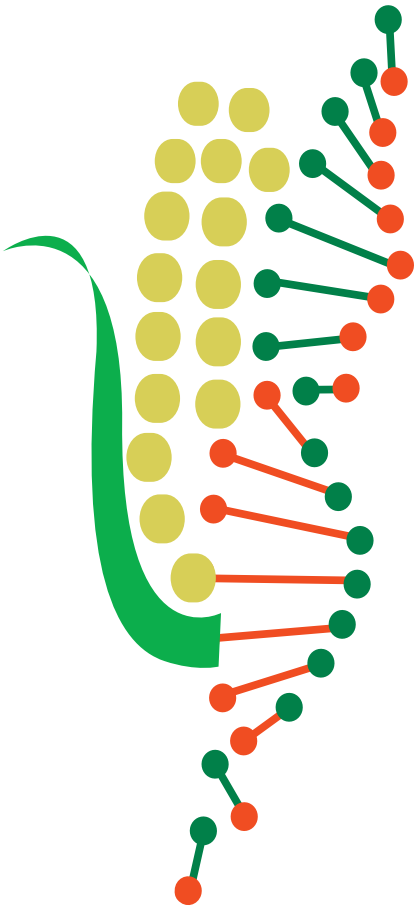
Following successful initial clinical investigations of MRT limited to the transfer of male embryos, FDA could consider extending MRT research to include the transfer of female embryos if clear evidence of safety and efficacy from male cohorts using identical MRT procedures to those proposed in females is available, even if it takes a long period of time to collect this evidence. In addition, the committee recommended that preclinical research in animals has to show evidence of intergenerational safety and efficacy, and that FDA's decision should be consistent with the outcomes of public and scientific deliberations to establish a shared framework concerning the acceptability of and moral limits on heritable genetic modification. — *Jennifer Walsh*

Mitochondrial Replacement Techniques: Ethical, Social, and Policy Considerations (2016, 200 pp.; ISBN 978-0-309-38870-2) is available from the National Academies Press, tel. 1-800-624-6242; $58.00 plus $6.50 shipping for single paperback copies; also on the Internet at <www.nap.edu/catalog/21871>. The study was sponsored by the U.S. Department of Health and Human Services' Food and Drug Administration.

GE Crops

A Fresh Look at the Evidence





There are few scientific subjects that have generated as much public uncertainty and controversy as genetically engineered (GE) crops and foods. So when the Academies began a study of the subject in 2014, the chair of the study committee and the principal staff officer knew they needed to make an extra effort to engage the public and let them follow along on the committee's investigation.

"Our approach was to encourage people with diverse perspectives to come forward and make us aware of their views about positive and adverse effects of genetically engineered crops," said Fred Gould, the committee chair and University Distinguished Professor of Entomology at North Carolina State University. "This helped us be sure that we examined the existing evidence about potential effects that were important to the public. In finalizing our report, we set up a website where the public could assess the evidence we used to address their specific questions and comments."

In conducting the study, the committee held three public meetings and 15 public webinars, hearing from about 80 presenters with expertise in a range of relevant topics and from others who had a variety of perspectives about GE crops. The committee and staff also read over 700 documents and comments submitted by the public through the project website. And they examined 20 years' worth of scientific literature — over 900 publications — on the use and effects of GE characteristics in corn, soybeans, and

cotton, which account for most GE crops planted to date.

No Evidence of Greater Risks to Health or Environment

One of the greatest areas of public concern has been about whether GE foods have negative effects on human health. To examine this question, the committee reviewed animal-feeding studies, long-term data on the health of livestock fed GE crops, and research on the chemical composition of GE foods and found nothing to indicate an increased risk to human health. The committee also compared rates at which various diseases — cancer, allergies, celiac

disease, and kidney disease, among others — occur in the U.S., where GE crops are widely consumed, and Europe, where they are not. They found no differences in disease rates between the two populations. Overall, the committee found no evidence that current GE crops pose any greater risk to human health than their conventionally bred counterparts.

The possible effects of GE crops on the environment have also been an ongoing public concern, so the committee examined the evidence on this as well. They found that the use of crops modified to be insect-resistant or herbicide-resistant did not reduce the overall diversity of plant and insect life on farms. In fact, insect-resistant GE crops sometimes resulted in greater insect diversity when they replaced the use of synthetic insecticides on crops. While gene flow — the transfer of genes from a GE crop to a wild relative species — has occurred, no examples have demonstrated that this transfer has led to adverse environmental effects. Overall, there is no conclusive evidence that GE crops have caused environmental problems, though the complex nature of assessing long-term environmental changes makes it difficult to reach definitive conclusions.

The study questioned whether the most common GE characteristics — insect resistance and herbicide resistance — can remain effective if current management practices continue. In places where insect-resistant crops were planted but resistance-management strategies were not followed, damaging levels of resistance have developed in some targeted insects, the committee found. And in some locations, many weeds have evolved to resist glyphosate, the herbicide to which most GE crops are engineered to be resistant.

Overall, the committee cautioned against sweeping, generalized statements about the benefits or risks of GE crops. New GE characteristics are being commercialized, and their effects will depend on the nature of each characteristic, the crops they in which they are used, and where the crops are planted.

Blurring the Line Between Conventional Breeding and Genetic Engineering

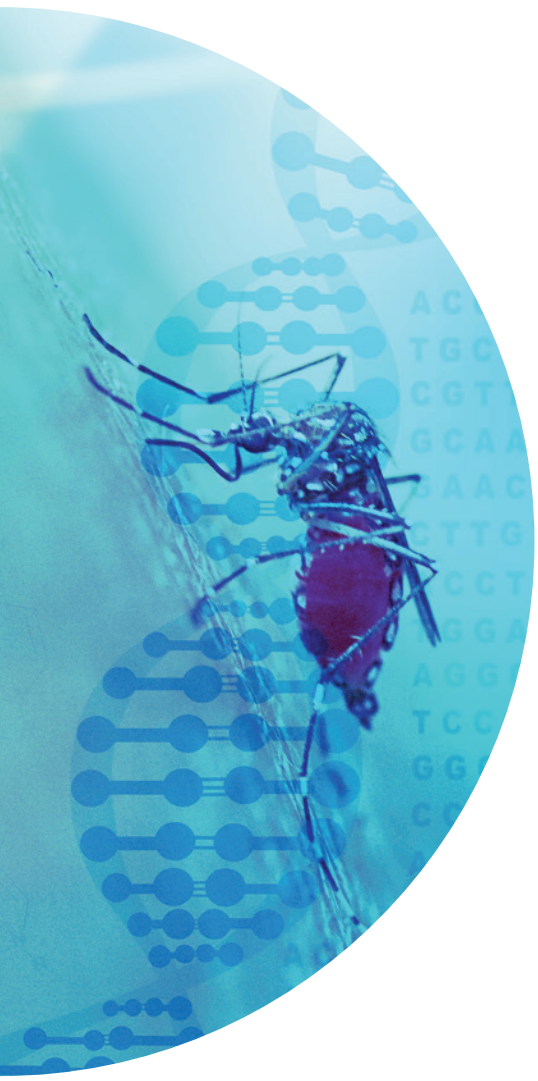
The emergence of new methods of genetic engineering and new techniques for conventional breeding is blurring the distinction between the two approaches, the committee found. Genome editing techniques such as CRISPR/Cas9 can now be used to make a genetic change by substituting a single nucleotide in a specific gene — a change that can also be made using other new techniques classified as conventional breeding.

The committee concluded that these developments are yet another reason to reiterate a recommendation made in a previous Academies report on GE crops: that regulation of new crops should focus on the characteristics of the crop itself, rather than the method used to produce them. A plant with novel characteristics with the potential to harm human health or the environment should undergo safety testing, regardless of whether it was developed using genetic engineering or conventional breeding. New molecular tools developed over the past 20 years enable researchers to examine thousands of specific plant traits, providing a fingerprint of any new crop variety's characteristics. These tools should be capable of detecting any unintended effects of plant breeding.

The report's release made a big media splash, triggering coverage in outlets ranging from NBC Nightly News to agricultural publications like Farm Industry News. The report has been downloaded over 35,000 times in 150 countries — and not just by scientists and policy wonks, notes staff officer Kara Laney. "Along with students, teachers, and dieticians, it's being downloaded by people who are just interested in the subject. It's exciting to see such widespread interest in the report."
— *Sara Frueh*

Genetically Engineered Crops: Experiences and Prospects (2016, 606 pp., ISBN 978-0-309-43738-7) is available from the National Academies Press, tel. 1-800-624-6242; $89.00 plus $6.50 shipping for single copies; also on the Internet at <www.nap.edu/catalog/23395>. The study was sponsored by the Burroughs Wellcome Fund, the Gordon and Betty Moore Foundation, the New Venture Fund, and the U.S. Department of Agriculture, with additional support from the National Academy of Sciences.

Gene Drives



NAVIGATING AN EMERGING SCIENCE

Almost 150 years ago, Gregor Mendel's principles of genetics established that offspring have a 50 percent chance of inheriting a gene from one of their parents. Although not observed as frequently in nature, gene drives are a system of inheritance that overrides Mendel's conventional rules and enhances the ability of sequences of DNA to pass from parent to offspring.

While gene drives occur in nature through a variety of mechanisms, new, more efficient gene-editing tools like CRISPR/Cas9 offer the potential to make modifications to a gene and spread it throughout a population of living organisms intentionally and quickly. Preliminary evidence suggests that gene drives developed in the laboratory could spread a targeted gene through nearly 100 percent of a population of yeast, fruit flies, or mosquitoes.

This breakthrough has the potential to control the spread of infectious diseases, eliminate invasive species, and address conservation-related issues and other challenges. Despite such promise, the two distinguishing characteristics of gene drives — the intentional spread of a genetic trait through a population and the potential for their effects on ecosystems to be irreversible — raise a number of concerns. A report from the National Academies says there is insufficient evidence available at this time to support the release of these gene-drive modified organisms into the environment, but the potential benefits for basic and applied research justify continued research in laboratories and highly controlled field trials.

The study committee that wrote the report concluded that a collaborative, multidisciplinary, and cautionary approach to research and governance of gene-drive technologies is needed to make informed decisions about each proposed application of a gene-drive modified organism.

"The science and technology associated with gene drives is developing very quickly," said committee co-chair James P. Collins, Virginia M. Ullman Professor of Natural History and Environment in the School of Life Sciences at Arizona State University. "But before gene-drive modified organisms are put into the environment, our committee urges caution — a lot more research is needed to understand the scientific, ethical, regulatory, and social consequences of releasing such organisms."

The report notes that gaps in our understanding of the biology of gene drives and the potential effects of gene-drive modified organisms on the environment are fundamental considerations in the development and release of these organisms. Laboratory and field research is crucial to refine gene-drive mechanisms and better understand how gene drives work, from the molecular level through species and ecosystem levels. Of parallel importance to the scientific questions is addressing value-based questions about the potential benefits and harms of gene drives to humans and the environment. The committee called for ecological risk assessment and broad engagement with communities, stakeholders, and publics as essential components of the research and development of this emerging technology.

"Responsible research on gene drives and gene-drive technology requires consideration of values and public engagement throughout the process," said committee co-chair Elizabeth Heitman, associate professor of medical ethics, Vanderbilt University Medical Center's Center for Biomedical Ethics and Society. "From

A collaborative, multidisciplinary, and cautionary approach to research and governance of gene-drive technologies is needed to make informed decisions about each proposed application of a gene-drive modified organism.

conducting basic research, to choosing a problem to address and an organism to modify, to devising strategies to pursue field testing safely, it is essential to examine each gene drive on a case-by-case basis and to engage stakeholders and the public in assessing their potential development."

Because the goal of using a gene drive is to spread genetic information through a population rapidly, it is difficult to anticipate its impact and important to minimize the potential for unintended consequences. The committee recommended a phased approach to guide research from the laboratory to the field, to facilitate evidence-based decision making at every step. Furthermore, each proposed field test or environmental release of a gene-drive modified organism should be subject to robust ecological risk assessment before being approved to determine a gene drive's potential impact.

The report committee emphasized that there are a range of approaches to governing research that span from personal responsibility of the investigator to legally binding and enforceable regulations. Some of the current U.S. mechanisms of governance may be inadequate for identifying the public health and environmental implications of individual gene drive applications. The report also calls for flexible and rapidly adaptable governance policies, including those such as the World Health Organization's Guidance Framework for Testing of Genetically Modified Mosquitoes, to facilitate international coordination and collaboration.

Public engagement should also be built into risk assessment and practical decision making to help frame and define the potential harms and benefits of using a gene-drive organism. The report recommends that the governing authorities, including research institutions, funders, and regulators, develop and maintain clear policies and mechanisms for how public engagement will factor into research, ecological risk assessments, and public policy decisions about gene drives. The outcomes of public engagement may be as critical as scientific outcomes in making decisions about whether or not to release a gene-drive modified organism into the environment.
— *Jennifer Burris Olson*

Gene Drives on the Horizon: Advancing Science, Navigating Uncertainty, and Aligning Research with Public Values (2016, 230 pp.; ISBN 978-0-309-43787-5) is available from the National Academies Press, tel. 1-800-624-6242; $79.00 plus $6.50 shipping for single copies; also on the Internet at <www.nap.edu/catalog/23405>. The study was sponsored by the National Institutes of Health (NIH) and the Foundation for the National Institutes of Health (FNIH), and the National Academy of Sciences Biology and Biotechnology Fund. The Defense Advanced Research Projects Agency and the Bill & Melinda Gates Foundation provided funding to NIH and FNIH, respectively, in support of this study.

Family Caregivers

Taking Care of an Aging America

Family members have long provided emotional support and helped older family members at home with their personal needs. Today's family caregivers still assume these traditional roles, but often they are also called upon to provide health and medical care at home and must navigate a complicated and fragmented health care system that offers them little support.

A recent Academies report examines the prevalence and nature of family caregiving. At present, nearly 18 million Americans care for family members 65 and older with serious health or functioning impairments, but the pool of potential family caregivers is shrinking. Families have fewer children, older adults are more likely to have never married or to be divorced, and adult children often live far from their parents or may be caring for more than one older adult or their own children.

While the supply of family caregivers shrinks, the demands of an aging population will continue to grow. By 2030, 72.8 million U.S. residents — more than 1 in 5 — will be 65 or older, raising overwhelming concern for who will care for this growing population. The number of older adults who are most likely to need intensive support from family caregivers — those in their 80s and beyond — stood at 27 percent of the population in 2012, and is projected to climb to nearly 40 percent by 2050.

The report confirms how essential family caregivers are to the health and well-being of the aging American population but also draws attention to our dependence on family caregivers as well as the potentially serious health and economic risks that caregiving can entail.

The study committee that wrote the report found that although caregivers' individual circumstances vary, family caregiving can negatively affect the mental and physical health of the caregiver and cause economic harm, including loss of income and career opportunities. Evidence indicates these individuals have higher rates of depressive symptoms, anxiety, stress, and emotional difficulties.

"Ignoring family caregivers leaves them unprepared for the tasks they are expected to perform, carrying significant economic and personal burdens," said Richard Schulz, committee chair and Distinguished Service Professor of Psychiatry at the University of Pittsburgh. "Caregivers are potentially at increased risk for adverse effects in virtually every aspect of their lives — from their health and quality of life to their relationships and economic security. If the needs of the caregivers are not addressed, we as a society are compromising the well-being of elders. Supporting family caregivers should be an integral part of the nation's collective responsibility for caring for its older adult population."

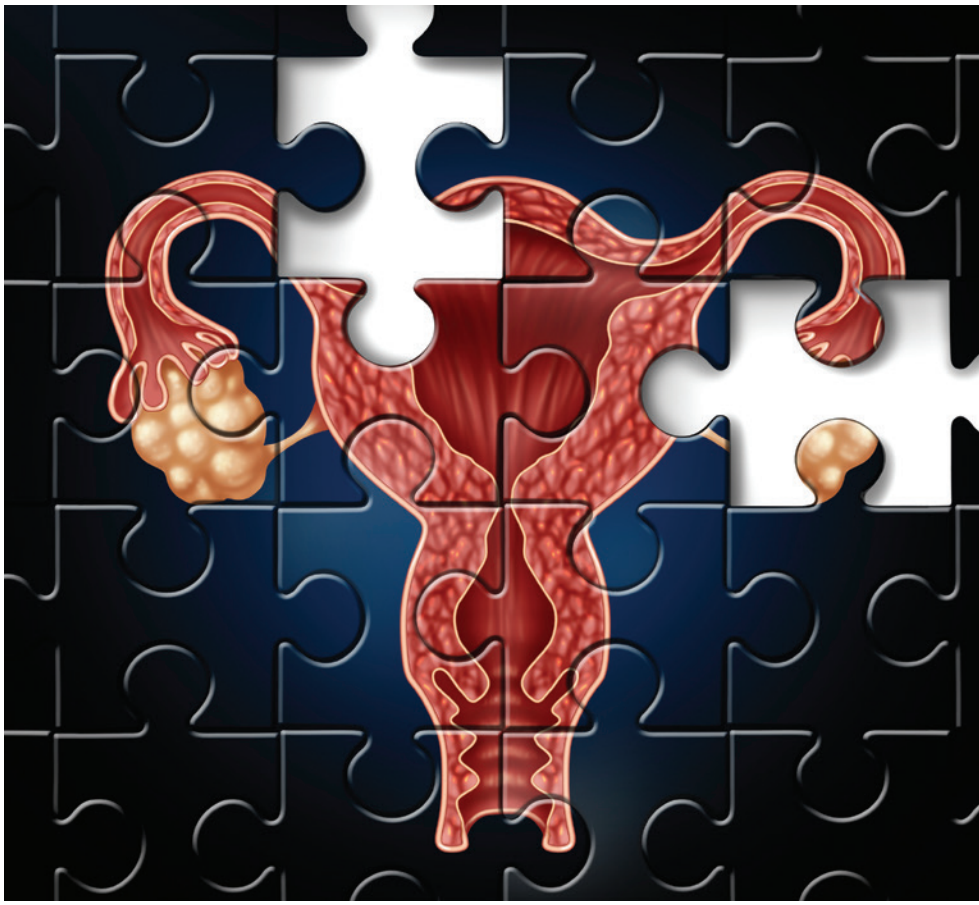
Little action has been taken to prepare health care and social service systems for this inevitable demographic shift. The report recommends that the new presidential administration take immediate steps to address the health, economic, and social issues facing family caregivers of older Americans. The secretary of the U.S. Department of Health and Human Services, in collaboration with the secretaries of Labor and Veterans Affairs, other federal agencies, and private-sector organizations should develop and execute a national family caregiver strategy. The strategy should include measures to adapt the nation's system for health care, workplaces, and long-term services and supports to recognize the essential role of family caregivers to the well-being of older adults. Specifically, the strategy should develop, test, and implement effective mechanisms with Medicare, Medicaid, and the U.S. Department of Veterans Affairs to ensure that family caregivers of older adults are routinely supported.

The committee also noted that most state governments do not yet address the health, economic, and social challenges of caring for older adults, and should look to the experience of states with caregiver supports and implement similar programs. The public's investment in family caregiving for older adults should be carefully considered, and public dollars should be shepherded responsibly. — *Jennifer Burris Olson & Jennifer Walsh*

Families Caring for an Aging America (2016, 366 pp.; ISBN 978-0-309-44806-2) is available from the National Academies Press, tel. 1-800-624-6242; $75.00 plus $6.50 shipping for single copies; also on the Internet at <www.nap.edu/catalog/23606>. The study was sponsored by the Alliance for Aging Research, Alzheimer's Association, an anonymous donor, Archstone Foundation, California HealthCare Foundation, the Commonwealth Fund, U.S. Department of Veterans Affairs, the Fan Fox and Leslie R. Samuels Foundation, Health Foundation for Western and Central New York, the John A. Hartford Foundation, May and Stanley Charitable Trust, the Retirement Research Foundation, the Rosalinde and Arthur Gilbert Foundation, Santa Barbara Foundation, and Tufts Health Plan Foundation.

Unmasking a Silent Killer

REPORT FINDS 'Surprising Gaps' IN WHAT WE KNOW ABOUT OVARIAN CANCER



With no distinct early symptoms and no effective screening tests, ovarian cancer is often called a silent killer. It is the fifth leading cause of cancer deaths among women, with a five-year survival rate of less than 46 percent.

A new Academies report aims to shed light on this stealthy cancer by identifying research opportunities with the greatest potential to reduce the number of women who develop or die from the disease. The committee that carried out the study and wrote the report pointed out that ovarian cancer is not a single disease but actually a constellation of different cancers that involve the ovary, and they often start in other locations besides the ovary, such as the fallopian tubes. Moreover, researchers do not have a complete understanding of how the many subtypes of ovarian cancer develop and progress. The committee recommended that a top priority in ovarian cancer research should be to determine the cellular origins and biological characteristics of each subtype.

"While progress has been made over the past few decades in ovarian cancer research, much remains to be learned," said Jerome F. Strauss III, chair of the committee and executive vice president for medical affairs and dean of Virginia Commonwealth University's School of Medicine in Richmond. "The more that is understood about the basic biology of various types of ovarian cancers, such as where they originate in the body, the more rapidly we can move toward advances in prevention, screening, early detection, diagnosis, treatment, and supportive care."

Better methods for identifying high-risk women could facilitate the prevention or early detection of ovarian cancers, the committee said. A family history of ovarian cancer, specific inherited genetic mutations, and certain hereditary cancer syndromes are strongly associated with ovarian cancer risk. The BRCA1 and BRCA2 genes, also associated with increased risk for breast cancer, are among the most recognizable genes related to ovarian cancer risk. Women with such gene mutations can take preventive steps to reduce their risk of ovarian cancer, such as surgical removal of the ovaries and fallopian tubes.

Multiple professional groups recommend that all women diagnosed with an invasive ovarian cancer receive genetic testing and counseling to assess the risk for other family members, yet this has not been universally adopted. The committee called for the development and implementation of innovative strategies to increase genetic counseling and testing for known inherited genetic predispositions to the disease.

The majority of women with an ovarian cancer, however, do not have an inherited gene mutation or a significant family history, and various factors limit the ability to accurately predict the risk of ovarian cancer at the individual level. Therefore, the committee called for the identification and evaluation of a range of potential risk factors for ovarian cancers in addition to genetics — including hormonal, behavioral, social, and environmental factors — in order to develop a risk assessment tool that accounts for the various ovarian cancer subtypes.

When assessing potential screening options for ovarian cancer, the committee found that no method tested thus far has had a substantial impact on death rates from ovarian cancer for general or high-risk populations. Imaging technologies are effective at

detecting pelvic masses but aren't sensitive enough to detect small, early lesions. And efforts to improve early detection technologies are hampered by an incomplete understanding of where and how the cancer cells form. The committee recommended that researchers and funding organizations focus on the development and assessment of early detection strategies that extend beyond current imaging technologies and blood tests.

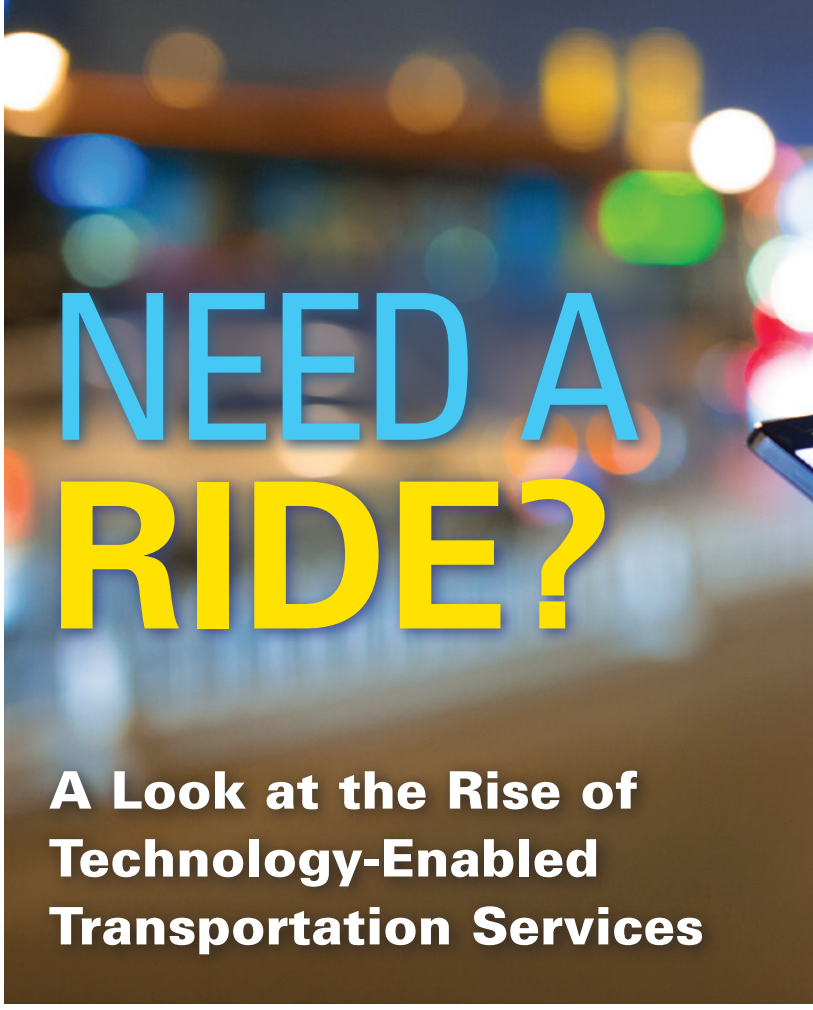
With regard to treatment, most women with newly diagnosed ovarian cancers undergo surgery to remove as much of the visible tumor as possible. For women in whom an optimal removal is not feasible, chemotherapy can reduce tumor size and facilitate subsequent surgical resection. The majority of women respond well to initial treatments, but most will unfortunately experience a recurrence of ovarian cancer, and virtually all recurrent ovarian cancers ultimately become resistant to the existing drug therapies. Better tools are needed to predict near- and long-term response to treatments for both newly diagnosed and recurrent cancers, the committee said.

While clinicians should have better ways to select the most appropriate treatment for individual patients, they also require more treatment options, and the development of better treatments depends in large part on clinical trials. A better understanding of the diversity of ovarian cancers would offer the potential for developing targeted treatments. Innovative early phase clinical trial designs that incorporate biomarkers predictive of treatment efficacy are needed to help identify which cancer subtypes are likely to be responsive to new therapies. With such tools, researchers could work toward the development of more effective therapies and combinations of therapies that take into account the unique biology and clinical course of the different subtypes of ovarian cancer.

The committee also found considerable variability nationwide in the quality of care provided to women with ovarian cancers. For example, survival times are markedly better for women who have complete surgical removal of the tumor, yet great variability exists in the extent of tumor removal. Being treated by a gynecologic oncologist and having treatment in a high-volume hospital or cancer center are the two most significant predictors of whether a woman with ovarian cancer will receive the appropriate standard of care and have better outcomes, but access to such care can be a challenge. To reduce disparities in care, clinicians and researchers should develop methods to ensure the consistent implementation of current standards of care — such as access to specialists, surgical management, a chemotherapy regimen, and universal genetic testing. — *Jennifer Walsh*

> "While progress has been made over the past few decades in ovarian cancer research, much remains to be learned."

Ovarian Cancers: Evolving Paradigms in Research and Care (2016, 396 pp.; ISBN 978-0-309-38046-1) is available from the National Academies Press, tel. 1-800-624-6242; $75.00 plus $6.50 shipping for single copies; also on the Internet at <www.nap.edu/catalog/21841>. The congressionally mandated study was sponsored by the Centers for Disease Control and Prevention.



NEED A RIDE?

A Look at the Rise of Technology-Enabled Transportation Services

The availability of on-demand transportation services through smartphone apps, such as Uber and Lyft, has dramatically boosted the numbers of people who choose such services to meet their daily travel needs over owning or driving their own cars. As of June 2015, Uber provided more than 1 million rides daily worldwide, while Lyft operated in 60 U.S. cities with more than 100,000 drivers.

For many years, the use of public transit and taxi services remained very low when privately owned vehicles with single occupants were the dominant form of ground transportation in the U.S. Today, innovative transportation services such as car sharing, bike sharing, and transportation network companies (TNCs) like Uber and Lyft are changing mobility for millions of people, yet regulation of these services and more established services such as taxis often varies greatly across geographic areas and industry segments, even when the services offered are similar. Most large cities with sizable street-hail markets extensively regulate taxis, while smaller cities where dispatch service is the norm tend to have lighter regulation.

An Academies committee recently examined the growth and diversification of technology-enabled transportation services and explored the implications they have for consumers. The committee also considered the challenges and opportunities that policymakers should consider as they begin to regulate these services. It recommended that policymakers and regulators formulate consistent policies that encourage competition among both new and traditional transportation services — such as taxis — in order to improve mobility, safety, and sustainability. Leveling the regulatory playing field requires a reassessment of existing regulations governing taxi and limousine services to determine the minimum rules necessary to ensure quality service. Re-evaluation will allow effective competition with TNCs while best serving the public interest.

To address public safety concerns, regulations for TNCs currently focus on background checks of drivers, vehicle inspections, and minimum standards for vehicle liability insurance. The various procedures for driver background checks are often based on common practice, but

their efficacy has not been rigorously evaluated; likewise, the safety benefits of viewing shared driver ratings and operator and vehicle images on mobile apps have not yet been well-documented. Therefore, regulators at the state and federal levels should evaluate these safety requirements for their effectiveness and cost, the report says.

Regulated taxis offer critical transportation options for people with disabilities in many areas, and although TNCs have introduced pilot programs to serve this population, they do not currently provide wheelchair-accessible services on an extensive or reliable basis, the committee's report says. About 10 percent of the U.S. population has a physical limitation; 3.6 million people use a wheelchair and another 11.6 million use a cane, crutches, or a walker. A decline in taxi fleets due to the continued rapid rise in TNCs could decrease the availability of for-hire vehicles for a substantial number of these travelers unless the quantity of TNC services for those with disabilities expands.

Furthermore, most shared mobility services require users to have a credit card on file with the provider and arrange the trip using a smartphone. However, roughly 8 percent of U.S. households lack bank accounts that allow them to have credit cards, and 50 percent of adults earning less than $30,000 and 73 percent of adults over age 65 do not own smartphones. The committee concluded that local officials should develop approaches for meeting the mobility needs of low-income, older, and disabled riders.

As personal transportation continues to evolve and use of innovative ways to get around continue to climb, transportation planning bodies should incorporate shared mobility into transportation planning initiatives and promote collaboration between public- and private-sector transportation providers. — *Dana Korsen*

Between Public and Private Mobility: Examining the Rise of Technology-Enabled Transportation Services (2016, 175 pp.; ISBN 978-0- 36964-0) is available from the Transportation Research Board, tel. 202-334-3213; $77.00 plus $9.00 shipping for single copies; also on the Internet at <www.nap.edu/catalog/21875>. The study was sponsored by the Transportation Research Board.

Climate Change's Influence on Extreme Weather

It isn't unusual to turn on the television and see a news report about an extreme weather event such as a heat wave, hurricane, or unrelenting drought, possibly leading one to wonder if these disasters are happening more often and getting worse, and if climate change is at the heart of the matter.

"An increasingly common question [to ask] after an extreme weather event is whether climate change 'caused' that event to occur," said David W. Titley, professor of practice in meteorology at Penn State and founding director of the university's Center for Solutions to Weather and Climate Risk, and chair of a study committee that wrote a recent Academies report on extreme event attribution. "While that question remains difficult to answer, given all the factors that affect an individual weather event, we can now say more about how climate change has affected the intensity or likelihood of some events."

Extreme event attribution — a fairly new area of climate science that explores the influence of human-caused climate change on individual or classes of extreme events compared with other factors, such as natural sources of climate and weather variability — typically estimates how the intensity or frequency of events have been altered by climate change and provides information that can be used to assess and manage risk, guide climate adaptation strategies, and determine greenhouse gas emissions targets. After a devastating hurricane or flood, communities may question whether to rebuild or relocate and look for input on how much more likely or more severe this type of event is expected to become in the future. Extreme event attribution could help inform these decisions.

The science of extreme event attribution has advanced rapidly in the past decade owing to improvements in the understanding of climate and weather mechanisms and the analytical methods used to study specific events. However, the committee noted, more research is required to increase its reliability, ensure that results are presented clearly, and better understand smaller scale and shorter

duration weather extremes such as hurricanes and thunderstorms.

In using this science, the most dependable findings are for those events related to an aspect of temperature and for which there is little doubt that human activity has caused an observed long-term change. For example, a warmer climate increases the likelihood of extremely hot days and

decreases the likelihood of extremely cold days. Long-term warming is also linked to more evaporation that can both exacerbate droughts and increase atmospheric moisture available to storms, leading to more severe rainfall and snowfall events.

Some extreme event attribution studies use observational records to compare a recent event with similar events that occurred in the past, when the influence of human-caused climate change was much less. Other studies use climate and weather models to compare the meteorological conditions associated with an extreme event in simulations with and without human-caused climate changes. The committee found results are most reliable when multiple and different methods are used that incorporate both a long-term historical record of observations and models to estimate human influences on a given event.

When conducting an extreme weather event attribution study, researchers are sensitive to the way the questions are framed and the context within which they are posed. For example, choices need to be made about defining the duration of the event, the geographic area impacted, what physical variables to study, what metrics to examine, and what observations or models to use. Assumptions and choices can lead to considerable differences in the interpretation of the results, and should be clearly stated.

Event attribution is also retrospective by nature. The report calls for the development of predictive weather-to-climate forecasts of future extreme events that account for natural variability and human influences that could be based on the concepts and practices used in the common day-to-day forecasts provided by the Numerical Weather Prediction framework.

— *Jennifer Burris Olson*

Attribution of Extreme Weather Events in the Context of Climate Change (2016, 186 pp.; ISBN 978-0-309-38094-2) is available from the National Academies Press, tel. 1-800-624-6242; $79.00 plus $6.50 shipping for single paperback copies; also on the Internet at <www.nap.edu/catalog/21852>. The study was sponsored by the U.S. Department of Energy, Heising-Simons Foundation, Litterman Family Foundation, David and Lucile Packard Foundation, National Aeronautics and Space Administration, National Oceanic and Atmospheric Administration, and the Arthur L. Day Fund of the National Academy of Sciences.

Building a National Trauma

The leading cause of death for Americans under the age of 46 is trauma. Of the 147,790 U.S. trauma deaths in 2014, as many as 20 percent — or about 30,000 — may have been preventable after injury with the help of optimal trauma care that includes prehospital care, such as emergency medical services, says a new report by the National Academies of Sciences, Engineering, and Medicine.

There have been some successes in the military sector in decreasing deaths after traumatic injury. Between 2005 and 2013, the percentage of wounded service members who died of injuries in Afghanistan decreased by nearly 50 percent. The civilian sector can deeply benefit by adopting best practices from the military, the report says. The study committee that wrote the report called for the White House to lead the integration of military and civilian trauma care to establish a national trauma care system and set an aim to achieve zero deaths that could have been prevented after injury.

To save the lives of Americans both on the battlefield and off, the committee's vision of a trauma care system is one with sound learning health system principles that can be applied across all phases of trauma care delivery — from prehospital care at the point of injury to hospitalization, rehabilitation, and beyond. Realizing this vision would require synergized military and civilian efforts, committed leadership from both sectors, and a strategy that aims to reduce variations in care and outcomes while supporting continuous learning and innovation.

"Both the military and civilian sectors have made impressive progress and important innovations in trauma care, but there

Care System

are serious limitations in the diffusion of those gains from location to location," said committee chair Donald Berwick, president emeritus and senior fellow, Institute for Healthcare Improvement, Cambridge, Mass. "Even as the successes have saved many lives, the disparities have cost many lives. With the decrease in combat and the need to maintain readiness for trauma care between wars, a window of opportunity now exists to integrate military and civilian trauma systems and view them not separately, but as one."

In the U.S., no single federal entity is responsible for trauma care capabilities and no level of government authority below the White House has the leverage to initiate collaborations within and across the military and civilian sectors. Furthermore, current research funding for the field falls below funding levels for other leading causes of death such as heart disease and cancer. The result is a piecemeal system for trauma care.

To build and sustain an expert military trauma workforce and help ensure the translation of military innovations into the civilian sector, the committee recommended embedding military trauma teams in the busiest and best civilian trauma centers across the nation. The report also calls for more military hospitals to become trauma centers, given that there are only three military hospitals currently verified as trauma centers.

Although ambitious, the committee's vision to improve the nation's trauma care through partnership between military and civilian sectors and a continued commitment from trauma system leaders at all levels is achievable. If followed through, the report says, casualties from future wars would experience better outcomes and all Americans would gain from the lessons learned on the battlefield.

— *Riya V. Anandwala & Jennifer Walsh*

A National Trauma Care System: Integrating Military and Civilian Trauma Systems to Achieve Zero Preventable Deaths After Injury (2016, 530 pp.; ISBN 978-0-309-44285-5) is available from the National Academies Press, tel. 1-800-624-6242; $75.00 plus $6.50 shipping for single paperback copies; also on the Internet at <www.nap.edu/catalog/23511>. The study was sponsored by the American College of Emergency Physicians, American College of Surgeons, National Association of EMS Physicians, National Association of Emergency Medical Technicians, Trauma Center Association of America, U.S. Department of Defense, U.S. Department of Homeland Security, and U.S. Department of Transportation.

Can You Hear Me Now?

Improving Access and Affordability for Hearing Health Care

Nearly 30 million Americans experience hearing loss, but only 14 percent to 33 percent of adults 50 years and older who stand to benefit from hearing aids use them. Various factors pose as barriers to access of hearing health care, such as the high price, lack of insurance coverage, and limited awareness of available options, as well as the stigma associated with wearing a hearing aid.

To tackle this significant health problem, a new report by the National Academies of Sciences, Engineering, and Medicine says efforts should be made to provide adults, especially underserved and vulnerable populations, with hearing health care options that are easily accessible and affordable.

Individuals cover the majority of the costs associated with hearing health care out of their pockets. The average price for a pair of hearing aids and the accompanying professional services was $4,700 in 2013. Typically, employers do not provide hearing health care insurance, and Medicare Part B covers only diagnostic hearing tests, not other services or technologies, although some Medicare Advantage plans do.

To make hearing health care easily available for the people, the committee that conducted the study and wrote the report recommended removing the regulation that an adult seeking hearing aids is required to first have medical evaluation by a physician or to sign a waiver of that evaluation. The committee found no evidence that this regulation provides any clinically meaningful benefit.

"Hearing loss has been relegated to the sidelines of health care," said committee chair Dan G. Blazer, J.P. Gibbons Professor of Psychiatry Emeritus at Duke University Medical Center in Durham, N.C. "For many people with hearing loss, trying to navigate the health care system to address their issues can be confusing and frustrating, and they can be left with no clear guidance on what will best fit their financial, health, social, and hearing needs."

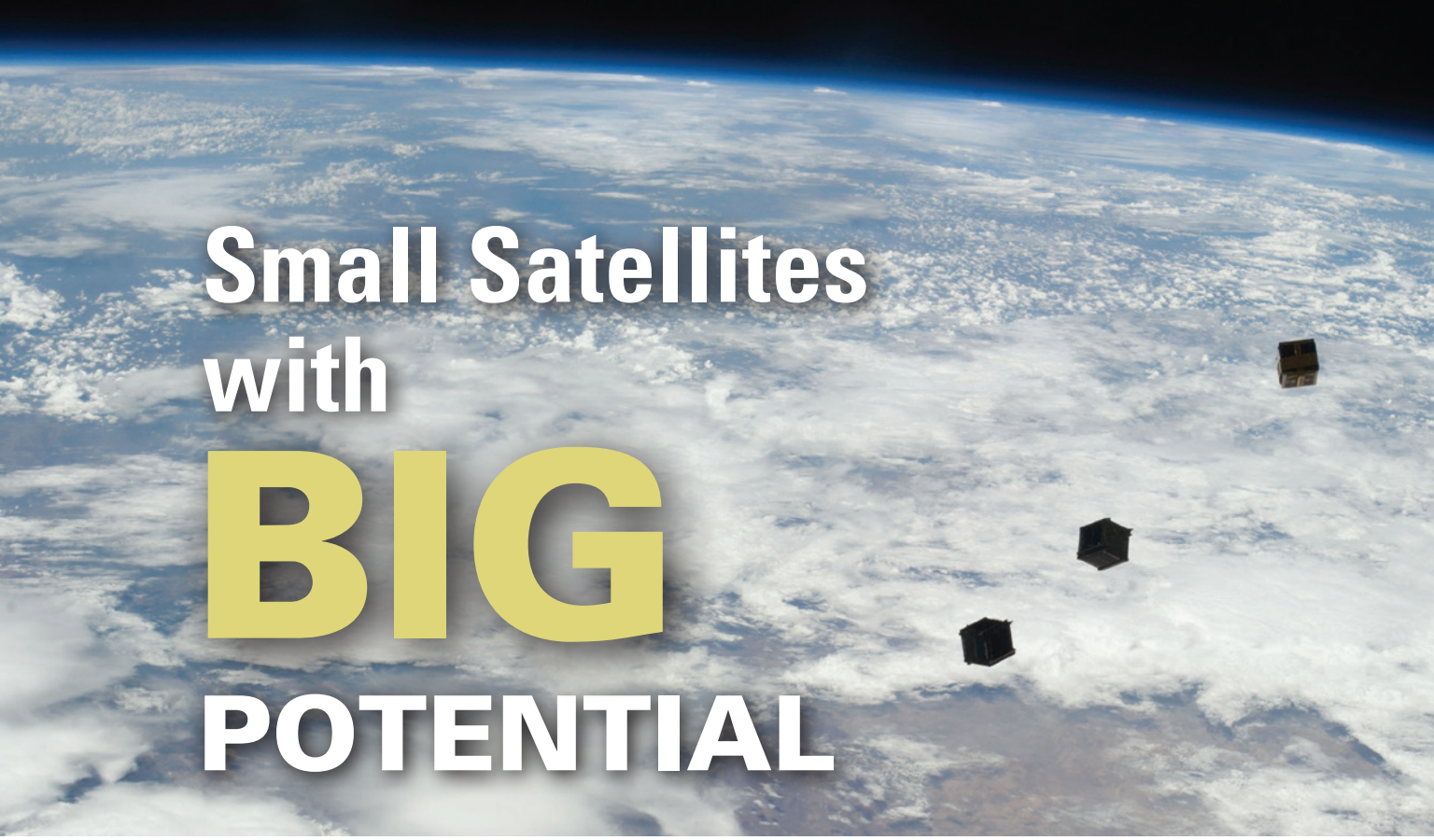
Currently, hearing aids are regulated by the FDA as Class 1 or Class 2 medical devices. However, people give several reasons for not using hearing aids, including their high cost, problems with fit and comfort, the stigma of looking old, and challenges with care and maintenance. The committee recommended that FDA establish a new category of over-the-counter hearing devices, intended for use by adults with mild and moderate hearing loss, that meet specific safety and quality standards. Electronic products termed as personal sound amplification products are available in the range of $50 to more than $500, and provide some or many technological features similar to hearing aids. FDA guidelines, however, note that these products cannot be marketed with the purpose of addressing hearing loss.

The committee also emphasized the need for greater transparency that provides consumers a breakdown of prices of technologies and related professional services to enable them to make more informed decisions. In addition, Medicare should evaluate options for providing coverage so that treating hearing loss is affordable for beneficiaries, and employers, private health insurance plans, and Medicare Advantage plans should evaluate options for providing their beneficiaries with affordable hearing health care insurance.

The report highlights steps people can take to manage their hearing health care, such as reducing exposure to noise that is at high volume levels for extended periods of time and use hearing protection, seeking information and help when they recognize difficulties in hearing and communication, and looking for peer-support groups for those living with hearing loss. The report recommends community-based organizations, advocacy organizations, employers, businesses, and government agencies promote work and community environments that are conducive to effective communication and support for individuals with hearing loss. Specifically, they should ensure compliance with the Americans with Disabilities Act and other related laws supporting those with disabilities and strive to exceed their minimum requirements as well as research and incorporate features into buildings and public spaces that improve hearing and communication.

— *Riya V. Anandwala & Jennifer Walsh*

Hearing Health Care for Adults: Priorities for Improving Access and Affordability (2016, 324 pp.; ISBN 978-0-309-43926-8) is available from the National Academies Press, tel. 1-800-624-6242; $80.00 plus $6.50 for single paperback copies; also on the Internet at <www.nap.edu/catalog/23446>. The study was sponsored by the Centers for Disease Control and Prevention, U.S. Department of Defense, U.S. Department of Veterans Affairs, U.S. Food and Drug Administration, Hearing Loss Association of America, National Institute on Aging, and National Institute on Deafness and Other Communication Disorders.



Small Satellites with BIG POTENTIAL

Want your own satellite, but having a hard time coming up with billions of dollars to get one? Not to worry. With around $50,000, you can build your own. Hundreds of CubeSats — 4 inch cube-shaped satellites that weigh about 2 pounds each — have been launched into low-Earth orbit in just the past few years. Universities, businesses, and government agencies are using single and multiple CubeSats to collect data, provide images, test technologies, and conduct a range of experiments.

But can these small satellites really provide high-value science data? The answer is yes, according to a National Academies of Sciences, Engineering, and Medicine report. In fact, CubeSats are already proving their worth to science and should be used to augment the capabilities of large satellite missions and ground-based facilities, the report says.

The report provides several examples of science goals that could be pursued with the technology. For example, CubeSats are uniquely suited to explore the Earth's atmospheric boundary region and examine the processes that shape it. The satellites could also be used to investigate the effects of microgravity and high levels of radiation on living organisms, or to provide multipoint, high-temporal resolutions of Earth processes such as severe storms. And CubeSats could be deployed by large satellite missions to conduct in-situ experiments on the physical and chemical properties or atmospheres of other planets.

To unlock the potential of CubeSats, continuing federal investment is crucial, the report says, especially in areas that hold little interest to the private sector. What's more, CubeSat projects offer hands-on educational and training opportunities to develop the leadership and project management skills of the

next generation of scientists and engineers. For these reasons, the National Science Foundation and NASA should continue to support their existing CubeSat programs and consider ways to expand into a variety of disciplines.

In addition, NASA and other agencies should invest in technology development programs that could have the biggest impact on science missions, including high-bandwidth communications, precision attitude control, propulsion, and the development of miniaturized instrument technology.

NASA should also build CubeSat capability to implement large-scale constellation missions — in which 10 to 100 science spacecraft are deployed. Such missions could enable critical measurements for space science and related space weather, weather and climate, and some astrophysics and planetary science topics.

CubeSats are evolving rapidly, and it is possible that they will have a much bigger impact and lead to new types of missions and scientific data. Along those lines, the report identifies some best practices that could guide the ongoing development of CubeSats.

As CubeSat missions grow more complex, they will need to be managed appropriately. Low-cost approaches should remain the cornerstone to CubeSat development, because more constrained platforms and standardization will create more technology innovation in the long run.

NASA should avoid premature "top-down" direction of technology development that would hinder experimental, riskier programs, slow progress, or limit potential breakthroughs. — *Molly Galvin*

Achieving Science with CubeSats: Thinking Inside the Box (2016, 130 pp.; ISBN 978-0-309-44263-3) is available from the National Academies Press, tel. 1-800-624-6242; $85.00 plus $6.50 shipping for single copies; also on the Internet at <www.nap.edu/catalog/23503>. The committee was chaired by Thomas H. Zurbuchen, professor of space science and aerospace engineering at the University of Michigan, Ann Arbor. The study was sponsored by NASA.

Science Priorities for a Changing Arctic

The Arctic is melting. The people and ecosystem of the Arctic region are facing significant effects from rapid warming, including the retreat of glaciers, melting of Greenland's ice sheet, thawing of permafrost, and loss of multiyear sea ice. These fast-paced changes to the Arctic environment are having growing impacts, some global in scale.

On Sept. 28, 2016, science ministers and advisers from 25 nations came together at the first-ever ministerial meeting on Arctic science hosted by the White House, to discuss collaboration and commitment to address the dramatic environmental changes facing the Arctic. This cadre of international leaders gathered to increase understanding of these environmental changes and identify priorities for international scientific cooperation. Some of the major themes the group focused on were solidifying and integrating data and observations on the region, building resilience and response mechanisms, and empowering citizens with STEM education.

The following day, the National Academies' Polar Research Board invited several of the representatives from the White House gathering to continue the conversation at a public event hosted

at the NAS building. Panelists at the Academies' forum were Nikolai Toivonen, director for international cooperation, Ministry of Education and Science of Russia; Hyoung Chul Shin, head of international cooperation at the Korean Polar Research Institute; Andrea Tilche, head, Climate Action and Earth Observation Unit and Directorate General for Research & Innovation, European Commission; and Satu Paasilehto, senior adviser, Finland Ministry of Education, Science, and Culture — each of whom fielded questions from the moderator, Julie Brigham-Grette, chair of the Polar Research Board, and from members of the audience. In addition, Ambassador Mark Brzezinski, executive director of Arctic Executive Steering Committee, Fran Ulmer, chair of U.S. Arctic Research Commission, and Kelly Falkner, director of National Science Foundation's Division of Polar Programs also spoke at the forum.

The ambition to contribute to Arctic science is different for each nation. The shrinking glaciers, receding sea ice, and coastal erosion are directly impacting the eight Arctic nations, but countries far away from the region are also feeling the consequences of a changing Arctic. For example, a warmer Arctic may be contributing to more extreme weather outbreaks around the mid-latitudes of the Northern Hemisphere.

"It's a delicate region, environmentally and also strategically, and no one country can dictate to everyone else what is needed," Brzezinski said at the Academies forum. "Following President Obama's visit to the

Arctic, we decided to convene this international gathering of science ministers to engage a process of cooperative setting of priorities in Arctic science."

The biggest takeaway from the White House event, according to Ulmer, was identifying the need to create a more robust observation system with an international governance regime and long-term financing. Observation is crucial in building the research infrastructure going forward and is also needed for improving weather, water, and sea-ice forecasting, and understanding how changes in the Arctic will affect conditions around the world and the evolution

of the Arctic under different global-emissions scenarios.

A number of efforts are underway to strengthen observation practices and improve data policies that promote sharing through full and open access. The work has already started moving in that direction with the European Union's five-year project to develop an Integrated Arctic Observing System (INTAROS) that will take shape starting this year. Also, the U.S. Office of Naval Research will start a five-year Arctic Mobile Observing System (AMOS) project that will develop new sensors, platforms, and techniques for a

science platform that will drift with the moving sea-ice cover or operate autonomously in the ocean below the ice.

The Arctic can also serve as a real-time laboratory to educate and train the next generation of scientists and engineers in a variety of disciplines. Efforts to incorporate Arctic science in STEM education will help to develop locally educated experts who can contribute to addressing some of their regional and global challenges.

For Toivonen, educating the Arctic populations is an important issue, and he also favors a working group to combine knowledge and competencies with other countries and build concrete research for data-sharing. "We care about the training and education of indigenous people, to help them stay in their native areas and develop their businesses for sustainable development of the Arctic region," he said.

The current challenges, and the potential to build unique solutions to address them, make this Arctic effort a model for setting sustainable development goals for the rest of the world, said panelists at the forum. Repeating the sentiments of one of the science representatives at the ministerial, Kelly Falkner said, "If we don't succeed in the Arctic, then we will have trouble succeeding in the world." — *Riya V. Anandwala*

Video recordings of the event can be viewed at <vimeo.com/album/4179625>.

Marcia McNutt Takes the Helm at the National Academy of Sciences

From the beginning of her career as a scientist and administrator, National Academy of Sciences President Marcia McNutt has never shied away from taking risks. In the early 1970s, for example, when McNutt was an undergraduate physics major at Colorado College, her adviser suggested that instead of pursuing astrophysics or high-energy physics as she had planned, she should try the relatively new field of geophysics for her future studies.

"He handed me the very first *Scientific American* article that had been written about plate tectonics — which had just been discovered in 1969," McNutt recalled. "I read that article and it just changed my life. I thought, 'This is so beautiful and so simple, it must be right.' I was hooked." She did an "about-face" and went on to become a marine geophysicist, traveling around the globe and serving as chief scientist or co-scientist on more than a dozen deep-sea expeditions while pursuing her research on the dynamics of the upper mantle and lithosphere on geologic time scales.

That sense of adventure and willingness to take on new challenges has been a hallmark of her impressive career. She left a comfortable academic position at the Massachusetts Institute of Technology in 1997 to become president and chief executive officer of the Monterey Bay Aquarium Research Institute, which under her leadership installed the first deep-sea cabled observatory in U.S. waters

and advanced the integration of artificial intelligence into autonomous underwater vehicles for complex undersea missions. As the head of the U.S. Geological Survey from 2009 to 2013, she directed the agency's response to a number of major disasters, including earthquakes in Haiti, Chile, and Japan and the Deepwater Horizon oil spill. In fact, McNutt was awarded with a Meritorious Service Medal from the U.S. Coast Guard for leading a team of government scientists and engineers at BP headquarters in Houston who helped contain

the oil and cap the well. And from 2013 to 2016, she served as the first female editor of the *Science* family of journals.

Now, as the first woman president of the National Academy of Sciences, she has taken the helm just as a new administration and Congress assume power in Washington. "I am deeply honored to be in this position. I don't think there has been any time in history when science has been more important," she says, or more an integral part of policymaking and decision making. "Just as no political leader or businessman would make a decision without consulting an attorney to make sure that anything they do is compatible with the laws of man, they should also never consider [taking action] without consulting scientists and making sure that their decisions are compatible with the laws of nature."

Personal connections will be key in working with newly elected leaders in Washington, McNutt says, just as they always have been. Toward that end, she wants to build upon the efforts of her immediate predecessor, the late Ralph J. Cicerone (see page 46), and continue to diversify the Academy's membership in every way — scientific discipline, geographical region, race, and gender. "We've got to have an Academy that is diverse and able to connect," McNutt explains. "For example, I suspect that this new administration will be very keen on technology and innovation. We really need members who are able to speak to that interest."

The Academies should also strive at being more nimble and responsive to study sponsors, McNutt says. "That's going to be especially important with this new administration. When they come to us for advice,

they're going to want it quickly. If we can't deliver on the time frames they want, I'm worried that they'll make decisions without our input." In addition, McNutt would like the Academy to raise more unrestricted funds to enable important new projects and activities that the government might not be able or willing to support.

Despite the challenges and uncertainties ahead, however, McNutt is confident that the NAS and the Academies will continue doing important work long after this administration leaves office. "A study can come and go. A decision can come and go. But our reputation is forever," she says. "We've been here for more than 150 years — a lot longer than any individual administration. As long as we continue to do what we do, and we stand our ground, the National Academies will be right here, where we've always been."

— *Molly Galvin*

New Fund Focuses on Enhancing the Resilience of Communities in the Gulf Region

Coastal communities in the Gulf of Mexico region have faced many difficult challenges over the years, from powerful hurricanes to the Deepwater Horizon oil spill. Efforts to improve resiliency — the ability of these communities to prepare and plan for, absorb, recover from, and adapt to adverse events — have focused on the necessary and important goals of strengthening infrastructure and the built environment.

However, there is another side to resiliency — the human side — that can often be overlooked. The physical and mental health of citizens, their culture and social cohesiveness, their socioeconomic health, and their well-being play important roles in the ability of communities to withstand and bounce back from adversity.

That's why the National Academies' Gulf Research Program and the Robert Wood Johnson Foundation joined forces to establish a $10 million fund to support projects that enhance the science and practice of community resilience in the Gulf region. Specifically, these projects would explore the complex and interrelated health, social, environmental, and economic factors that can influence a community's capacity to adapt and thrive in response to the adverse impacts of climate change, severe weather, or major environmental disasters.

A broad array of projects will be encouraged through the program. For example, one focus could be on identifying underlying issues that affect resilience in coastal regions such as health equity or economic and workforce patterns, and developing or testing strategies to address them. Other research could examine how approaches to minimizing or repairing environmental impacts could also produce additional 'co-benefits' for health and well-being, or how strategies for enhancing mental and physical health of communities can also influence resilience.

"This funding opportunity seeks to find effective, evidence-based approaches for improving resilience by bringing scientists and practitioners from diverse fields together with leaders in the community, public, and private sectors," said LeighAnne Olsen of the Gulf Research Program.

"We need more research that illuminates connections between community resilience and health, which is absolutely essential to building the evidence base for a 'Culture of Health,'" added Brian C. Quinn, assistant vice president of Research-Evaluation-Learning at RWJF. — *Molly Galvin*

For more information, visit <national-academies.org/gulf/grants/index.html>.

Committee on Human Rights Celebrates Its 40th ANNIVERSARY

Nearly six years ago, Omid Kokabee, an Iranian physicist and Ph.D. student at the University of Texas, was arrested in Iran when he returned to visit his family over the university's winter break. Sentenced to 10 years in prison on charges related to contact with a hostile government, Kokabee said that his arrest followed his refusal to work on security and military nuclear energy-related projects in Iran. Amnesty International considered Kokabee a prisoner of conscience and the charges against him to be spurious. Making matters worse, Kokabee suffered from severe health problems in prison — including kidney stones and intestinal bleeding — for which he was long denied care.

Kokabee was diagnosed with kidney cancer in early 2016. He was finally granted access to medical care, including a needed kidney operation, and, in August 2016, freedom on parole. Among the groups who had worked persistently for his release and access to medical care was the Committee on Human Rights (CHR), a standing committee of the National Academy of Sciences, Engineering, and Medicine which in 2016 celebrated its 40th anniversary of advocating on behalf of individual scientists, engineers, and health professionals who are subjected to severe repression for exercising internationally recognized human rights. The committee, composed of 14 members of the three Academies, is led by Martin Chalfie, a member of NAS and NAM.

"We're currently following over 60 cases around the world and taking action at points in the process where our advocacy is

most likely to be effective," said Rebecca Everly, who directs the committee at the Academies and coordinates the work of its many volunteers.

A large part of the committee's work involves reaching out to high-ranking officials abroad and in the United States who are in a position to provide assistance in individual cases, says Everly. CHR shares information about its cases with about 1,600 members of NAS, NAE, and NAM who have agreed to be CHR correspondents, as well as members of 80 academies abroad, inviting them to advocate on behalf of individuals experiencing human rights abuses. "Over the 40 years that CHR has been in existence, Academy members have provided a great deal of support to colleagues," said Everly. The committee also uses a confidential United Nations complaint procedure that enables indirect conversations with governments and helps to ensure answerability for human rights abuses.

The idea of an Academy committee dedicated to human rights originated in 1976, as a recommendation of the NAS Council Committee on National Science Policy. The committee was created to serve as the official voice of the NAS on individual cases of human rights abuse involving colleagues. The Council also invited the National Academy of Engineering and Institute of Medicine (now National Academy of Medicine) to take part in the committee's work.

In connection with its 40th anniversary, CHR also celebrated the contributions of Carol Corillon, who served as director of the committee for 33 years before she retired in 2015. "I was fortunate to chair and serve on the CHR for several years during the Corillon era," said Peter Agre of the Johns Hopkins Bloomberg School of Public Health, who chaired CHR from 2005 to 2007. "It was obvious to all of us that Carol was a major force in organizing the CHR and establishing its mission. With her pleasant but relentless guidance, an amazing legacy of human rights advances was accomplished."

Why is it important for the Academies to do this kind of work? "There are many human rights organizations out there, but we play a unique role as a body of scientists, engineers, and health professionals providing support to colleagues under threat," said Everly. "We emphasize the non-political nature of our work and stress the connection between science and human rights, given that rights to freedom of thought and expression, as well as many other fundamental rights, are themselves essential for scientific work."

CHR doesn't do its work alone. It engages with other human rights organizations on issues of common interest — for example, the Institute of International Education's Scholar Rescue Fund, which provides fellowships for academics who face threats to their lives and careers in their home countries, so that they can continue their work in safety at academic institutions elsewhere. — *Sara Frueh*

In Memoriam

Ralph J. Cicerone

National Academy of Sciences President Emeritus Ralph J. Cicerone — a leader of science and world-renowned authority on atmospheric chemistry and climate change — died at his home in New Jersey on Nov. 5. He was 73.

Cicerone served as the 21st president of the National Academy of Sciences from July 1, 2005 to June 30, 2016. Throughout his tenure, Cicerone was a steady voice for science in Washington, always maintaining a civilized and respectful dialogue with politicians and policymakers on some of the most challenging and controversial scientific issues of our time. At the same time, he remained a strong advocate for independent scientific advice — the hallmark of the Academy since its founding in 1863 — to inform government decision-making and public discourse.

"The entire scientific community is mourning the loss of this great leader who has been unexpectedly removed from the forefront of the scientific issues that matter most to the future well-being of society," said Marcia McNutt, Cicerone's successor as president of the National Academy of Sciences. "Ralph Cicerone was a model for all of us of not only doing what counts, but doing it with honesty, integrity, and deep passion."

Cicerone was an atmospheric scientist whose research uniquely situated him to shape science and environmental policy, both nationally and internationally. In 2001, he led a key National Academy of Sciences study about climate change requested by President George W. Bush. Ten years later, under Cicerone's leadership, a comprehensive set of reports called *America's Climate Choices* was issued, calling for action on reducing greenhouse gas emissions while identifying strategies to help the nation and world adapt to a changing climate. Also under Cicerone's guidance, the NAS and the Royal Society

— the science academy of the U.K. — teamed up in 2014 to produce *Climate Change: Evidence and Causes,* a publication written for policymakers, educators, and members of the public.

Engaging the general public in science was a major priority for Cicerone, who spearheaded the creation of the Academy's Science & Entertainment Exchange. This unique program connects entertainment industry professionals in Hollywood with top scientists and engineers to assist in the portrayal of science in film and TV. He also worked on the development of the widely cited 2008 book *Science, Evolution, and Creationism,* which laid out the scientific evidence supporting evolution in a readable way for many audiences.

Within the NAS, Cicerone's initiatives demonstrated his commitment to maintaining the institution's relevance in a rapidly changing world — while still upholding its values of independence and excellence. Under his leadership, the NAS focused on increasing the number of women, minorities, and younger scientists elected to its membership. Cicerone also spoke out publicly for the need to maintain integrity and transparency in research. In his frequent visits and consultations with members of Congress, key Hill staffers, and federal agency heads, he spoke out on behalf of science and science education.

In May 2016, at its 153rd annual meeting, the National Academy of Sciences announced the creation of the Ralph J. and Carol M. Cicerone Endowment for NAS Missions. With a $10 million challenge grant from the Simons Foundation to launch a special campaign to raise matching funds, the endowment will strengthen the Academy and be used to develop and support NAS programs and policy studies on newly emerging topics before they are widely recognized as major challenges to the nation.

"This endowed fund will help underpin the Academy's roles: to validate scientific excellence, enhance the vitality of the scientific enterprise, guide public policy with science, and communicate the nature, values, and judgments of science to government and the public," Cicerone said when the endowment was announced.

Cicerone is survived by his wife Carol, their daughter, and two grandchildren.

THE SURPRISING CONNECTIONS THAT CAN TAKE **RESEARCH** TO

A commonly used piece of ICU equipment can lead to serious — and sometimes fatal — infections. Intensive care units use central venous catheters to deliver medications and fluids to patients via a narrow tube inserted into a large vein. Those tubes, however, can become infected and deliver bacteria or fungi directly into a patient's bloodstream. But a solution to this problem came from an unexpected place: social science.

Every year, about 80,000 patients nationwide were infected this way. The medical community saw these infections as an inevitable risk of using these catheters. But social scientists found that changing the ICU's culture could drastically reduce the risk of infections.

Their experimental use of a checklist, along with support from hospital administrators to follow it diligently, saw dramatic reductions in catheter infections, resulting in saved lives and reduced medical costs.

That's just one example of a serious issue solved through basic research featured in "From Research to Reward," a series of online articles and videos launched by the National Academy of Sciences that tells stories of surprising connections that have saved lives and improved society. Some of the others are:

- **Economists who found a better way to match kidney donors with those who need them.**
- **Political scientists who developed methods to predict the actions of foreign adversaries.**
- **A psychologist who figured out how to reduce car collisions.**
- **An economist who devised a "cap and trade" system to confront acid rain.**

The series makes an important point: Public support of scientific research is vital to improving our economy, our society, our nation, and our world. Not all research seems to have practical implications at first glance, but the outcomes can produce remarkable benefits that no one foresaw. And those benefits can pay for the initial research investment many times over. — *Stephen Mautner*

"From Research to Reward" can be found at <www.nasonline.org/r2r>.

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