

nih record



ABOVE • Circus clown Pickles visited NIH Mar. 14, entertaining children. See back page for more.

features

	1
Duke's Califf Has Prescription for Ailing Clinical Trials System	
	3
NIH'er Saves a Life Using CPR	
	5
GulF Study Marks Milestone	
	12
R&W Treats Kids to the Circus	

departments

Briefs	2
Feedback	9
Milestones	10
Volunteers	11
Seen	12

Baby Steps Not Enough

Clinical Trials Need Major Remodeling, Califf Says

By Carla Garnett

We need to rethink the clinical trials system—from the ground up. That's what Dr. Robert Califf proposed at a recent Mind the Gap seminar, "Innovative Approaches to Clinical Trials."

"I hope to convince you that incremental changes in our clinical trials system will not be sufficient," he said. "We really have to prepare ourselves for a major transformational change."

Vice chancellor for clinical and translational research and director of the Duke Translational Medicine Institute, Califf has studied the business of conducting clinical studies for decades. Outlining some of the problems with the current system, he said the nation's biggest challenge might be overcoming a mindset about the way we've always done clinical trials until now.

"You'll see that in the context of defining the problem, it's technically a non-problem," he explained. "[The hurdle] turns

SEE CLINICAL TRIALS, PAGE 6

Duke's Dr. Robert Califf calls for a major overhaul of clinical trials in the U.S.



Tomic-Canic Explores Science Of Wound-Healing

By Rich McManus

Normal human skin has a mind of its own. Wound it, even in the Petri dish, where you can grow massive sheets of it from a single biopsy, and it will start to heal itself.

But there is a population of patients, many elderly or with diabetes, whose wounds just don't heed the chemical rallying cries of growth factors, cytokines and chemokines that instantly set to work once our protective covering has been breached.

In a talk she titled "Wizardry of Tissue Repair and Regeneration: A Tale of Skin Cells When Their Magic Is All But Gone," Dr. Marjana Tomic-Canic, director of the Wound Healing



Dr. Marjana Tomic-Canic

SEE WOUND-HEALING, PAGE 8

Improvements to Cycling Culture Undertaken at NIH

In an effort to increase the percentage of NIH'ers who commute to work by bike from a current 3 percent, NIH recently completed an inventory of its cyclist-friendly amenities, with an eye to making pedaling an even more attractive option.

The Office of Research Facilities surveyed such infrastructure as bike racks (volume and location), showers and lockers and connectivity of the campus to the burgeoning network of local bikeways. The report card came back satisfactory, but with a number of recommendations for improvement.

"We should be making it easier to cycle to work than to drive," said Dan Wheeland, ORF director, who touted the health benefits of bicycle commuting, its removal of cars from congested local roads and crowded parking lots, its environmental friendliness and even its benefit to NIH patients: they can have more places to park.

SEE CYCLING CULTURE, PAGE 4



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NIH...Turning Discovery Into Health

briefs

Bike to Work Day, May 18

Celebrate National Bike Month and Bike to Work Day with the NIH Bicycle Commuter Club (NIH-BCC), Friday, May 18, from 7 to 9:30 a.m. on the Paul Rogers Plaza in front of Bldg. 1. NIH will host three of the many local pit stops supported by the Washington Area Bicyclists Association in a national salute to bicycle commuting.

Last year, more than 11,000 area residents participated in this annual event and even more are anticipated this year. NIH has won the Metropolitan Washington Council of Governments award 5 years in a row for being the area's biggest employer of Bike to Work Day participants. Help us defend our title this year by registering online at www.recgov.org/r&w/nihbike/. Even if you do not choose NIH as your pit stop, writing in "National Institutes of Health" as your employer will help us defend our title.

NIH will again be hosting two other pit stops: Executive Blvd. and the Marriott-sponsored stop at Rockledge (pit stop name "Rock Springs Business Park"). The Executive Blvd. stop runs from 8 to 9:30 a.m. and Rockledge runs from 6:30 to 9 a.m. At all NIH pit stops, employees and contractors who show up riding a bicycle and wearing a helmet may enjoy breakfast snacks and participate in a raffle including such prizes as cycling gear and equipment and Fitness Center memberships. All pre-registrants get a free Bike to Work Day T-shirt (you may want to bring a print confirmation of your registration as back up).

If you have never tried commuting by bike to NIH and aren't sure how to begin, explore the Commuting link at the URL above. The NIHBC offers advice on topics ranging from purchasing a bicycle to favorite NIH commuting routes from all over the D.C. area.

Bike to Work Day is a rain or shine event. Volunteers are always appreciated to help with preparations before or on the day of the event. If you would like to help, email Diane Bolton (dbolton@nih.gov).

Author Tannen To Present at DDM Seminar

The Deputy Director for Management (DDM) announces the second DDM seminar of the 2011-2012 series "Management and Science: Partnering for Excellence." The event on Thursday, Apr. 19 from 11 a.m. to 12:30 p.m. in Masur Auditorium, Bldg. 10, will feature Dr. Deborah Tannen, author of *You Just Don't Understand: Women and Men in Conversation*, which was on the *New York Times* best-seller list for nearly 4 years. Tannen will

address the NIH community in a presentation about gender, culture and communication in the workplace titled "Can We Talk? How Gender and Culture Affect Who Gets Heard, Who Gets Ahead and What Gets Done at Work."

Videocasting and sign language will be provided. Individuals who need reasonable accommodation to attend should call (301) 496-6211 or the Federal Relay Service at 1-800-877-8339. For more information about the series, visit www.ddmseries.od.nih.gov or call (301) 496-3271.

NIH Mentoring Program Is Recruiting

Federal employees interested in serving as learners and advisors across the NIH community are invited to join the April 2012 cohort of the NIH Mentoring Program. Program components include senior-to-junior and peer-to-peer mentoring relationships, online application and matching system to connect individuals, mentor-mentee online orientation, 1-year mentoring relationship commitment and professional development events and activities. The deadline for online registration and matching is Apr. 30. For more information, visit http://trainingcenter.nih.gov/hhs_mentoring.html.

National Day of Prayer, May 3

This year's observance of the National Day of Prayer will be held Thursday, May 3 from 11:30 a.m. to 1 p.m. on the lawn in front of Bldg. 1. Come out and join fellow NIH'ers, patients and friends to celebrate a day Congress has set aside for our country. Federal and military compounds all over the country will have their National Day of Prayer program on the same day with guest speakers, music and prayer. All are welcome.

NIH Minority Health Promotion Day, Apr. 19

The first NIH Minority Health Promotion Day will take place on Thursday, Apr. 19 from 10 a.m. to 4:30 p.m. in the south lobby of the Clinical Center and Masur Auditorium. The celebration will commemorate National Minority Health Month.

The day will begin with a display of health promotion resources and posters highlighting a variety of areas related to improving minority health. Representatives will be on hand from 10 a.m. to 1 p.m. to distribute health promotion materials, share information about their programs and answer questions. The day's events will culminate in the afternoon with a speakers' forum starting at 1 p.m. in Masur Auditorium focusing on the social determinants of health. Keynote speakers include Shawn Malarcher of the U.S. Agency for International Development; Dr. Thomas E. Feucht of the Department of Justice; Dr. Peter J. Ashley of the Department of Housing and Urban Development; and Dr. Brian D. Smedley of the Joint Center for Political and Economic Studies.

The event is open to the public; no registration is required. Visit www.nimhd.nih.gov for more updates about the event.

nih record



Dr. Elodie Ghedin (second from r) poses with (from l) Dr. Janine Austin Clayton from the Office of Research on Women's Health, NIAID deputy director Dr. Hugh Auchincloss, and Nalini Anand from the Fogarty International Center.

MacArthur Fellow Helps NIAID Celebrate 2012 International Women's Day

Dr. Elodie Ghedin, assistant professor of computational and systems biology at the University of Pittsburgh School of Medicine and Center for Vaccine Research, served as guest speaker at the 2012 International Women's Day Lecture at NIH on Mar. 7.

Her lecture, titled "Genomics and Neglected Tropical Diseases: The View from My Half of the Human Race," discussed her work studying the genomes of parasites that cause neglected tropical diseases (NTDs) such as leishmaniasis, Chagas disease, elephantiasis, river blindness and African sleeping sickness. NTDs affect more than 1 billion people worldwide and historically have not received as much attention as other diseases. Ghedin emphasized the importance of collaboration among lab researchers, bioinformatics scientists and field workers to improve the understanding of NTDs and to find better ways of preventing and treating them.

Ghedin is a former NIAID postdoctoral fellow and current NHLBI grantee who received a 2011 MacArthur Fellowship for establishing herself as "a leader of international projects that coordinate the efforts of scores of scientists to decode the function of some of the most virulent human pathogens," according to the MacArthur Foundation.

CPR Training Helps NIH'er Save a Life

When Allan Muise, a project officer in the Office of Research Facilities, took CPR training at NIH a few months ago, he had no idea that he would soon be employing his life-saving lessons.

On the morning of Mar. 9, while walking to a Metro station with his wife, Muise came upon a woman lying motionless on her back on the sidewalk. "As we approached, one man was talking on a cell phone and said desperately, 'Just send somebody quick!' Someone else said, 'We didn't find a pulse.' A third woman was on her knees, trying to give chest compressions to the victim, but it was obvious that she didn't know what she was doing."

Muise said the victim appeared lifeless. "When we see people, they have a healthy glow in their skin," he said. "The victim had no such glow. The body almost looked like a hunk of clay, totally motionless."

He began giving chest compressions, during which the body jerked several times. "I yelled, 'Are you okay?' but I didn't expect to get an answer. After giving about 40 chest compressions, I put my cheek down by the victim's mouth, and I felt a warm, moist breath coming out."

Muise later found out from the Rockville Fire Department that the woman had suffered cardiac arrest, spent 4 days in the ICU and later went home.

Muise now gives motivational speeches at NIH CPR training sessions. He said the victim has indicated that she wants to get in contact with those who helped her.

"I would be very pleased to meet her," Muise said. "The [Rockville] fire department expressed an interest in using me to promote CPR and I told them that I was more than willing."

The CPR training course Muise took is called NIH Lay Responder AED/CPR Training and is available at www.ors.od.nih.gov/sr/dohs/HealthAndSafety/aed/Pages/AED-and-CPR-Training-.aspx.



PHOTO: STEVE MCCAWE

Sills To Head Society of Toxicologic Pathology

When the Society of Toxicologic Pathology (STP) gathers in June for its annual symposium, its new president will be NIEHS/NTP pathologist Dr. Robert Sills, who is chief of NIEHS and NTP pathology and the Cellular and Molecular Pathology Branch.

"We [at NIEHS and NTP] have been honored with my selection as president-elect of the Society of Toxicologic Pathology, which, personally, is very humbling," he said. Sills joined NIEHS/NTP in 1991, became head of the molecular pathology group in 1997, and has been chief of pathology since 2007.

Sills has served on the STP executive council and editorial board of the STP journal *Toxicologic Pathology*. He is also associate editor of the environmental pathobiology section of the journal *Veterinary Pathology* and has served on UN/WHO and FDA advisory committees.



CYCLING CULTURE

CONTINUED FROM PAGE 1

Above:

No, there wasn't any snow this past winter. This is a photo of the type of covered bike shelter that will soon debut on the grounds of the recently renovated Bldg. 3.

The ORF survey found that the campus has an adequate number of bike racks (62), but 42 of them are going to be relocated in 5 areas to meet the highest demand. A map of all rack locations is being prepared. NIH is also adding bike shelters in some locations; the recently renovated Bldg. 3 will get one of the first new stand-alone sheltered racks.

There is presently parking for 1,003 bikes on campus. Twice a year, in spring and fall, the NIH Bicycle Commuter Club counts the number of bikes in all campus bike racks. That gives NIH leadership an idea of how many people currently bike to work and helps ORF determine where best to locate racks.

In its survey of changing rooms, ORF identified 84 shower/changing rooms scattered across campus and issued 68 maintenance tickets to address such problems as malfunctioning or missing shower plumbing fixtures, broken lockers and insufficient lighting. In most of these facilities, there are one or two showers and a handful of lockers.

Wheeland acknowledged that more shower facilities are needed on campus and said that current renovations to Bldg. 10's F-wing will include such facilities on floors 2-13. "We will do the same thing when we renovate the E-wing, if funds are available," he added. "It will be a priority for all future building renovations on campus."

The availability of lockers is also a priority for many cyclists. "I was lucky to snag a shower room locker," said Dr. Calman Prussin, an NIAID investigator who commutes to campus by bike. He said he tripled the number of his bike-commute days when a locker became available.

ORF is also exploring ways to make it easier for cyclists to enter campus by providing alternatives to waiting in vehicle lanes or dismounting and guiding bikes through pedestrian turnstiles, said David Derenick, an ORF project officer.

Last fall, NHLBI facility planner Bobby Klosowski wrote a review of NIH's bicycling program as part of work towards a master's degree in urban planning at Catholic University. "There is an enormous opportunity to increase the number of bicycle commuters through a concerted planning effort that aims to create a safe, supportive, reliable bike culture at the NIH," he wrote.

His report advises NIH to apply to become a Bicycle Friendly Business through the League of American Bicyclists' Bicycle Friendly America program, which establishes standards of quality in the bike-commuting world. NIH could therefore rank with such outstanding cycle cultures as Stanford University, Oregon Health and Science University and the University of Colorado at Boulder.—**Rich McManus** 📧

National Research Center Honors Birnbaum

NIEHS/NTP director Dr. Linda Birnbaum will receive the 2012 Health Policy Hero Award May 11 during the annual awards luncheon of the National Research Center for Women & Families (NRC), held at the Cosmos Club in Washington, D.C.

Katharine Weymouth, publisher of the *Washington Post*, will emcee the program.

Birnbaum is being honored "for...outstanding leadership at the National Institute of Environmental Health Sciences and the National Toxicology Program," said NRC president Dr. Diana Zuckerman. "We are inspired by your work on behalf of all Americans, as groundbreaking research, prevention and intervention efforts make our homes and communities safer across the country."

Birnbaum joins a select group of past winners, including Dr. Margaret Hamburg, commissioner of the Food and Drug Administration; Dr. Catherine DeAngelis, former editor of *JAMA*; and two members of Congress, Rep. Rosa DeLauro and Sen. Chuck Grassley.

The NRC is dedicated to improving the health and safety of adults and children by using research to encourage more effective programs and policies. The organization achieves its mission by gathering, analyzing, critiquing and explaining scientific and medical research.



PHOTO: STEVE MCCAWE

GuLF Study Marks Recruitment Milestone

Nearly 2 years after the Deepwater Horizon oil spill in the Gulf of Mexico, more than 10,000 cleanup workers and volunteers have enrolled in the Gulf Long-term Follow-up (GuLF) study.

The study is a national effort conducted by NIEHS to determine if the oil spill led to physical or mental health problems. Recruitment continues, with



Dr. Dale Sandler and her team have held community meetings in towns affected by the oil spill, in conjunction with media tours to raise awareness of the GuLF study.

PHOTO: STEVE MCCAWE

the goal of reaching 55,000 participants, which would make it the largest health study of its kind.

“Ten thousand people have stepped forward to help find answers for their community and for the health concerns that linger after the oil spill,” said Dr. Dale Sandler, chief of the NIEHS Epidemiology Branch and principal investigator of the study. “I encourage anyone who helped in the cleanup effort to enroll in the GuLF

study. We want to hear everyone’s story. Everyone is important to this study.”

For more information, people can call the toll-free number at 1-855-NIH-GULF (1-855-644-4853) or visit www.niehs.nih.gov/gulfstudy/.

NIEHS was in the Gulf at the beginning of the oil disaster that occurred on Apr. 20, 2010, and offered safety training to more than 150,000 cleanup workers. Now, some of these workers have concerns about their health as a result of participating in the cleanup. The GuLF study was designed to answer some of these questions and will generate data that may help guide policy decisions on health care and services in the Gulf region. Findings may also influence responses to future oil spills.

The GuLF study staff reached out to the 150,000 people who took the cleanup worker safety training, but volunteers have been hard to find. Many have moved to new residences or changed telephone numbers, so the study has been using a range of approaches to invite people to join the study, including billboards, radio and TV, Facebook and Twitter and community meetings.

When volunteers join the GuLF study, they are

asked to complete a survey over the telephone. Most participants will also get a medical exam at home and provide blood, urine and other samples. When the medical visit is complete, participants will receive a gift card worth \$50.

“We are grateful to have the support of more than 100 community and professional groups across the Gulf that represent workers who believe in the GuLF study and who have endorsed it,” said Sandler. “The study was developed to make participation as easy and convenient as possible and participation is confidential. We protect the identity of every participant.”

Grady Promotes Clinical and Translational Science at UC Irvine

NINR director Dr. Patricia Grady highlighted the importance of interprofessional and multidisciplinary teams in science and evidence-based health care at a recent clinical and translational science (CTS) event presented by the University of California Irvine Program in Nursing Science. She served as the kickoff speaker for the new seminar series, which is cosponsored by the Robert Wood Johnson Foundation (RWJF) and the UC Irvine Institute for Clinical and Translational Science.

Drawing from the 2010 Institute of Medicine report *The Future of Nursing: Leading Change, Advancing Health*, Grady noted, “Nursing science, because of its exceptionally broad mandate and the cross-cutting nature of its research portfolio, is active in virtually every field of clinical translational science.”

Grady described several NINR CTS research efforts that are taking bench and bedside discoveries and translating them into sustainable and scalable solutions to advance health care in real-world settings. Examples include microchip technology for HIV detection in Africa; radio frequency identification technologies in surgical suites; theory-driven health promotion and disease prevention interventions for underserved inner-city communities; and national initiatives in transitional care supported by the Affordable Care Act, the National Quality Forum, the Veterans Administration, CMS, AARP and Kaiser Permanente.

Grady also discussed two major CTS initiatives that are transforming the health sciences and health care: the Campaign for Action, a nationwide initiative sponsored by RWJF, AARP and the AARP Foundation that is implementing IOM’s *Future of Nursing* recommendations, and the CTSA Consortium, now part of the new National Center for Advancing Translational Sciences.

In conclusion, Grady said, “Nursing research—and its translation into evidence-based practice and policy—stands as a keystone for improving the health and welfare of people around the world, and at NINR we see CTS and implementation research as essential components of our core mission.”



NINR director Dr. Patricia Grady (c) poses with (from l) Dr. Ellen Olshansky, professor and director of the University of California Irvine Program in Nursing Science, and Dr. Alison Holman, assistant professor, UC Irvine Program in Nursing Science and Robert Wood Johnson Foundation nurse faculty scholar. Grady holds the UC Irvine mascot.

PHOTO: ELIZABETH EASTIN

Right:

Califf said it costs an estimated “\$400 million to do a global clinical trial with industry for a chronic indication.” We could do a more efficient version for less than half that amount, he surmised.

PHOTOS: BILL BRANSON



CLINICAL TRIALS

CONTINUED FROM PAGE 1

out to be a social and cultural set of issues that we’re going to have to get over if we want to make the next set of advances in health and health care.”

‘Toss of a Coin’

Califf said the medical research community should develop a system that continuously records well-defined, coded data in practice, and in the midst of quality improvement and observational studies, it should not lose “focus on interventional trials that are randomized...The only difference between clinical practice and a pragmatic randomized trial should be the toss of a coin. That’s the way we need to change the fundamental way we’re thinking about medicine and clinical practice, as we evolve into a true learning health system.”

Much of what we assume about our current medical practices may be based on myth anyway, he pointed out. Using national clinical practice guidelines to examine the evidence base for medical decisions, for example, he and some of his colleagues in heart disease research asked themselves a question.

“How often,” he asked, “when we make a significant recommendation do we have high-level evidence from multiple randomized trials, and how often is it ‘level C,’ which means, ‘We have no earthly idea, but there are experts who think they know’?”

The answer surprised them.

“About 15 percent of the time we have high-level evidence to back up a recommendation,” Califf reported. “So far no other specialty has been willing to stand up and say they base their decisions on more than 13 percent. We’re making decisions every day that are life and death—or chronically important—knowing that empirically it’s pos-

sible to answer the question, but [we’re] just not doing it...because the way we currently do [clinical trials] is so labor-intensive and so expensive that we could only answer a very limited number of questions in the universe.”

The same team of researchers took the query a step further: “What percentage of the time are we completely flying without instruments?” they wondered. The answer: “It’s about half the time.”

What’s Stopping Innovation?

That’s not to say the data is not available to inform decisions, Califf noted. Truth is, we now have so much information that we’ve run out of ways to harness it for our purposes.

“The problems I’m talking about are a good thing,” he said. “We have these problems because we’ve made so many advances that we’ve exhausted the old methods and the old way of thinking...The bottom line is, our knowledge has accelerated beyond the ability to provide empirical support for decision-making.”

Califf suggested a “3-compartment model, with innovation in every compartment.” The components would be proof-of-concept and biological mechanism trials, studies to identify risk/benefit balance (late phase 2, early phase 3 trials) and studies to gauge effectiveness at societal and individual levels.

“Types 2 and 3 are merged,” he proposed. “We’re going to increasingly see less of a distinction between risk/benefit balance of individual products and effectiveness in the community.”

Another big problem, Califf suggested, is too many needless rules. Overregulation defeats innovation, he said.

“In such a regulated industry—where there’s so much at stake if an error is made—it leads to a situation where people are so afraid to take risks that they rarely do anything new,” he said. “We need an ‘innovation envelope’ to try new things until the system is transformed. Experiment with agreement ahead of time, [so researchers know] it’s okay to do the experiment and you’re not going to be punished for trying, even if things go bad.”

Streamline Trial Design

In closing, Califf addressed two other issues that prevent advancement: health systems, driven by the need for efficiency, are not supporting clinical research, which in its current form is prohibitively expensive; and protocol design, which has become too complex and burdensome.

“I call it the ‘Christmas tree effect,’” he said. “You



Califf (r) greets well-wishers after his lecture.

start out with a beautiful green tree that should be admired and then everybody in the family wants to put an ornament on it...and no one will take grandma's ornament off the tree. So you end up with a protocol that is impossible to do and is very distracted from answering the question you originally had."

Califf said it costs an estimated "\$400 million to do a global clinical trial with industry for a chronic indication." We could do a more efficient version for less than half that amount, he surmised.

"It's our belief," he concluded, "that you could markedly reduce the costs of clinical trials if you are willing and able to take the streamlined approaches that we've all talked about for years now."

Watch Califf's entire talk online at <http://videocast.nih.gov/> under Past Events. NIH's Office of Disease Prevention, NHLBI, NIA and NIAAA presented the lecture. 📺

First Schatzkin Lecture Set, Apr. 16

The first Arthur Schatzkin Distinguished Lecture in Nutritional Epidemiology will be held on Monday, Apr. 16 at 3 p.m. in Lipsett Amphitheater, Bldg. 10. Dr. John Potter, senior advisor of the division of public health sciences at Fred Hutchinson Cancer Research Center and professor of epidemiology at the University of Washington, will discuss "Nutrition, Environment, Development and Cancer: Casting a Wider Net." NCI established the lecture in memory of Schatzkin, a leader in the field of nutrition and cancer.

5th Annual Free Community Shred Day, Apr. 20

On Friday, Apr. 20, from 4 to 7 p.m., FAES, in collaboration with Torn2Shredz, will be sponsoring a Free Community Shred Day. Bring up to 2 boxes worth of personal documents for free destruction and recycling. Limited compact fluorescent light bulb and battery recycling will also be available. Location is the FAES Social & Academic Center, 9101 Old Georgetown Rd. For more information, contact Rose McNeely, (301) 530-2194 or email FAESSAC@gmail.com.



Togo West (l), former secretary of the Army and Veterans Affairs, addresses participants during the INRO 10-year anniversary celebration. At right, INRO participant Carlos Castrodad-Rodriguez of the University of Puerto Rico at Cayey asks a question during a scientific talk.

NIAID Diversity Program Celebrates 10 Years and Counting

By Marci Karth Better

"Take a look at those around you; these will be your future colleagues." That was only one of many suggestions Dr. Michael Gottesman, NIH deputy director for intramural research, gave the 10th class of NIAID's diversity program—Intramural NIAID Research Opportunities (INRO). The 2012 class included 20 minority students from across the country selected to visit NIAID to learn about its research portfolio and training opportunities.

The 10th anniversary celebration also included former participants, one for every year of INRO, who came to inspire and offer advice to the students and to current NIAID trainees. Juliana Lewis, part of the first INRO class in 2003, agreed with Gottesman: "You're not just here for the labs, but you are also here to build a scientific community for yourself [that] you can take with you no matter where you go." She is finishing her doctoral dissertation at Tufts University-Sackler School of Biomedical Sciences and is considering a postdoc traineeship at NIH.

According to INRO founder Dr. Wendy Fibison, associate director of NIAID's Office of Training and Diversity, "These lasting relationships are the hallmark of the program's success." The program has a mantra, "Once an INRO, always an INRO." Fibison believes the network she is building is just as important as the science in engaging young minority students to stay in STEM fields.

NIAID has had a long-standing commitment to address the lack of minorities in biomedical research. In keeping with that commitment, Fibison created INRO to fit the needs of the institute's intramural program. Over 10 years, she recruited the best students she could find and enlisted the support of senior investigators willing to accept the responsibility of mentoring junior minority students.

More than 200 students have participated in INRO since its inception. Of those, 50 percent have returned to NIAID for a traineeship and most continue to embrace research careers.

Although the past 10 years have been successful, there is more work to be done. Some ethnic populations continue to be dramatically underrepresented in biomedical research. Their representation within NIAID labs and among the senior leadership is disproportionate to the U.S. population. The next 10 years are promising, says Fibison, but only if programs such as INRO are fully supported. "Until we have appropriately diverse research staff in our labs, we must continue to make INRO and other programs like it a priority," she said.

Keynote speaker Togo West, former secretary of the Army and Veterans Affairs, capped the anniversary with a talk about some of America's trailblazing historical figures. His comments illustrated some qualities of a leader. "You teach the life you live," he concluded.



WOUND-HEALING

CONTINUED FROM PAGE 1

Above:
Tomic-Canic (l) speaks with NIH deputy director for intramural research Dr. Michael Gottesman at a reception in the NIH Library after her talk.

PHOTOS: MICHAEL SPENCER

and Regenerative Medicine Research Program at the University of Miami Miller School of Medicine, showed how cutting-edge science (no pun intended) is revealing more about the biology of skin, our largest organ.

“We are now in the midst of an epidemic of chronic wounds,” she said at a Wednesday Afternoon Lecture on Mar. 7. According to 2005 data, worldwide, a lower limb is lost to diabetes every 30 seconds. In the United States, more than \$25 billion is spent annually on wound care.

Tomic-Canic’s lab is exploring why some wounds don’t heal. “There are very few effective products,” she said, and wound-healing represents “a tremendous clinical burden.” While more than 3,000 products have been approved for treatment on the basis of safety, only a handful have reached the efficacy threshold for FDA approval, she said.

Tomic-Canic comes by her interest in skin honestly; she began her career as a pediatric nurse in a burn unit. “Skin has this enormous regenerative and proliferative potential,” she said. It is no surprise, she noted, that skin cells (fibroblasts) were the cell type to yield the world’s first induced pluripotent stem cells. Skin cells are robust and eager to do their job of maintaining a protective barrier to the outside world.

“These cells really do know what to do on their own, without our help,” Tomic-Canic marveled.

Back in 2002, she applied to the National Institute of Nursing Research for a grant to study non-healing wounds and was told her proposal was impossible to accomplish. That only motivated her to work harder and resubmit her proposal to obtain gene expression profiles from

biopsies taken from the non-healing edge of patients’ venous ulcers. That work won NINR funding and has, to date, yielded a roster of some 1,557 genes that are de-regulated in non-healing wounds. It also established a new translational research field that has already changed clinical practice.

Tomic-Canic and her colleagues have employed what she calls “wound-omics” to distinguish tissue that is healing-competent from healing-incompetent.

The non-healing phenotype is characterized by loss of:

- cellular migration
- appropriate signals and response to growth factors, and
- differentiation in the epidermis.

Further analysis, she said, identified two distinct cell/tissue phenotypes within chronic wounds—healing-impaired and healing-competent—that can be linked to clinical outcomes in patients.

Signal loss, she explained, originates from high protease activity, decrease of receptors and signaling molecules that mediate the signals, and an increase of specific miRNA molecules.

One approach to restore the healing phenotype is to use biomarker-guided removal of cells that are non-healing. “Gene profiles can serve as a guiding tool for surgical debridement—it’s, in a simplified sense, a kind of pregnancy test for wounds,” said Tomic-Canic. Her team’s goal is to uncover a small set of genes that will serve to predict what wound is healing, and to distinguish tissue within a wound that can heal from tissue that can’t.

“We are narrowing down the list of genes and cellular biomarkers,” she said. “Our hope is that one day there will be a gene chip for wounds.”

She thinks skin is the ideal tissue in which to attempt gene and progenitor cell therapy approaches, since it could be applied topically and temporarily, with a goal of restoring a healing phenotype. Cell sources could be from the patient’s own tissue; progenitor cells could be generated and introduced in a similar way.

“These are probably the most exciting times in biomedicine,” she enthused. “The good days are coming.” ●

feedback

Have a question about some aspect of working at NIH? You can post anonymous queries at www.nih.gov/nihrecord/index.htm (click on the Feedback icon) and we'll try to provide answers.

Feedback: Why is smoking tolerated in the parking lot area behind Bldg. 10 (adjacent to the cafeteria) when NIH is supposed to be a "smoke-free" campus? While I understand that only employee supervisors are empowered to address this, it seems unimaginable that this daily occurrence has gone unnoticed to this point. I see the same thing on the dock area along Bldg. 13.

Reply from the Office of Research Services: NIH has collective bargaining agreements with unions representing employees who work at NIH. Until the Tobacco Free Policy can be made a part of all these agreements, there will be individuals who are allowed to smoke on the campus as long as they abide by the previous NIH Smoking Policy. For more information about the current policy, visit <http://tobaccofree.nih.gov/tfpolicy.htm>.

Feedback: When are NIH and other federal agencies going to stop discriminating against committed same-sex couples? Whereas committed opposite-sex couples are allowed the same access to federal benefits as legally married opposite-sex couples (such as health insurance), committed same-sex couples are not. In light of the recent repeal of the "Don't ask, don't tell" regulation in the United States military, isn't it time to offer federal benefits to all the committed couples, regardless of their sexual orientation? It seems a bit unfair that a newly formed opposite-sex couple gets federal benefits, yet a same-sex couple that's been in a committed relationship for 20 years does not.

Response from the Office of Human Resources: In June 2010, a Presidential memorandum directed federal agencies to implement the changes necessary to extend benefits to same-sex domestic partners of federal employees that are currently available to opposite sex spouses, wherever permitted by law. The benefits extended include, among others, access to day care for the children of employees' domestic partners, travel and relocation allowances and access to employee assistance programs. In addition, same-sex

partners are eligible to apply for coverage under the Federal Long Term Care Insurance Program and can be designated as the beneficiary to receive payment of life insurance, retirement contributions, Thrift Savings Plan account balance and unpaid compensation.

Some other programs, however, such as the Federal Employees Health Benefits Program, Federal Employees Dental and Vision Insurance Program, Federal Employees Group Life Insurance Program and Flexible Spending Accounts Program could not be extended to same-sex partners. The Defense of Marriage Act narrowly defines a spouse to be a person of the opposite sex who is a husband or a wife and marriage to be a legal union between one man and one woman as husband and wife.

Questions may be directed to the Benefits and Payroll Liaison Branch at (301) 496-4556. 📞

Shrubs at NIH Provide Food for Insect Zoo

NIH recently donated prunings from about 15 Photinia fraseri plants on the main campus to the National Museum of Natural History's insect zoo. The zoo uses the plant—common name red-tip photinia—as diet for most of its walking stick insects. Shown at right, the shrubs are located along the west edge of lot 14G, just outside the entrance to Bldg. 14G. The mature plants have not been sprayed with any pesticides. "It is not really a rare plant as it is used at many new housing developments because it is very hardy, insect- (except walking sticks!) and disease-free and is inexpensive," notes Lynn Mueller, landscape architect, Office of Research Facilities. "Photinia are a broad-leaf evergreen like azaleas and rhododendrons, so in that respect it is somewhat rare. They have nice small clusters of white flowers in early summer that are attractive. It's a good plant but must be used in a particular site since they are strong growers—as you can see from our planting—but they can take severe pruning." A museum technician came to NIH and clipped the 20 or so branches needed for eats at the insect zoo.



3rd Annual Halo Chase, Apr. 19

The 5K run/1-mile walk, sponsored by R&W and the NIH Health's Angels Running Club, will take place on Thursday, Apr. 19 at 11 a.m. at the Bldg. 1 flagpole. Suggested donations of \$10 are being accepted and will go to benefit the NIH Charities. For more information about this event, including how to register, visit www.recgov.org/halochase/.

milestones



Dr. Rajesh Ranganathan is new director of NINDS's Office of Translational Research.

Ranganathan Tapped for NINDS Office

NINDS recently named Dr. Rajesh Ranganathan director of its Office of Translational Research. He will lead the institute's efforts to more quickly and effectively convert basic and clinical research results into new treatments for patients.

Ranganathan was formerly a senior advisor in the NIH Office of the Director, where he led the effort to assess the translational medicine pipeline across NIH and helped develop a strategy that led to the formation of NCATS.

Prior to coming to NIH, Ranganathan was global head of the education office and a director in the program office at Novartis Institutes for Biomedical Research from 2005 to 2010. He held responsibility for global postdoctoral training, scientific strategic planning and scientific review.

Ranganathan received his undergraduate degrees in biology and chemistry at Amherst College. He received his Ph.D. in biology at Massachusetts Institute of Technology, where he worked on genetics of behavior modulation in *C. elegans* with Nobel laureate H. Robert Horvitz. Ranganathan completed postgraduate training with Dr. Linda Buck, also a Nobel laureate, at Harvard Medical School and Fred Hutchinson Cancer Research Center in Seattle, where he studied sensory mapping of neural circuits involved in mammalian pheromone regulation.

Endocrinology Society Honors Korach

NIEHS senior researcher Dr. Kenneth Korach is this year's winner of the Dale Medal, the highest accolade awarded by the Society for Endocrinology (SfE). As part of his award, Korach delivered an acceptance lecture for the Dale Medal, "Estrogen receptor insensitivity: basic and clinical consequences in hormone and endocrine physiology," Mar. 20 at the annual SfE meeting in Harrogate, England.

The Dale Medal recognizes outstanding studies that have changed the understanding of endocrinology in a fundamental way. Criteria for it



PHOTO: STEVE MCCAWE

include an international reputation in high-quality science in high-impact journals.

In 1976, Korach joined NIEHS, where he currently heads the receptor biology group investigating estrogen hormone action in numerous tissues by the generation of estrogen-receptor knock-out mouse models with a goal of understanding the basic mechanisms of estrogen's influence on physiological processes and disease. He is chief of the Laboratory of Reproductive and Developmental Toxicology.



NIAID's Handelsman Mourned

Dr. Edward Handelsman, chief of the Maternal, Adolescent and Pediatric Research Branch in NIAID's Division of AIDS, passed away unexpectedly on Mar. 5 while attending the annual Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle. He was 49 years old.

"Ed will be sincerely missed and remembered not only for his dedication to his work, but for being a kind, thoughtful man who truly wished to make the world a better place," said NIAID director Dr. Anthony Fauci.

Prior to joining NIAID in 2006, Handelsman worked as a pediatrician specializing in caring for children and adolescents infected with HIV. For 14 years, he worked in all areas of pediatric HIV care in Brooklyn at the State University of New York Downstate Medical Center and at Kings County Hospital Center, treating patients, conducting research, developing standards of care and teaching medical students. During this time, Handelsman also was co-principal investigator for NIH-funded clinical sites affiliated with the pediatric AIDS clinical trials group and the Women and Infants Transmission Study. Additionally, he served as assistant medical director for pediatrics for the New York State department of health's AIDS institute.

"Ed was a wonderful, kind, supportive physician with a passion for caring for HIV-infected women, children and adolescents," said Dr. Carl Dieffenbach, director of DAIDS. "His unexpected death has robbed the world of a physician-scientist who dedicated his career to seeing that the research fostered by NIH provided meaningful benefits to these individuals with HIV. His humor, warmth and love of life will be sorely missed."

According to Dieffenbach, Handelsman's most important achievement at NIAID was his work on the Children with HIV Early Antiretroviral (CHER) study, which in 2007 found that the risk of death for HIV-infected infants treated with antiretroviral therapy (ART) immediately after diagnosis was significantly lower compared with that for babies who did not begin treatment until they showed signs of illness or of a weakened immune system. Based on this finding, the World Health Organization revised its treatment guidelines the following year to recommend that ART begin immediately after HIV diagnosis in HIV-infected children, regardless of their health status.

On Mar. 6, the CROI meeting featured a presentation announcing that additional analysis of the CHER study provided evidence that HIV-infected infants who received immediate treatment could safely stop ART after 1 to 2 years and continue to fare significantly better than infants who did not receive immediate treatment. Further, many infants who discontinued treatment were able to remain off antiretrovirals during the follow-up period of approximately 5 years.

Handelsman is survived by his mother, Carol Handelsman; his sister Helene Simons; his two nieces, Anna and Rebecca Simons, and his nephew, Will Simons. The family has requested that contributions in Handelsman's memory be made to one of the following charities that were important to him: Liquid Camp/Healing Waters Wilderness Adventures, 167 Fell St., San Francisco, CA 94102-5106; The Joey Dipaolo AIDS Foundation/Camp TLC, 1 Garrett Place, 1I, Bronxville, NY 10708; or the Elizabeth Glaser Pediatric AIDS Foundation, 1140 Connecticut Ave., NW, Suite 200, Washington, DC 20036.—**Tasheema Prince**

NINDS Mourns Program Director Miller

Dr. Thomas Miller, a program director in the NINDS Office of Translational Research, died suddenly on Feb. 26 of a heart attack. He was 63.

He joined NINDS in 1997 as a program director in the technology development cluster (now the Office of Translational Research) in the Division of Extramural Research.

Miller's research interests included technology development, genomics, research infrastructure and translational research. He played a critical role in the microarray consortia, the P30 Core Centers and in establishing many key features of the NINDS translational research program. He also provided the NIH RAID program with outstanding leadership.

"Tom was amazingly dedicated to the success of these programs and worked tirelessly to educate investigators about the goals of the programs," said NINDS director Dr. Story Landis. "Those of us who worked with Tom will always remember his passion, dedication and commitment to excellence."

News of Miller's death spread quickly among investigators. One of them wrote, "The guy was a *mensch*. We thought the world of him."

Miller received his Ph.D. in physiology from the University of California, San Francisco in 1980, and his M.B.A. in finance from the Wharton School of the University of Pennsylvania in 1987.

He is survived by his wife Anita, who works in the Grants Management Branch, NINDS.—**Shannon E. Garnett** 



Midlife & Menopause Research Studies Seek Healthy Volunteers

Healthy women ages 40-65 are invited to participate in outpatient research studies. Compensation is provided. Call (301) 496-9576 and refer to studies 88-M-0131 and 03-M-0175.

Did You Ever Have Postpartum Depression?

If you suffered from postpartum depression (PPD) following the birth of any of your children, consider participating in this 8-month outpatient research study at the Clinical Center. The NIMH research study is designed to examine the role of hormones in the onset of your PPD. To participate, you must be 18-50 years old with regular menstrual cycles and not taking any medications. Call (301) 496-9576 and refer to study 95-M-0097. There is no cost to participate and compensation may be provided.

Suffering from Chronic Abdominal Pain?

Are you suffering from chronic abdominal pain? The National Institute of Nursing Research has developed a clinical trial investigating gastrointestinal pain symptoms in males and females in order to better understand the origins of abdominal pain. Males and females who are between the ages of 13-45 and have experienced abdominal pain for 6 months or more may be eligible to participate. The study requires two outpatient visits and will be conducted at the Clinical Center. Compensation will be provided and all study-related tests will be provided without cost. For more details, call (301) 443-4693.

Thousands Entertained at Annual Circus Premier Night

On Mar. 14, the NIH Recreation & Welfare Association continued delighting children and their families at the 15th annual Children's Premier night at the Ringling Bros. and Barnum & Bailey Circus. The event, held at the Verizon Center, featured the theme "Fully Charged."

"This year, between the Easter Seals and the R&W, over 8,500 individuals attended the circus," said Randy Schools, R&W president. "The R&W has now treated 37,500 children to the circus."

The youngsters came not only from the NIH patient community, but also from social service agencies such as Bethesda Cares, Interfaith Works, YMCA family services, City of Gaithersburg and Rockville shelters, Schools said. Guests also attended from Children's National Medical Center, Howard University Hospital and Georgetown University Medical Center.

"Additionally we had two buses from Walter Reed Hospital with wounded warriors. It was a great evening, with a special party, and a time for families to meet with the entertainers," said Schools. "The R&W received many notes of thanks."

At midday on Mar. 14, circus clown Pickles (Sean Davis) visited both out- and inpatient pediatric units at NIH, as well as the Children's Inn. As you can see in the photos at right, the kids loved him.



Above, the family and friends of NIH patient Arjanae Penny enjoy pre-circus festivities at Verizon Center. Below (l), Santiago Rodriguez trades poses with a clown named Pickles. Also amused by Pickles' antics are (below, r) Alexandra Kniffin (l) and Osiris Year (r).



Above, ringmaster Brian Crawford Scott (in hat) and sidekick Vas meet circus guests. At right, Paulina Y. Mejia plays with daughter Marian Y. Madrid at a pizza dinner preceding the circus. Below, Circus strongman Pickles visits NIH patients Jalen Strawder (l) and Rylan Pederson.

PHOTOS: MICHAEL SPENCER

