

THE NIH RECORD

Still The Second Best Thing About Payday

Sea Snail Venom Yields Powerful New Painkiller

By Alisa Zapp Machalek

People whose pain is unresponsive even to morphine may now find relief from an



Dr. Baldomero Olivera

unlikely source—the venom of a poisonous sea snail. A new drug derived from this venom became available to patients just recently. It is the culmination of decades of basic research supported by the

National Institute of General Medical Sciences.

The new medicine, called Prialt, or ziconotide, has its roots in a boy's curiosity

SEE NEW PAINKILLER, PAGE 4

Update on Campus Construction Projects

While there is a great deal of construction activity on campus right now, more is on the way. On Jan. 6, the National Capital Planning Commission approved NIH's most recent update of its 20-year Campus Master Plan (see *NIH Record*, Nov. 23, 2004, for details), along with the Commercial Vehicle Inspection (CVI) facility and the main Gateway Center near the Medical Center Metro station on Rockville Pike.

Construction on the CVI should begin about Mar. 1, according to Karen Rhodes, program manager with the Office of Research Facilities. This 12-month project is overseen by Project Officer Johnny Madlangbayan and will stretch from Wilson Drive north to North Drive. Once completed, the inspection station will include a

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Setting a 'Higher Standard'

'Sweeping' Ban on Outside Activities Announced, Affects All Employees

By Carla Garnett

NIH director Dr. Elias Zerhouni announced on Feb. 1 a "sweeping" ban on consulting and other activities employees may engage in outside of their federal jobs. The new ethics regulations—which apply not only to NIH's approximately 5,000 intramural scientists, but also to every federal employee at the agency—took effect on Feb. 3, the day they were published in the *Federal Register*.

"We believe we need to hold ourselves to a higher standard," said Zerhouni at a 45-minute news conference called in Bldg. 1 to announce the new policies.

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NIH director Dr. Elias Zerhouni (r) and NIH deputy director Dr. Raynard Kington discuss ethics rules.

Changing the Landscape

NIH To Make 'Public Access' Effective May 2

By Rich McManus

After a long period of public comment and controversy, NIH made official on Feb. 3 its intent to create an online public archive of the research it funds. Starting May 2, the National Library of Medicine's PubMed Central will host an electronic, searchable database of peer-reviewed journal articles funded by NIH money within 12 months of the articles' appearance in print, but preferably as soon as possible. NIH-funded investigators will be asked, not required, to post their manuscripts to PMC so that citizen-taxpayers will have free access to the work their money has purchased.

In telephone briefings first with stakeholders then reporters, NIH director Dr. Elias Zerhouni provided his rationale for what he called a dramatic change in the landscape of science. "Until today, there has been no policy on public access to NIH science," he said. "We felt strongly that a change was needed, that the status quo was not good enough, and that the interests of the public were not served."

Zerhouni noted that some 93 million Americans visit the World

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Women's Health Research: Looking to the Future

The Office of Research on Women's Health recently sponsored a meeting titled "Looking to the Future" to discuss major paths of women's health and sex/gender research and career development for women scientists that ORWH and NIH should pursue in the coming years. More than 90 representatives of institutes and centers, extramural research institutions, interdisciplinary research programs, professional societies and advocacy organizations attended.



ORWH director Dr. Vivian Pinn

Dr. Vivian Pinn, ORWH director, invited wide-ranging input: "There is no predetermined outcome—we want to hear from

the constituents of

women's health research about the directions they believe should be taken in the future."

Attendees praised ORWH for its 14-year history of "collaboration, outreach and a vision for research across the life span of women" and urged that these hallmarks of its approach continue in the future. A brief overview of a formal evaluation of ORWH's first 10 years set the stage for the discussion. Among the highlights were an increase of 143 percent in the number of RFAs and PAs addressing women's health issues, a 48 percent increase in research project grant

(RPG) applications involving women's health research, and substantial increases in the number of RPG and F32 fellowship applications submitted by women and awards to women.



Gerson Weiss, M.D.

Dr. Gerson Weiss

Over the years, ORWH has expanded the concept of women's health research to distinguish sex (biological) and gender (self-concept and societal) factors, as recommended by an Institute of Medicine report, *Exploring the Biological Contribution to Human Health: Does Sex Matter?* Attendees

suggested that more research be conducted with comparative data analyses for women and men to determine the effects of sex and gender factors on health and disease.

Other approaches included expanding interdisciplinary research to encourage more collaboration with fields such as engineering, physics and the behavioral and social sciences; considering public/private research collaboration; and developing international research and treatment programs.

Multiple career issues persist for women in biomedical research that require expanded efforts in the future, according to several attendees. The increased enrollments of women in medical institutions can obscure the fact that the ceiling is still low for women in the academic environment for faculty positions and advancements. Also, Dr. Gerson Weiss, chair of the department of OB/GYN at New Jersey Medical School, pointed out that, of those who begin in research, "many do not continue and many are lost, especially women and minorities." He said that mentors are needed at all levels of entry and advancement, and training for women and minorities is needed in such practical matters as how to negotiate a contract and how to combine personal and professional roles.

Dr. Leslie Wolfe, president of the Center for Women Policy Studies, pointed out the importance not only of research but also of ORWH itself: "Essential to creating these new research opportunities is advocacy for sustaining and even enhancing the NIH and ORWH ability to support them." Women's health advocates indicated that many in Congress think "the job is done" because they are beginning to hear about results. Attendees suggested that advocates enhance their organizational partnerships in order to become more active in appealing for continuing support of women's health research.—Barbara S. Lynch ■

All Beethoven's Quartets in Concerts

The FAES Chamber Music Series presents the Auryn Quartet performing all of Beethoven's Quartets on the following dates:

- Saturday, Mar. 5 at 8 p.m.
- Sunday, Mar. 6 at 4 p.m.
- Saturday, Mar. 12 at 4 p.m.
- Sunday, Mar. 13 at 4 p.m.
- Saturday, Mar. 19 at 8 p.m.
- Sunday, Mar. 20 at 4 p.m.

All performances are at the Landon School's Mondzac Performing Arts Center, located at 6101 Wilson Lane in Bethesda. Tickets may be purchased at the door or in advance (in Bldg. 60, Suite 230, or the FAES Bookstore in Bldg. 10, Rm. B1L101). Individual tickets are \$25; students, postdocs, pre-IRTAS and fellows pay \$10. ■

NIH Sailing Association Open House

The NIH Sailing Association invites everyone to its open house on Thursday, Mar. 3 from 5 to 7 p.m. at the FAES House on the corner of Old Georgetown Road and Cedar Lane. Would you like to learn to sail? Does the idea of racing sailboats appeal to you? Can you imagine being part of a group filled with skilled sailing instructors, enthusiasts and boat owners? Membership includes instruction, sailboats for charter, racing, cruises, parties and fun. Admission is \$5 at the door and includes pizza and sodas; \$2 for beer or wine. For more information, visit www.recgov.org/sail.

CONSTRUCTION, CONTINUED FROM PAGE 1

canopy similar to the one on the Gateway Center, to shield inspectors and drivers from the weather. It will also have inspection lanes, a "toll booth" security station and a rejection lane to take drivers back to Rockville Pike. Vehicles approved for campus entrance will proceed over the creek on a new bridge that is part of the project.

The Gateway Center design is complete and includes three components: an underground multi-level parking garage outside the fence on Rockville Pike with space for 350 visitor vehicles; an inspection station; and the Gateway Center itself. ORF's Mayra Sequeira manages the Gateway project.

Another new project involves installation of a new campus fire alarm system to bring obsolete equipment up to code and increase reliability. Project Officer Ben Buck says that although the project includes installation of new cable between the fire house and all campus buildings, campus operations will be only minimally affected. "Most of the new cabling will be installed in existing tunnels and underground duct banks," he said. Many buildings will also get new fire alarm devices. This project will take about 3 years to complete.

In addition to the new construction, some projects are coming to an end. The Edmond J. Safra Family Lodge, managed by ORF Project Officer Shah Saleh, is nearly complete and ready for occupancy, although the gardens, a separate project, will not be finished until this spring. Many on campus are also curious about why Wilson Drive between Bldg. 1 and the Pike is chopped up. "That's the Northeast Utility Tunnel Extension to supply utilities to Bldg. 33," explained Rhodes. Kyung Kim is the project officer managing both the utility tunnel and the Bldg. 33 project. The tunnel work should be complete and the roadway returned to a permanent route by April. Project Officer Tony Francis says construction on the new MLP-9 parking garage under construction next to Bldg. 10 has been restarted following a fatality on the site last November, and the garage should be finished sometime this summer.

For answers to questions about campus construction projects, send email to orfresponse@mail.nih.gov. ■

Volunteers Needed for Jet Lag Study

NICHD is looking for travelers going east 6-8 time zones to study the effects of replacing hormones disrupted by jet travel. Participants will take a study medication (hydrocortisone, melatonin or placebo), fill out questionnaires and obtain salivary samples. Travel stay of 4-10 days at destination required. Healthy men and women, between ages 18-65 are encouraged to call 1-800-411-1222. Compensation provided for a completed study. ■

Dr. Bill Suk, director of the NIEHS Superfund Basic Research Program, has been named a member of the Collegium Ramazzini, an independent, international academy made up of experts in environmental and



occupational health from more than 30 countries. It examines critical scientific issues in occupational and environmental medicine worldwide, and periodically issues statements on topics with potential impact on public health. The group is governed by 180 elected fellows. The Collegium Ramazzini transmits its views to policy-making bodies, authorities, agencies and the public. Suk came to NIEHS in

1987, joining the Superfund Basic Research Program, a network of university grants targeting complex health and environmental issues associated with hazardous waste sites. He is also director of the Center for Risk and Integrated Sciences within the SBRP.

African-Americans, Africans Sought

Healthy African-Americans or Africans are needed for a blood count study. You can help us understand why individuals have different white blood cell counts. Call 1-800-411-1222 (TTY 1-866-411-1010) and refer to study # 03-DK-0168. Compensation available. ■

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NEW PAINKILLER, CONTINUED FROM PAGE 1

about the deadly poisons inside the beautiful shells he collected in his native Philippines. Now a professor of biology at the University of Utah, Dr. Baldomero Olivera analyzes the highly toxic venoms of these cone snails. His research is backed by 25 years of NIGMS funding.

Prialt is 1,000 times more powerful than morphine, but, unlike morphine, it is not believed to be addictive. The FDA approved its use for chronic, intractable pain such as that suffered by people with cancer, AIDS or certain neurological disorders. It is delivered directly into fluid surrounding the spinal cord by external or implanted pumps.

The new drug is a synthetic compound identical to a toxin in the venom of the *Conus magus* snail. This is remarkable in itself, because natural compounds are almost always chemically modified to make them work better as drugs. In this case, nature perfected the

compound on its own.

Also noteworthy is that the toxin was discovered by a teenager named J. Michael McIntosh, who, just days after graduating from high school, began assisting Olivera with his research. Now, 25 years and an M.D. degree later, McIntosh is a research psychiatrist at the University of Utah. He still collaborates with Olivera on the cone snail research.

Prialt, which is marketed by Elan Corp. of Dublin, Ireland, may be just the first of many new medicines derived from cone snail venom. There are about 500 different types of cone snails, and each one typically produces about 100 different toxins in its venom. According to Olivera's research, the toxins affect the nervous system in different ways—some instantly shock the snail's prey, as does the sting of an electric eel, scorpion or sea anemone. Others cause paralysis, like the venoms of cobras and Japanese puffer fish.

Olivera's investigations further revealed that each toxin targets a certain type of molecule, usually a "channel" protein that helps pass messages in the nervous system. For example, the Prialt molecule blocks calcium channels in specific nerve cells, preventing certain pain signals from reaching the brain. The toxins are so accurate at pinpointing their targets that researchers now use them to identify and study specific brain proteins.

The extreme specificity of the compounds—a characteristic highly prized in drug molecules—has not escaped the notice of pharmaceutical companies.

Already, they are testing the potential of dozens of cone snail toxins to treat epilepsy, cardiovascular disease and other disorders.

Olivera continues to study and synthesize toxins produced by cone snails. He believes—and his research supports—that the snails are a treasure trove of novel chemical compounds with the potential to be useful in the clinic or laboratory. Eventually, Olivera hopes to harness the molecules to treat Alzheimer's disease, Parkinson's disease, schizophrenia and depression.

For more information about Olivera and his work on cone snail toxins, visit <http://www.nigms.nih.gov/news/findings/sept02/snails.html>. ■

Minority Trainee Research Forum Set

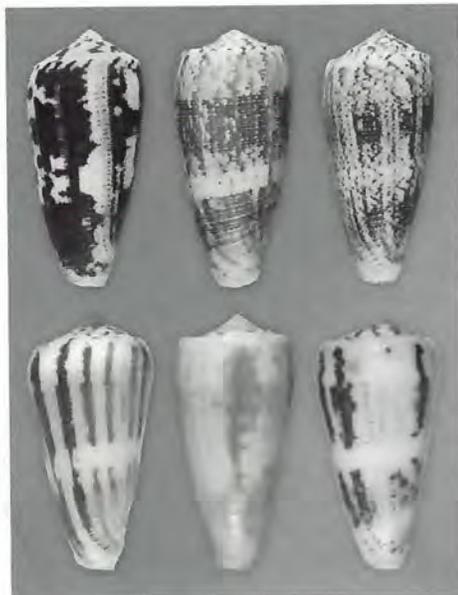
A minority trainee research forum sponsored by the NIH Office of Equal Opportunity and Diversity Management will be held Mar. 16-18 at the Natcher Conference Center. The forum runs from 8:30 a.m. to 5 p.m. on Mar. 16 and 17; scientific presentations take place on Mar. 18 from 8:30 a.m. to noon. A national competition invites minority biomedical trainees from academic, industry and government laboratories to present wet bench research. The trainees include postdoctoral, graduate, medical, undergraduate and high school levels of the biomedical research pipeline. All are welcome to attend. Sign language interpreters will be provided. For more information, call Rose Pruitt at (301) 594-5157 or Kay Johnson Graham at (301) 496-3403. For reasonable accommodation, call Carlton Coleman at (301) 496-2906. ■

NIH Golf Association Seeks Members

The NIH Golf Association (18-hole coed league) is looking for new members for the 2005 season. We currently have seven teams of up to 25+ players each and schedule eight spring/summer stroke-play outings, plus up to five match-play outings each year at local courses (all mid-week and play is optional). We cap the year off in October with an outing including golf/cart/food for all members and their guests. Prizes and trophies are awarded and handicaps are maintained from 0-40, so all interested golfers are welcome. For more information, contact Howard Somers at somersh@mail.nlm.nih.gov or visit <http://www.recgov.org/nihga/>. ■

Healthy Volunteers Needed

Healthy volunteers, ages 18-44, are wanted to participate in an investigational preventive HIV vaccine study conducted at NIH. Medical tests will determine eligibility. Compensation provided. Call 1-866-833-LIFE (TTY 1-866-411-1010). ■



These are shells of Conus magus, or magician's cone snail, from which the new drug Prialt is derived. Native to coral reefs in the Pacific Ocean, the 2-inch-long snail uses its venom to hunt fish. Some of the larger cone snails contain enough venom to kill a human with a single sting.

Hellinger Named NIA Associate Director

Lynn C. Hellinger knows how to deal with change, which will come in handy in her new role as associate director for management at the National Institute on Aging.

As former associate director for management and operations at NIAID, she led the post-Sept. 11 efforts to set up an infrastructure for biodefense research. At NIA, the challenges do not come from an immediate crisis, but from the steady and accelerating aging of the population.

"NIA is at the forefront of aging research, and I look forward to finding ways to support the scientists grappling with the issues facing us with unprecedented aging in America and the world," Hellinger says.



Lynn C. Hellinger

She played a key role in recruiting staff, acquiring and building facilities and developing training programs as NIAID became the lead agency for several presidential mandates to combat bioterrorism. Like others at NIH, she operated against a backdrop of administrative freezes, A-76, reorganizations and management changes.

"We had to reorganize our work and make it much more efficient as we were exploding in our growth," said Hellinger, noting that NIAID's budget nearly doubled with the \$1.7 billion increase the institute received after 9/11. "I feel I have put things in place (at NIAID) but I am one of those people who believe that you never really cross the finish line. There is always a way to make things better," she said.

At NIA, Hellinger will continue a career of leadership in human resources, organizational efficiency and public management. She said she will take cues from the scientists, asking how the administration can best support their work and the overall scientific mission of the institute.

NIA director Dr. Richard Hodes welcomed her to the institute. "NIA has been fortunate to have exceptional leadership in its administrative functions over the past years, and the institute looks forward to continuing this tradition with the addition of Lynn Hellinger. She comes to NIA with an outstanding background of service at NIAID and as a widely respected member of NIH's leadership community."

A unique feature of Hellinger's career is her activity and leadership in professional societies and in building future public managers. She has focused on

mentoring young professionals in public administration and management so they are prepared to "hit the deck running." A 20-year NIH veteran, she serves as the federal representative to the International Public Management Association's executive council and has served as president of the Montgomery County chapter and eastern region of the association. ■

NIH Hosts Women's History Month Events

NIH's annual Women's History Month observance opens with a themed celebration, "Spirit, Courage and Critical Thinking," on Wednesday, Mar. 9 from 11:30 a.m. to 1 p.m. at the Natcher auditorium. Communications artist Ann Timmons will perform *Off the Wall, the Life and Works of Charlotte Perkins Gilman*, a one-woman, one-act play about critical thinking skills. A workshop discussion of the play, and a Q-and-A session will follow in Conf. Rm. B.

The celebration continues with "Spirit, Courage and Global Collaboration," a mentoring seminar on Tuesday, Mar. 29 at Stone House from 11:30 a.m. to 1 p.m., featuring Cheryl Kelley, FDA special emphasis program manager.

Both events are sponsored by the NIH Office of Equal Opportunity and Diversity Management. All are welcome to attend. Sign language interpreters will be provided. On-site registration will be available for NIH training credit. For more information, call Glenda Keen at (301) 594-3282 or via the Federal Relay, 1-800-877-8339. Individuals with disabilities who need reasonable accommodation should call Carlton Coleman at (301) 496-2906 voice or (301) 496-9755 (TTY).

Women's Day Celebration, Mar. 8

The Fogarty International Center and the NIH Office of Research on Women's Health will host an International Women's Day celebration to honor women in the sciences. The event will take place Tuesday, Mar. 8 from 4 to 5:30 p.m. in Wilson Hall, Bldg. 1.

"International Women's Day gives us the opportunity to celebrate the important achievements in science by women all over the world," said FIC acting director Dr. Sharon Hrynkow. "In particular, we are recognizing women worldwide for the tremendous contributions they have made in the sciences and the critical impact they have made on our quality of life."

The event features three NIH international scientists who will participate in a panel discussion entitled, "International Women Scientists at NIH: Their Research and Career Paths." The panelists are Dr. Grace Yeh (from Taiwan), NCI; Dr. Maria Morasso (from Venezuela), NIAMS; and Dr. Linda Peters (from New Zealand), NIDCD.

A light reception will follow. The event is free and open to the public. ■

CONFLICT OF INTEREST, CONTINUED FROM PAGE 1

Accompanied by NIH deputy director Dr. Raynard Kington, who has served as the agency's point man on conflict-of-interest issues, and Holli Beckerman Jaffe, director of the NIH Ethics Office, Zerhouni told the room of reporters, "The guiding principle for these regulations is that we will do whatever is necessary to ensure that the advice of the NIH receives the highest level of trust."

Strict Limits Set

In general, the new rules prohibit all NIH'ers from engaging in three kinds of activities for four types of organizations: Banned are paid and unpaid employment; paid teaching, speaking, writing and editing; and self-employment for "substantially affected organizations" such as pharmaceutical and biotechnology companies; supported research institutions, including NIH grant recipients; health care providers

and insurers; and related trade, professional or similar associations.

In addition, financial interests in organizations substantially affected by NIH, such as the biotechnology and pharmaceutical industries, are also banned for those employees who are required to file financial disclosure reports, and are restricted to \$15,000 for all other staff. The prohibited holding rule applies also to spouses and minor children of NIH'ers.

Scientific awards, too, are now subject to stricter limits. Generally, senior employees may "accept the honor" of any award, but must reject any associated prize money or

other tangibles valued at more than \$200. There is an exception for awards that confer extremely high honors in the fields of medicine or scientific research such as the Nobel Prize or Lasker Award. [The full text of the new regulations can be found online at http://www.archives.gov/federal_register/index.html.]

Stressing that his goal is to draw a "bright line so clear" and unambiguous that crossing it would be obvious and not permitted, Zerhouni briefly recounted events over the last 18 months that led to what he termed "drastic measures." With a majority of institute and center directors and deputies looking on from the audience, he said, "What has happened is that we needed to absolutely achieve the



NIH deputy director for intramural research Dr. Michael Gottesman and NIH Ethics Office Chief Holli Beckerman Jaffe talk about the new rules. PHOTOS: JANET STEPHENS

number one goal: Nothing is more important for NIH than preserving the public's trust in our advice, our science, in our ability to provide public health advice with no taint of conflict of interest or the appearance of conflict of interest. I have always felt that people look to us for the most accurate health information and to fund the most outstanding medical research without any other considerations in mind. I feel that that's why we are here and that's why people trust us with their tax dollars. And that trust cannot be compromised in any way—even by the perception that something might taint our ability to carry out our public health mission."

Putting Events in Context

In Masur Auditorium on the day after the rules were announced, Zerhouni again faced a room filled with expectancy. This time the large majority of attendees were NIH employees—many of them intramural scientists—called to a quickly arranged town hall meeting to discuss implications of the new policies.

"Between yesterday and today I've had mixed feedback," Zerhouni said. "A good portion of the NIH community, some intramural scientists included, feel that this may be a bright day. We are solving and closing an embarrassing chapter. We couldn't sustain the loss of integrity and the fact that NIH fell from its pedestal. At the other end of the spectrum I have a group that says, 'This is the darkest day. You're taking away the ability of our scientists to be equal to those in the private sector, to have the same opportunities and rights.'"

To put the ethics decisions in context, Zerhouni recalled the July 2003 congressional query about cash awards that prompted an internal review of ethics policies and regulations. The self-exam pointed out areas of "major vulnerability," he said. Instead of the balanced, uniform NIH-wide standard he had expected, Zerhouni said he and other NIH officials found differing interpretations and uneven enforcement of rules among the ICs. In response, Zerhouni established in November 2003 a trans-NIH ethics advisory committee (the NEAC) to

What You Can Still Do Officially

Official duties: Government ethics rules, including the new regulations, do not affect the agency's authority to conduct business with outside entities. Therefore, as assigned and approved through all appropriate channels, NIH employees may, as part of their official duties:

- ◆ collaborate with a university researcher,
- ◆ be involved in a cooperative research and development agreement (CRADA) with a pharmaceutical company,
- ◆ be involved in a material transfer agreement (MTA) with a biotechnology company,
- ◆ serve as an officer or board member of a professional or trade association,
- ◆ peer review grant applications.

In addition, an offer of travel reimbursement from the outside organization may be accepted by the employee's institute or center with respect to these duties, as appropriate.

“reorganize our thoughts” and give consistent review to requests for approval of outside activities and awards.

Meanwhile a series of news articles was alluding to a far more serious problem—possible conflict of interest among some NIH scientists—and hinting that patients and NIH research could potentially be compromised because of financial ties with pharmaceutical companies. Congress asked Zerhouni to a special hearing about the articles. On Capitol Hill, he defended the customary and beneficial practice of scientific collaboration among peers, but also acknowledged that NIH needed to tighten its policies in the area. He testified that he could “find no evidence that any patient was harmed or that any decision...was corrupted” by NIH’s consulting. Next, Zerhouni enlisted the aid of outside advisors, establishing a blue-ribbon panel to study the ethics situation in depth and make expedited recommendations that he immediately implemented.

The Final Straw

Congress, however, was not satisfied and began gathering information independently. Not long afterwards, the NIH director was called to Capitol Hill on June 22, 2004, for another hearing.

“Everybody has their own emotions about that day,” he said, candidly, “but I can tell you that I felt like I was out in front, fighting whoever was in front of me, and getting shot in the back by my own troops”...because some employees evidently had not disclosed what their activities were. “That was discovered by congressional inquiry to the pharmaceutical companies.”

After more fact-finding, NIH “found instances that were very disturbing...some were purely and simply product-endorsement activities” by employees, Zerhouni pointed out, showing a slide quoting Congress’s FY 2005 appropriation for NIH that warned that the conflict issue could jeopardize budget support for the agency. “It’s a shame that the actions of a few have tainted the great service that many thousands of scientists here render every day, selflessly, with no taint,” he continued. “I have to protect the reputations of the 5,000 scientists who are doing their jobs...I am convinced that we owe nothing less to the American public than what we are doing today.”

NIH ethics head Jaffe then gave an overview of the new “interim final” regulations, which are considered permanent unless the Department of Health and Human Services makes changes to them.

During Q&As, employees—many visibly upset—asked why spouses should have to divest themselves of certain financial assets and why NIH’s were being held to stricter limits than grantees or advisory councilors, who often have equal or greater influence on research. How could NIH ask its employees to divest of personal assets during poor market

conditions, and why did the rules apply to NIH’s without grant-making authority? Who exactly is defined as an NIH employee, and how could longterm NIH’s be required to accept new employment practices midstream?

“The department did not do this casually,” stressed Kington, who worked with HHS to craft the regulation. “The fundamental explanation is that the world changed over time. The industry became more complex. It became more difficult to track our relationships with industry. Our influence on the market became greater.”

‘First, Do No Harm’

Emphasizing that “we do not want to put any obstacles in the way of normal scientific academic interchange,” Zerhouni concluded: “You have to ask yourself, is it ‘first, do no harm’ or [is it] prove that no harm is being done to the integrity of science? I think the previous policy was, ‘Let’s just do and then worry about the consequences.’ The attitude of these regs is, if we have to err on the side of uncertainty, then we will err on the side of protecting the agency’s integrity in the public eye.”

Over the next few months, NIH and HHS will be looking for unintended consequences of the rules—detrimental effects on recruitment and retention, for example—that may prompt changes. A 60-day comment period began with the *Federal Register* posting; NIH’s who have comments are encouraged to submit them by Apr. 4, 2005. Comments may be emailed to ethics@hhs.gov. Use the subject line “Comments on Interim Final HHS Supplemental Ethics Rule.”

A dedicated NIH email address was also created, ConflictofInterest@od.nih.gov. To help direct email quickly, use either “question” or “comment” in the subject line. ■



Dr. Sandra Melnick recently joined the Center for Scientific Review as a scientific review administrator in the health of the population integrated review group. She will oversee a new study section that will review grant applications on the epidemiology of infectious diseases, reproductive health, asthma and other pulmonary diseases. Melnick has been chief of the NCI Analytic Epidemiology Research Branch for the past 8 years. Prior to that, she was with the Office of AIDS Research and the NIAID Division of AIDS.

Lecture on Vitamin B-12, Folate

Dr. Irwin H. Rosenberg will deliver a lecture entitled, “Vitamin B-12 and Folate: Pathways to Your Bright Future,” on Wednesday, Mar. 9 at 11 a.m. in the Neurosciences Bldg., Conf. Rm. D, 6001 Executive Blvd. The talk is part of the Office of Dietary Supplements’ seminar series.

A member of the Institute of Medicine and the National Academy of Sciences, Rosenberg is senior scientist and director of the nutrition and neurocognition laboratory at the Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University. His current research interests include nutrition and aging; folate nutrition; relationship between homocysteine, B vitamin nutrition, vascular disease and cognitive decline. He has published more than 300 scientific papers in top journals, is editor of two journals and is on the board of several others.

Four Join NIAID Advisory Council

Four new members have joined the National Advisory Allergy and Infectious Diseases Council. They are Dr. Richard Insel, executive vice president of research at the Juvenile Diabetes Research Foundation International, New York; Dr. Martin G. Myers, professor of pediatrics and preventive medicine and community health at the University of Texas Medical Branch, Galveston; Dr. Shelley M. Payne, professor of molecular genetics and microbiology at the University of Texas at Austin; and Dr. Gary Schoolnik, professor of medicine, microbiology and immunology at Stanford Medical School.

Insel leads the strategic direction and oversight for



NIAID director Dr. Anthony Fauci (l) welcomes new council members (from l) Dr. Martin Myers, Dr. Shelley Payne, Dr. Gary Schoolnik and Dr. Richard Insel.

the approximately \$100 million in research grants annually awarded to universities and researchers by JDRF—the world's largest charitable supporter of juvenile diabetes research. He previously served as a professor of pediatrics, microbiology and immunology at University of Rochester School of Medicine and Dentistry Medical Center.

Myers serves as associate director for public health policy and education of the Sealy Center for Vaccine Development at the UT Medical Branch, Galveston. He is also president and board chair of a new nonprofit corporation, Immunizations for Public Health, and is the director and editor for National Network for Immunization Information.

Payne is a member of the Institute of Cellular and Molecular Biology, and distinguished teaching professor at the University of Texas. Her research focuses on the molecular biology of bacterial pathogens including *Shigella* and *Vibrio cholerae*; she received an NIH MERIT award for studies on *Shigella* pathogenesis.

Schoolnik is an attending physician in infectious diseases at Stanford Medical Center. His research employs molecular genetic and genomic methods and combines laboratory and field work (in Mexico and Bangladesh) to study infectious agents in developing countries. ■

STEP Forum on Clinical Trial Design

The staff training in extramural programs (STEP) committee will present a Science for All forum on the topic, "Clinical Trial Design: What To Do When the Shoe Doesn't Fit," on Tuesday, Mar. 8 from 8:30 a.m. to 12:30 p.m. in Lister Hill Auditorium, Bldg. 38A.

A clinical trial is a clinical trial, right? It depends. Health care professionals and the public look to randomized clinical trials (RCT) for the most reliable evidence upon which to base critical health care decisions. But for ethical or other reasons, some clinical trials do not fit the gold standard: placebo-controlled, double-blind RCT design. In these situations, which trial design is best or appropriate? This forum will address alternative clinical trial designs when the "shoe doesn't fit." Come participate in the event and gain a better understanding of some of the study design issues that ultimately affect your health care. Participation in the training session will earn ESA training credits.

Children's Premiere Night at Circus, Mar. 23

The Recreation & Welfare Association has tickets to children's premiere night of the 134th edition of Ringling Bros. & Barnum and Bailey Circus. Your evening at the Greatest Show on Earth begins on the arena floor, 1 hour before show time, as you join in the fun during the pre-show party called the Three Ring Adventure. Then the main event includes high-wire trampoline stunts, acrobatic troops, sway poles, motorcycle madness, animal acts and more. Join us on Wednesday, Mar. 23 at the MCI Center. The Three Ring Adventure begins at 6 p.m. and the main event starts at 7 p.m. Bring your family and friends and help R&W raise money for the NIH charities. Tickets are now on sale at the activities desk in the R&W store. Discounted tickets are \$30 (regularly \$50-65, front row and center court lower level), \$16.50 (regularly \$27, 100 & 200 level) and \$12.50 (regularly \$18, ends). ■

Tongue Study Needs Vols

NIH invites you to participate in a clinical study to learn more about the tongue. Information obtained from this study may assist in improving treatment for individuals with swallowing difficulties. Call 1-800-411-1222, or TTY 1-866-411-1010, for information. Or visit www.cc.nih.gov. All study-related tests or treatments are provided at no cost. Participants will be compensated. ■

Wednesday Afternoon Lectures

The Wednesday Afternoon Lecture series—held on its namesake day at 3 p.m. in Masur Auditorium, Bldg. 10—features Dr. Jennifer A.M. Graves on Mar. 2, speaking on "Weird Mammal Genomes and Sex." She is director, ARC Centre for Kangaroo Genomics and head, comparative genomics research group, Research School of Biological Sciences, Australian National University, Canberra.

On Mar. 9, Seth G.N. Grant will lecture on "Organization and Function of the Synapse Proteome: A Cognitive Machine." He is principal investigator, Genes to Cognition Project, Wellcome Trust Sanger Institute, Cambridgeshire, U.K.

For more information or for reasonable accommodation, call Hilda Madine, (301) 594-5595.



Dr. Elisabeth Koss is now a scientific review administrator for the risk, prevention and health behavior integrated review group at the Center for Scientific Review. She received her Ph.D. in psychology from the City University of New York and first came to NIH as a senior staff fellow in the Laboratory of Neuroscience at NIA. She went on to serve as project officer and NIH liaison for the World Health Organization Special Program for Research on Aging before joining the faculty at Case Western Reserve University, where she studied cognitive and behavioral aspects of aging and dementia. She returned to NIH to serve as assistant director of the Alzheimer's Disease Centers Program at NIA for the past 4 years before joining CSR.

PUBLIC ACCESS, CONTINUED FROM PAGE 1

Wide Web yearly in search of reliable medical information, and that 58 percent of these browsers go on to use information gleaned from the Internet in their visits to physicians. "It is vital in the new world of rapid access to electronic information that we establish an NIH archive," he said.

Three goals are accomplished by NIH's new policy, Zerhouni noted: It ensures and accelerates the public's access to cutting-edge science; it establishes for all time a searchable, online archive of NIH-funded publications; and it allows NIH "better management of our investment in research" by serving as a report card on what scientists are doing with NIH money. Indeed, participation in the archive wins NIH grantees a reprieve from the obligation to fill out annual progress reports.

"This policy creates a new platform and changes the landscape for the display of NIH-funded research," said Zerhouni, who noted that the agency faced an array of opposition—chiefly from established publishing interests—to entering the publishing arena. "Many encouraged NIH to stay out of the [public access] debate."

More than 6,200 comments on the proposed policy arrived at NIH between September, when the policy was first made public, and November 2004, Zerhouni noted. "We've been extremely responsive to the comments," he said, noting repeatedly that the policy is "flexible" and designed to encourage "maximum participation."

The policy applies to any research supported in whole or in part by NIH direct costs, regardless of funding mechanism, explained Dr. Norika Ruiz Bravo, NIH deputy director for extramural research. "It requests, but does not require, that authors deposit in PMC an electronic version of the final, peer-reviewed manuscript. The author specifies when the article will be made public. We expect them to do that as soon as possible, and within 12 months of the [journal] publication date."

She enunciated three benefits to participants: increased visibility of the author's work; an enhanced ability to gain access to datasets (potential collaborators, for instance, could test-drive an author's data); and an alternate means of complying with NIH's requirement for annual progress reports from grantees.

The benefits to NIH, Ruiz Bravo continued, are that we get a new and expanding archive that allows both macro- and micro-management of NIH's portfolio. The benefit to the public, she concluded, is "better access to peer-reviewed, credible scientific information."

Both Zerhouni and Ruiz Bravo—joined in some instances by NLM's Dr. David Lipman, whose National Center for Biotechnology Information hosts PMC—took 14 phone queries from the stakeholders' group and an additional 19 calls from reporters

(several of whom called twice) in back-to-back telebriefing sessions Feb. 3 that lasted about 30 minutes each.

During the exchanges, Zerhouni explained that "Congress, patient groups and others let us know that the current system is just not performing sufficiently...We are adding, not detracting, from current publishing practices. The status quo just isn't acceptable in the world of modern communications...It wouldn't serve the country if NIH did not display its research."

He said NIH got pressure both to shorten and to lengthen the authors' submission time to PMC, and observed, "We're establishing a venue for scientists that will change and transform science, and the diffusion and transmission of science. We do want to encourage [PMC submission] as soon as possible after the date of [journal] publication." He said NIH wants to "create a momentum toward earlier submission...people are getting too hung up on timing, but forgetting that we want maximum participation, not partial participation."

NIH deliberately avoided mandating participation in the archive, Zerhouni explained. "We thought we'd do more harm than good by relying on a mandate...We trust our scientists to do what's right by the public that funds them." Added Ruiz Bravo, "We think scientists are among the most independent people you could find—it's hard to make them do something."

Several callers asked about potential penalties for noncompliance with the policy. "No penalties are planned at all," stated Ruiz Bravo. "We are requesting, not requiring. We have no plans to punish anybody who doesn't comply with the policy...There will be record-keeping, though, since compliance represents an alternative to required progress reporting."

Zerhouni assured participants in the phone sessions that NIH will keep an eye on the policy's progress. "There will be an evaluation process," he said. "The NLM board of regents is establishing a public access advisory working group" that will track the policy and any needed amendments.

Starting May 2, NIH will be ready to start accepting manuscripts, Ruiz Bravo said. The cost of establishing and maintaining the archive is expected to be \$2 million-\$4 million a year, Zerhouni predicted.

NLM's Lipman says that officials here estimate that NIH supports around 60,000 research papers each year, and that the size of the new archive will depend on the percentage of authors who elect to participate. "Our goal is a comprehensive, up-to-date archive, but we realize that it will have to evolve," he said. "There's a culture change involved here. No one's done this before."

For more details on NIH's public access plan, visit <http://www.nih.gov/about/publicaccess/index.htm>. 

Long-time Administrator Luecke Retires

By Mary Sullivan

After a career spanning nearly three decades at NIH—at four institutes and one division—Dr. Donald Luecke retired on Dec. 31. In his most recent position, he was a senior advisor to the NIH director, working closely with Dr. Dushanka Kleinman, assistant director for roadmap coordination.

A native of St. Paul, Minn., Luecke received his M.D. degree with honors from Michigan State University and an M.S. in immunology and microbiology from the University of Illinois.

His involvement with NIH began after several jobs as a clinical microbiologist in the public health departments of North Dakota and Michigan. While at the University of North Dakota, he was supported by the National

Cancer Institute for studies on the transmission of tumor viruses by certain insects and other arthropods.

In 1975, Luecke joined NIH as a medical officer in NCI's Viral Oncology Program. He later became head of the clinical studies section in the Division of Cancer Cause and Prevention. His extramural career at NIH began in the NIGMS Burn and Trauma Program where he later headed the physiological sciences section.

After NIGMS he returned to NCI, this time to head the newly created Special Programs Branch where he was responsible for multiple activities including establishing extramural programs in cancer epidemiology, biometry, diet/nutrition and tobacco carcinogenesis.

Then came a series of high-level managerial positions at NIH, many of them as a deputy director. In 1981, he became deputy director in the Stroke and Trauma program at the National Institute of Neurological and Communicative Disorders and Stroke, focusing on spinal cord and brain injuries. In 1982, he accepted the deputy directorship of the NINCDS' Extramural Activities Program. He received the Commendation Medal of the Public Health Service for providing administrative support and coordinating the institute's grants and contracts programs.

Luecke's next deputy job came as a result of a detail to the Division of Research Grants. In 1986,

DRG director Dr. Jerome Green recruited Luecke as his special advisor for extramural activities. A year later he became DRG's deputy director. He received the PHS Outstanding Service Medal for planning,



Luecke addresses crowd.

directing and evaluating the operations and functions of the division. "As deputy director, I became involved in every aspect of the peer review process—it was challenging and provided me with great opportunities to work closely with others within and outside of DRG," says Luecke.

When Green left DRG, Luecke was asked to serve as acting director, a post he held for 2 years. He was engaged in many activities related to improving peer review and the extramural research and research training programs at NIH.

His next deputy job was with the National Institute on Deafness and Other Communication Disorders, a position he held for 8 years beginning in 1996. "I had been at DRG for 10 years and felt it was time to move back to a program area," says Luecke. At NIDCD he participated in the day-to-day operations of the institute and contributed extensively to an evaluation of its extramural programs, leading to an increase in the number of individual postdoctoral fellowships and career development awards, more emphasis on new investigators and significant changes in the small grant program.

In 2000, Luecke retired from the Commissioned Corps with a rank of rear admiral.

Most recently, he has served as an advisor to the NIH director on the roadmap initiative. "The roadmap has been a wonderful final step in my career. It is very gratifying to see the tremendous enthusiasm of staff across the institutes for working together as project teams," says Luecke.

At his retirement party, it was evident that his colleagues both respected him and enjoyed his company. He was praised for providing "senior leadership at critical junctures for the evolution of the NIH" and for "contributions that transcend all ICs." He received numerous accolades from high-level staff including Kleinman, Dr. Ruth Kirschstein, senior advisor to the NIH director, and former DRG director Green, who described Luecke as a "senior statesman," an "agent of change," and a "people person." Noting Luecke's fondness for cars, Green said it was especially fitting that he was involved



Attendees at Dr. Donald Luecke's retirement party included former NIDCD director, Dr. James B. Snow (r) and current director Dr. James F. Battey (l).

with the NIH roadmap.

Kleinman read a letter from Dr. Elias Zerhouni, NIH director, commending Luecke for his "many contributions to the NIH, including his expertise and broad-based experience, which were critical to the success of the inaugural year of the NIH roadmap, and his ceaseless dedication to the NIH and its mission."

Dr. James Battey, NIDCD director, noted that he and Luecke "shared a passion for developing young scientists," and that Luecke had worked tirelessly to help young scientists establish themselves in research careers and to obtain research grants.

A donation was made to the NIH Children's Inn in Luecke's name and a poem, written by a friend who could not attend the party, was read in his honor.

Commenting on what he describes as a common theme across the various positions he's held at NIH, Luecke expressed his appreciation of "the incredible opportunities I've had working with outstanding people at all levels of the organization. It has provided me with constant reminders that good ideas and dedication are not exclusive to a particular group of individuals." Some of his newfound friends include people he met while exercising in the NIH Fitness Center, an activity he intends to maintain in retirement. "I'd like to see more people at NIH use the fitness center, it's such a great resource for the NIH staff."

He's also planning to stay busy doing volunteer activities, spending time with his grandchildren and "spending some Fridays at the track in my Subaru WRX." ■

NIH Training Center Classes

The Training Center supports the development of NIH human resources through consultation and provides training, career development programs and other services designed to enhance organizational performance. For more information call (301) 496-6211 or visit <http://LearningSource.od.nih.gov>.

Advanced Basic Time & Attendance Using ITAS	3/3
Consolidated Purchasing Through Contracts	3/17
Federal Supply Schedules	3/17
Buying from Businesses on the Open Market	3/18
Simplified Acquisitions Refresher	4/4
Professional Service Orders	4/5
Travel for Administrative Officers	4/5

HIV-Positive Volunteers

NIH invites individuals with HIV to participate in an investigational treatment interruption study. HIV-positive adults with a CD4 count greater than 500 cells/mm³ are asked to call 1-800-411-1222, or TTY 1-866-411-1010, for information, or visit <http://clinicalcenter.nih.gov>. ■

NIDA Mourns Jackie Porter

Jacqueline Porter, of the National Institute on Drug Abuse, died at her home on Oct. 20, 2004, after a battle against cancer. She had been special assistant to the director of NIDA's Office of Extramural Affairs for many years. She prepared RFAs and PAs for publication in the *NIH Guide*, prepared Certificates of Confidentiality and served as the institute's expert on the Privacy Act.



Jacqueline Porter

Within OEA her role was also pivotal, with a range of responsibilities that included managing the budget, personnel, NIDA advisory council travel and expense vouchers, and special NIH and NIDA announcements such as the PECASE award and the review of B/START and CEBRA applications.

Porter began her career as a secretary when NIDA was a small program within NIMH. Her intelligence, organizational skills and work ethic were quickly recognized and she was promoted a number of times and received many awards, including the NIDA Director's Award.

Porter was also devoted to her faith and her family. She spent many hours volunteering at St. Catherine's Catholic school and shared her many interests with her son, her parents and her 11 siblings. She especially loved to garden and her office "family" was always delighted to find fresh vegetables from her garden awaiting them. Often, Porter would bring in delicious breads and cakes that she had baked. NIDA employees remember her as generous, direct, tenacious, honest and dedicated to the mission of the institute. She was also known as a brave and optimistic friend and colleague.

Porter is greatly missed by all her NIDA colleagues who benefitted from her assistance, appreciated her efficiency, respected her knowledge and candor and enjoyed her humor and energy.—Teresa Levitin

R&W Has Orioles, Nationals Tickets

The R&W will once again be offering tickets to the Baltimore Orioles and will also be receiving season tickets and other special games for the Nationals—Washington, D.C.'s new baseball team. Tickets for the Orioles will go on sale Wednesday, Mar. 30 in Bldg. 31, Rm. B1W30 (outside the R&W gift shop) at 8 a.m. You may buy one set of tickets the first time through the line. After the initial line ends, you may come back through again to purchase more tickets. Arrive early to get in line if you have a particular game in mind. Remember, you must be a 2005 R&W member to purchase tickets—have your card and '05 sticker on hand. R&W memberships can also be purchased at the time you buy tickets. Membership is \$7 for the year. The next day, on Thursday, Mar. 31, R&W will be selling tickets to the Nationals, also with an 8 a.m. sale time. Get ready for a great season of baseball! ■

Book Describes NIMH, NINDB Research in the Fifties

The Office of NIH History, NIMH and NINDS have collaborated on a new book that describes intramural research in the 1950s. The book grew out of a symposium held on campus Apr. 11, 2003: "NIMH and NINDB Intramural Research in the 1950s." The book *Mind, Brain, Body, and Behavior: Foundations of Neuroscience and Behavioral Research at the National Institutes of Health* is

edited by Ingrid G. Farreras, Caroline Hannaway and Victoria A. Harden (Amsterdam: IOS Press, 2004).

The 2003 symposium drew attention to the historic work of NIMH and NINDB intramural programs during their first decade of research at NIH. Twelve distinguished alumni from the basic and clinical programs of the two institutes presented talks about

research in the 1950s, and many scientists donated personal historical photographs, correspondence, unpublished documents, laboratory notebooks, artifacts and other items from this time period to the Office of NIH History.

In the book, the 12 speakers' talks are placed in a broader context to illustrate how this early research laid the foundation for later work. The first part of the book gives a detailed account of the history of the institutes and situates the individuals, events and research referred to by the scientists. It uses records of the time and oral histories of institute scientists to portray the context of research. It shows how the Division of Mental Hygiene of the Public Health Service evolved into the NIMH and how the new institute was organized. A similar history of the establishment of NINDB is then provided and also tied to that of NIMH, as both institutes shared a joint intramural basic research program throughout the 1950s.

The second part of the book presents succinct reviews of the research conducted by the 15 laboratories and branches of the NIMH and NINDB intramural basic and clinical research programs. The third part of the book offers first-hand recollections of the noted scientists' and administrators' experiences when they were at the institutes during the 1950s. The current NINDS director also gives her view of how that original research has changed over the course of time.

The book ends with four appendices providing information about the organizational structure of the two institutes, the scientists who worked there, citations of illustrative landmark papers that were published based on their research, and selected primary and secondary resources related to the

history of these institutes.

Histories can only be written if records are kept and resources are available. A major aim of this volume is to spur scientists and administrators at NIH to collect, preserve and donate their archival materials to the Office of NIH History and the National Library of Medicine. The book also aims to foster further descriptive and analytical research on NIH and the history of biomedical sciences in the 20th century.

Copies are available at a discounted price to members of the NIH community in the FAES Bookstore in Bldg. 10. ■

New Pay System Has Benefits

The last issue of the *NIH Record* reported that the Department of Health and Human Services is replacing the old payroll system, IMPACT, with the Defense Finance and Accounting Service (DFAS) on Mar. 20. A few features of DFAS that will affect you are: the official payday will be Friday instead of Tuesday; you will be allowed to increase your number of allotments from 3 to 7; awards will be paid on the official payday instead of Tuesday, as they are now; and lump sum payments for accrued annual leave will be made immediately after you leave federal service.

One of the biggest benefits of the change from IMPACT to DFAS is that a system called "MyPay" will be implemented, taking the place of the current Employee Express system. Would you like a more user-friendly system to manage your finances and government benefits? Would you like to be able to print your Leave and Earnings Statements (payslips) from anywhere? Would you like to be able to print your own W-2 at the end of the year, without waiting for "snail mail" or worrying about receiving it before Apr. 15? If you separate, would you like to be able to print out your own last payslip and lump sum annual leave payment payslip? If you answered "yes" to any of these questions, then MyPay matters to you. With MyPay, all employees, including committee members and other intermittent employees, will be given a PIN, and allowed to make changes to their health benefits, life insurance, Thrift Savings Plan and tax data, as they do now through Employee Express, but in an easier fashion.

Be looking for posters, fliers, table tents, emails and more *Record* articles to alert you to updates and employee briefings about DFAS and MyPay. ■

Men with Osteoarthritis Sought

A study of osteoarthritis is recruiting men ages 30-65. They can take part in NIH study # 04-AT-0239 evaluating hormones in men with osteoarthritis pain. Compensation provided. Call 1-800-411-1222 (TTY 1-866-411-1010). ■



Drs. James Birren (l) and Joseph Brinley work in 1958 with the Psychomet instrument designed and built at NIMH to measure the difference in speed of response to complex stimuli.