

NO 'SUGAR-COATING' New Oversight Coming to Clinical Center, Intramural Research

BY RICH MCMANUS

Sometimes, hospitals themselves have to take medicine. That was the conclusion of a working group of the advisory committee to the NIH director whose 11 recommendations about Clinical Center management were unanimously accepted by the ACD and then immediately acted upon by NIH director Dr. Francis Collins on Apr. 21.

The next morning, Collins, CC director Dr. John Gallin and NIH deputy director for intramural research Dr. Michael Gottesman presented the so-called "Red Team's"



At a town hall meeting Apr. 22, NIH director Dr. Francis Collins (l) and Clinical Center director Dr. John Gallin hear employee concerns following release of "Red Team" report on the hospital.

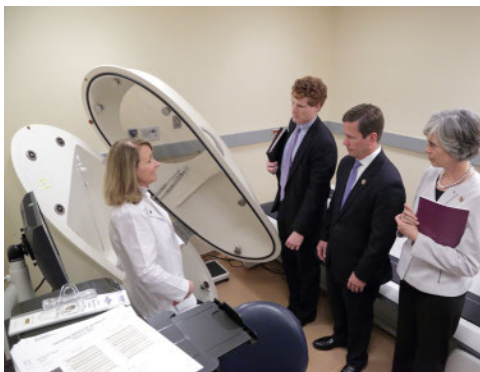
findings to the intramural community at a town hall meeting in Masur Auditorium. They assured employees that steps taken to address shortcomings identified almost a year ago in the CC's pharmaceutical development section (PDS) will result in renewed

emphasis on patient safety and continuation of world-class research.

The issue that led to what Collins characterized as a nearly year-long period of therapeutic "soul searching" at NIH was a CC pharmacy department employee's complaint to the FDA in May 2015 about procedures involving sterile injectables. The whistleblower, lauded as "something of a hero," by Gallin, exposed a culture wherein overworked PDS employees, struggling to please researchers, sometimes cut corners in the rush to provide products, then found that complaints to superiors about the situation never rose to top CC management.

NIH responded quickly to the complaint last summer, and in the process of reviewing sterile procedures discovered that the CC pharmacy, opened 10 years ago in the Clinical Research Center, never received certification under Good Manufacturing Practices

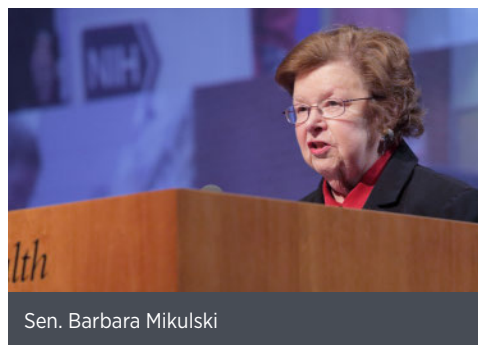
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Lawmakers explore NIH's "bod pod." See p. 12.

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Sen. Barbara Mikulski

LEAVING SENATE, BUT NOT THE FIGHT In Farewell Visit, Longtime NIH Champion Mikulski Vows Continued Support

BY CARLA GARNETT

Perhaps no lawmaker has packed a more powerful punch for NIH throughout a career in Congress than Sen. Barbara Mikulski (D-MD). As she prepares to depart the legislative body this term as the longest-serving woman in its history, Maryland's senior

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EMPOWERING PATIENTS

How Doctors Can Embolden Patients to Choose the Right Treatment

BY DANA TALESNIK

Does doctor always know best? Patients often ask their doctor: "What would you do in my situation?" But as the doctor explains the risks and benefits of treatment options and imparts advice, it's important to remember there's a human behind that medical chart, a patient with unique values, opinions and personal preferences.



Dr. Peter Ubel

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Davidson Gives Next 'Mind the Gap' Seminar, May 16

Dr. Karina W. Davidson, director of the Center for Behavioral Cardiovascular Health and vice-dean of organizational effectiveness at Columbia University Medical Center, will present on the topic "N of 1 and Novel Within-Subject Trial Methods" at the next Medicine: Mind the Gap seminar. It will be held Monday, May 16 from 11 a.m. to noon via NIH



VideoCast, <http://videocast.nih.gov/>.

When a patient wants to achieve a health behavior change, a clinician can recommend the best intervention based on the evidence from randomized controlled trials (RCTs). However, due to the heterogeneity of response in the RCT, it

is unknown if the intervention will be successful for the individual patient.

The most scientifically rigorous—and potentially efficient—method for determining optimal clinical care for a specific patient is a single-patient (N-of-1) RCT. Davidson's research interests include N-of-1 trial designs for health behaviors and health services research to improve the education of future physicians and the care of hospital patients.

Davidson will accept questions before and during her presentation via email at prevention@mail.nih.gov and on Twitter with #NIHMTG. Register for the event at <https://prevention.nih.gov/programs-events/medicine-mind-the-gap>.

Pride Month Events, May 25-June 30

The Office of Equity, Diversity, and Inclusion, along with the Sexual & Gender Minority Research Office and the National Institute on Minority Health and Health Disparities, is sponsoring several events to celebrate Pride Month.

The theme for this year is "Telling Our Stories, Claiming Our Power, Standing in Our Truth." Four events will take place on campus between May 25 and June 30. Information about each event is listed below.

- May 25 (10-11:30 a.m.) Heading the ManDate – Project Healthy Living, Porter Bldg., Rm. 640
- June 8 (1-3 p.m.) Catalyzing Efforts to Collect Sexual and Gender Minority Health Research and Workforce Data, Natcher Bldg., Balcony A
- June 14 (1-2:30 p.m.) Fostering an Inviting Workplace for Transgender & Gender Nonconforming Employees (training), Bldg. 31, C Wing Rm. 7
- June 30 (10-11:30 a.m.) Health Care and Research



Gates Visits NIH for Global Health Meeting

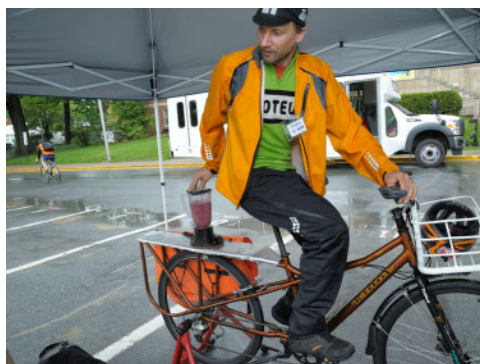
The Bill & Melinda Gates Foundation and NIH held their 3rd annual consultative workshop on Apr. 18 at the Porter Neuroscience Research Center. On hand for a discussion of such global health issues as Zika virus and HIV/AIDS were (above, from l) Bill Gates, NIH director Dr. Francis Collins and NIAID director Dr. Anthony Fauci. At right, Gates speaks during a break with NIDA director Dr. Nora Volkow.

PHOTOS: BILL BRANSON



for the Transgender Community, Bldg. 10, Masur Auditorium

For more information visit edi.nih.gov.



Bike to Work Day, May 20

Bike to Work Day will be held, rain or shine, on Friday, May 20. Registration is free and you can sign up for one of the NIH-affiliated pit stops. Events will be held at Bldg. 1 from 7 to 9:30 a.m.; Rock Springs Business Park from 6:30 to 8:30 a.m.; and Rockville-Falls Grove (near NCI Shady Grove) from 6:30 to 9 a.m.

You must pre-register for the pit stop you plan to visit in order to receive a 2016 Bike to Work Day T-shirt (available while supplies last). At Bldg. 1, all NIH'ers who pedal up wearing a helmet may enjoy


breakfast snacks and participate in a raffle. Register by Monday, May 16 at biketoworkmetrodc.org. Be sure to mark NIH as your employer.

Employee Viewpoint Survey Open

The 2016 Federal Employee Viewpoint Survey (FEVS) is now open through the week of June 13. This is your opportunity to provide input on a variety of topics, including: work experience, organization, leadership, diversity and inclusion.

NIH values your feedback and uses the survey results to make positive changes throughout the organization. The FEVS is one of the fundamental ways the NIH community learns how to improve as both a place to work and as an agency that sets standards of excellence in medical research.

Eligible NIH employees (full- and part-time permanent, non-seasonal employees, hired on or before Oct. 31, 2015) should have received an email invitation from the Office of Personnel Management containing a unique link to participate in the survey. The survey takes 20-25 minutes to complete and responses will be confidential.

For questions about the FEVS, contact the NIH Office of Human Resources at NIHFEVS@mail.nih.gov. 

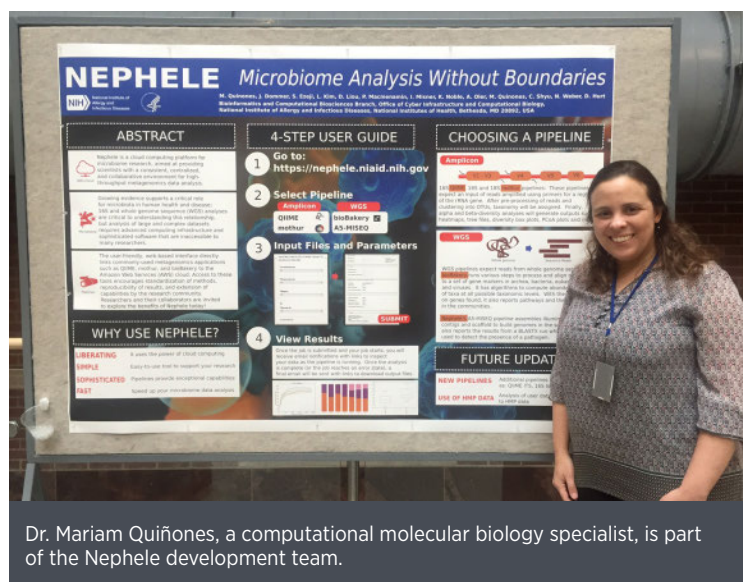
ICs Show Off Latest Tech Tools at ‘Show & Tell’

BY DANA TALESNIK

In large agencies, any tool that might facilitate better data-sharing and faster turnaround is greatly appreciated. Several ICs unveiled an array of such IT solutions at the recent NIH IC Applications Show & Tell, sponsored by the NIH chief information officer.

Presenters from NCI, NHLBI, CIT, NIAID and OD demonstrated applications created to help the extramural, intramural and administrative management communities find, share and evaluate data. These innovative platforms, networks and repositories are promoting greater collaboration and efficiency, said Stacy Charland, NIH deputy CIO, during introductory remarks.

NCI-Frederick has developed a web-based, cutting-edge rendering tool that supports large-size image visualization. The tool displays 2-dimensional images of 3-D volumes, allowing mouse-finger image rotation and a JavaScript-based transfer function. It even works on older devices so investigators don't need expensive equipment to view the images. Dr. Yanling Liu, who demonstrated this technology, said investigators also save time by not having to download the large files.



Dr. Mariam Quiñones, a computational molecular biology specialist, is part of the Nephele development team.

NIAID created a user-friendly, web-based interface for microbiome research called Nephele (<https://nephele.niaid.nih.gov>). Built on the Amazon Web Services cloud, Nephele helps researchers analyze large, complex datasets without having to struggle through complicated computing software and programs, explained NIAID's Nick Weber. Designed by a team of software developers, analysts, computational biology experts and communication specialists, Nephele lets users view and compare genomic sequencing data and encourages reproducibility of results.

Another genomics tool is traC (Translational

Research Application for Cohorts), based on the open-source tool transMART developed by NIAID's Laboratory of Parasitic Diseases. TraC creates research cohorts and analyzes multiple research scenarios quickly, so users no longer have to spend months searching multiple disparate data sources to find the right datasets. This secure central data repository lets scientists view individual patient data and, using data curation and mapping features, follow patients' progress over time.

NHLBI has a program to share pediatric trial data collectively and securely. The Pediatric Heart Network (PHN) Grid (www.phngrid.org, www.pediatricheartnetwork.org) supports a consortium of 30 children's hospitals, a data-coordinating center and core labs that analyze ultrasound echo images, ECGs and clinical data submitted by PHN sites. The grid platform employs open-source image de-identification and image archive solutions to store and distribute clinical trials data to help investigators assess treatment therapies for congenital heart disease, said NHLBI's Anna Fernandez. The grid contains image-based data for more than 3,000 patients across multiple PHN trials and uses MatchPlus to remove personally identifiable information before the data leaves the sites.

NCI also has a platform for researchers to share data, tools and other digital assets. NCIP Hub (www.nciphub.org) helps the cancer research community collaborate on these shared resources,

serving as a collaboratory, said NCI's Ishwar Chandramouliswaran. He said NCIP Hub serves as an outreach solution that can reduce costs by providing a digitized home for contributor-controlled content. More than 1,700 users are sharing hundreds of public and private resources and the site is growing.

SCS OnDemand is a web-based scientific coding solution managed by CIT. So far, six ICs are using this solution for scientific coding of NIH grants, contracts, intramural projects

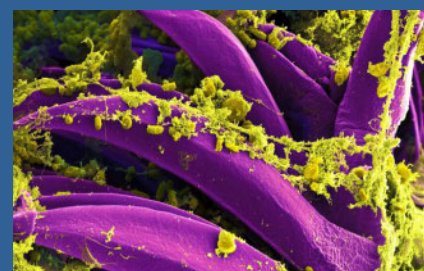
and intra-agency agreements. Each IC develops its own unique coding structure and process to reflect reporting and portfolio analysis needs and requirements, which are supported by SCS OnDemand. The system also allows participating ICs to categorize and report their portfolio as a formatted data feed to various NIH-wide reports, said CIT's Rakesh Nayak and NCI's Byron Adams.

OD has created a tool to streamline the job recruitment process. HR CARDS (<https://hrcards.nih.gov>), started in 2014, is a web-based repository for standard position descriptions and related classification and recruitment documents. The

site contains more than 450 PDs for more than 80 different series. Vacancies are posted 4-5 days faster when using this system, said OD's Nathalie Ivanovich-Rodriguez. Users can search by series, title, pay plan, HR CARDS number and keywords. There are multiple levels of access: non-HR personnel can search and view documents; HR specialists and administrators can modify records, run reports and delete/modify records or users.

NHLBI also demonstrated its Reporting Analytics Tool that facilitates advanced reporting and analytics, allowing users to create and review budgets and grants, travel reports, contracts, clinical research data and other reports across extramural and intramural programs.

If your IC has developed an application to enhance data sharing and collaboration, let the NIH Office of the CIO know about it: nihciocommunications@mail.nih.gov. The event was the third Show & Tell hosted by the NIH CIO, with another planned for this fall. **R**



ON THE COVER: *Bubonic plague bacteria on spines in the digestive system of a rat flea*

IMAGE: B. JOSEPH HINNEBUSCH, ELIZABETH FISCHER & AUSTIN ATHMAN, ALL OF NIAID

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Collins discusses Red Team recommendations.

PHOTOS: DANIEL SOÑE

Red Team

CONTINUED FROM PAGE 1

criteria; it had only a certificate of occupancy, said Norm Augustine, former CEO of Lockheed Martin and Red Team chair.

“I must point out that no one was intentionally negligent or indifferent,” said Augustine. “In fact it was quite the opposite. They were extremely dedicated.” But the zeal to answer any and all requests for products “sometimes involved cutting corners.”

The Red Team found that NIH’s “strong commitment to research has inadvertently” been in conflict with safety standards. He cautioned, “You can’t have one at the expense of the other, even to a small degree.”

Augustine, who said his team has “not tried to sugar-coat anything,” emphasized that putting patient safety secondary to research needs was never done consciously. He added, “We would all [Red Team members] go to the Clinical Center without any hesitation if the need arose.” Of the whistleblower he said, “That person should be commended.”

Collins underscored repeatedly that no patients were harmed as a result of the safety lapses, and that the patients, all of whom were notified right away, would continue to be followed for any sign of trouble. NIH immediately closed the sterile part of the PDS last summer and has now decided not to rebuild it, citing an estimated cost of \$50 million as too high.

★ ★ ★

“This is a fantastic example of how to face problems head-on.”

—DR. CORI BARGMANN

★ ★ ★

For the moment, investigators’ needs for sterile injectables are being met by an NCI facility in Frederick. Gottesman said non-sterile PDS products remain on hand in sufficient amounts, but new sources will be needed soon for them.

The PDS problems prompted a thorough review of 11 other NIH facilities that prepare sterile products for patient use; that study remains ongoing. In its wake, an NCI laboratory involved in immunotherapy and an NIMH lab that uses PET tracers have temporarily shut down operations related to the products.

“This is a fantastic example of how to face problems head-on,” said ACD member Dr. Cori Bargmann of the Rockefeller University.

“I want to thank the Red Team and the ACD for a job well done,” said Collins. “This has been a difficult period for us, but we want to look forward, not backward.” He put NIH principal deputy director Dr. Lawrence Tabak, NIH deputy director for science, outreach and policy Dr. Kathy Hudson and Gottesman in charge of enforcing a set of changes he announced immediately.

These include:

- Creation of an external hospital board that will meet quarterly, chaired by Dr. Laura Forese, executive vice president and chief

operating officer at New York-Presbyterian Hospital. She is an expert in the field who already oversees 6 major hospitals in the greater New York area, said Gottesman, and has committed to 2 years of work with NIH.

- Creation of a new compliance office within the Office of Intramural Research, with oversight not just of the CC, but of the entire IRP. Its interim director will be Dr. Kathryn Zoon, who was lured out of retirement plans. Collins lauded her as the best possible person for the job, having headed FDA’s Center for Biologics Evaluation Research and having served as scientific director at NIAID.

- Hiring two companies with expertise in safety and compliance to assess all facilities involved in creation of sterile products at NIH.

- Modifying the performance plans of all who have patient-care responsibility, to include a critical element on safety and compliance with regulations.

In the longer term, Collins said he’s certain NIH “can achieve essential patient safety without slowing down advances in research...This is going to be top-of-the-list for us...Patients who come to the Clinical Center can be confident that they are getting the best possible care.”



Gallin speaks about a key quote from the Red Team report, visible in the slide.



Gallin tells the Masur Auditorium crowd about the culture change called for in Red Team recommendations.

He assured employees at the town hall meeting that they are valued.


“I want to make one thing absolutely clear,” he said. “The Clinical Center staff is simply top notch, each and every one of you...I receive countless notes of thanks from patients...Thanks to you, many lives have been saved and many more will be saved in the future.”

Collins acknowledged that the coming changes “won’t be easy. There may be a few bumps. But having seen you all in action, I think you’re totally up to the challenge...I have the utmost confidence that this is an opportunity for growth. Together, I know we can do it.”

Gallin said that when the Clinical Research Center opened, “we instituted the word ‘sharing.’ We are now extending that sharing to efforts to improve safety.” He said he read the Red Team report 4 times, “and I think the recommendations are really, really good...I believe in my heart that implementation is really a good thing.”

Gottesman said a detailed implementation plan for Red Team recommendations would be unveiled by May 21. “I’ve been here long enough to know that NIH can survive this,” he concluded.

During a Q&A session with employees, Gallin noted that while the culture change called for in the recommendations “is free [of charge], it is also hard to do. No patient should be scared of going here.” Collins also pointed out that the CC’s current advisory board for clinical research, “which has been in place for some time,” will be “sunsetting” in favor of more stringent external board oversight that is common in community hospitals nationwide.

More on Red Team recommendations can be found at <http://acd.od.nih.gov/meetings.htm>, under the Apr. 21 heading. 

OMS’s Jackson Helps Save Neighbor’s Life

BY RICH MCMANUS

Back during January’s blizzard, Gary Jackson, a nurse for 40 years who has spent the last 3 years at NIH’s Occupational Medical Service in Bldg. 10, just wanted to relax and warm up after shoveling his walk in Kensington.

He had just sat down to rest and was contemplating braving the storm to visit his wife, who was briefly hospitalized at Suburban Hospital, when a knock came at the door.

A neighbor who knew that Jackson was a nurse said only that a man had fallen and needed help.

“I thought it was a broken ankle or arm,” said Jackson.

What he found was a neighbor in full cardiac arrest—no heartbeat, unresponsive.

The man, who several years ago had had a heart attack and the insertion of stents, had been out operating a snow blower when he collapsed.

Two neighbors who saw him dragged him indoors, out of the cold, then sought Jackson.

One of the men—Jackson only knows him as neighbor Mike—was a former EMT who knew CPR. Jackson is a CPR expert, having taught hundreds of people the lifesaving technique over the last 4 decades. The two slammed into a rhythm of compressions and respirations for the better part of 15 minutes before an ambulance made it through the snow.

The neighbors managed to restore a weak and quavering heartbeat, then the EMTs took over and were able to shock the patient into a steady rhythm and transport him to the hospital.

“I’ve done CPR lots of times,” Jackson said, “but this was the first time I did it off the job. It wasn’t that different to me.”

Jackson, 65, a Kansas City, Mo., native who spent 20 years in the Navy, knows he’s saved lives before, but most of the time, he is too busy with current cases to find out what happened with yesterday’s patients.

“I miss that part of the chain,” he said.

But he knows that the man he helped save is now recovered, going to cardiac rehab and able to do light gardening. “But he isn’t shoveling snow anymore—he’s given that up.”

Jackson and his wife see the man, a retiree in his 70s, when they walk their Redbone Coonhound through the neighborhood. “He really looks as well as he did before the event,” Jackson said. “[The couple] are really quite grateful and gracious.”

It is casual dog-walking that introduced them to Mike (whom Jackson hasn’t seen since the incident) and Lucas, the man who had come knocking on Jackson’s door, and who knew from sidewalk conversation that Gary was a nurse.

Now, the whole neighborhood knows about the incident. So does Montgomery County Fire & Rescue, which recently honored Jackson and the EMT crew that took over for him as EMS Providers of the Month.

Jackson, who is a member of the Sudden Cardiac Arrest Foundation, thinks everyone should know CPR, not just nurses and other caregivers.

“Everybody has to learn how to do compressions,” he said, acknowledging that it is quite a violent act—the goal is to press a victim’s chest anywhere from 2 to 2.5 inches inward, at about 110 pushes per minute, which is roughly the beat of the Bee Gees’ *Stayin’ Alive*.

“I don’t like that song,” says Jackson, “so I use [Queen’s] *Another One Bites the Dust*.”

Whatever works.

DURING ‘SNOWZILLA’



Gary Jackson

PHOTO: RICH MCMANUS



At NIH Over the Years. At left, Mikulski chats with acting NIH director Dr. William Raub (l) and NIAID director Dr. Anthony Fauci (center, r) in 1987; at right, in 2013, greeted by Fauci and former NIH director and then-NCI director Dr. Harold Varmus, she comes to “raise hell” about the potential effects of sequestration.

Mikulski

CONTINUED FROM PAGE 1

senator visited campus Apr. 11 for a town hall meeting that was part “farewell,” part “not finished yet.”

“We can talk about the past, but it is the past,” Mikulski said. “Though I want to savor the past, I want to focus on fighting for the future.”

Once again, she vowed to work her earrings off “so that the last appropriation for the NIH under Barbara Mikulski’s watch is going to be the best damn appropriation you’ve ever seen.

“I want to be sure that we get the right resources going in the right direction so that you get to do you,” she noted. “That’s been my passion for the time I have represented you. My single goal was to let you be you, so that you could come up with the cures and the breakthroughs, the new ideas, the new science that would help the American people and people all around the world.”

Last year—serving in her fifth term in the

Senate—the lawmaker recalled the decision she had to make.

“It takes 2 years to run in an election and 6 years to serve,” she said. “How did I want to spend those 2 years—working to keep my job or worrying about your job and the American people? Was I going to spend my time worrying about the next election or the next generation? What was I going to do—raise money for me or raise hell for you? That’s when I said, I want to raise hell for you! I want you to know that although I won’t be running for office, I won’t be running from service.”

“NIH has been fortunate to have such a fierce champion on our side and NIH is a better place because we’ve been challenged to work hard to live up to Sen. Mikulski’s standards,” said NIH director Dr. Francis Collins, opening the town hall meeting.

In brief remarks at what she has often referred to as the “National Institutes of Hope,” the dean of Senate women said, “Serve is in my DNA. If you take the sample, take the swab, you’ll find the serve gene.”

She spent several moments reminiscing about some of NIH’s best known research accomplishments during the years she has represented the agency in Congress.

Saluting Collins, she recalled with pride his victory on behalf of the U.S. in the race to map the human genome.

“A rich nation could have found a way to map the code,” she acknowledged, “but a great nation like ours gave the information to the world.”

She recognized NIAID director Dr. Anthony Fauci for leading efforts that now have made “HIV/AIDS a chronic condition rather than a death sentence.”

And acknowledging what she likely considers her crowning achievement here—her efforts to ensure that women are represented in all aspects of biomedical science, as investigators as well as volunteers in clinical research—Mikulski warmly greeted a familiar face who surprised her at the town hall: Dr. Vivian Pinn, former director of NIH’s Office of Research on Women’s Health, now retired, had returned for Mikulski’s visit.



In her final visit as senator, Mikulski (l) receives warm regards from those at NIH, including her “pal on the barricades,” former ORWH director Dr. Vivian Pinn (second from l), NIH principal deputy director Dr. Lawrence Tabak, NIH deputy director for science, outreach and policy Dr. Kathy Hudson and NCCIH director Dr. Josephine Briggs. At right, in addition to one-of-a-kind “National Institutes of Hope” guitar pick-shaped earrings, a plaque featuring a golden Petri dish was presented to Mikulski by NIH director Dr. Francis Collins in recognition of her outstanding support of medical research over a 30-year career in Congress.

PHOTOS: ERNIE BRANSON



At left, at a farewell town hall Apr. 11 in Masur Auditorium, Mikulski said she intends to leave NIH with the “best damn appropriation you’ve ever seen.” She also reminisced about past triumphs at NIH, including success of several gender equity initiatives with the late Dr. Bernadine Healy (center, l) and then-ORWH director Pinn, shown in 2010. In fact, Mikulski has worked closely with every NIH director in the last 30 years; at right, in 2007, she oversees an MOU signing with (from l) NIH director Dr. Elias Zerhouni (l), NASA administrator Dr. Michael Griffin and NIAMS director Dr. Stephen Katz.

The senator fondly remembered how the concept of ORWH was formed.

In the early 1980s, she and other lawmakers were learning that much of the current knowledge about health and disease might not accurately apply to women because females had been excluded from participating in the majority of research trials.

Mikulski recalled an encounter she had with pioneering surgeon and medical consultant Dr. Edgar Berman of Baltimore, who tried to explain why women had been left out of so much clinical research: “You girls have those raging hormones,” he told her.

Mikulski said she replied, without missing a beat, “We have those raging hormones because of guys like you!”

The Masur Auditorium crowd erupted in laughter and applause.

Mikulski phoned the former director shortly before she died, and in the course of the call, noted that the WHI the two helped orchestrate had resulted in a 12 percent decrease in deaths from breast cancer.

“Her last words to me were, ‘Wasn’t that great? We saved lives a million at a time,’” the senator recalled.

Unwilling to rest on past laurels, however, Mikulski emphasized that as good as previous victories are, she’s not done fighting yet. She has, she said, a strategy for her remaining time in office.

As she first revealed at an appropriations hearing just days before her NIH visit, Mikulski outlined three guiding principles for her final funding negotiations as U.S. senator:

“First, do no harm,” she roared, in her

sustainable, don’t-screw-with-it, keep-it-going—and that’s exactly what we’re going to do.”

And finally, she said, we want to identify new money for new ideas. “Let’s see if we can find bonus money so that you get a bigger shot at the [Cancer] Moonshot and all of the other great things you’re working on.”

Mikulski ended by reemphasizing her concern and support for young people and the next generation. She endorsed STEM education initiatives for all age groups, particularly middle school kids, and proposed term limits on student loan debt.

Acknowledging that when she came to the U.S. Senate, she had a rotary telephone and a typewriter, Mikulski marveled at the tremendous changes over the years.

“Who would’ve known the dawn of the



“No matter where I go, no matter what I do, I’m going to continue to be your advocate all the way up to my last hours in the U.S. Senate...I will never ever forget you.”

-SEN. BARBARA MIKULSKI



Not long after the Berman conversation, Mikulski—one of just two women in the Senate at the time—joined with HHS and NIH leadership to plant the early seeds for what would become ORWH.

The lawmaker, visibly moved, also reflected on her last conversation with the late Dr. Bernadine Healy, NIH’s first woman director, who led the agency to undertake “the famous hormone study that changed clinical practice,” the Women’s Health Initiative.

signature plain terms. “What I mean by that is no [government] sequestration, no shutdown, no slam down! Let’s get our job done! You do your job—we need to do ours. If we can be half as good as you, we will find a cure for this political toxicity!”

Next, she said, she wants to “capitalize on existing programs”—the BRAIN Initiative, Precision Medicine Initiative, efforts for young investigators. “We need to make sure that what you’re doing gets funded. You need something that’s reliable, undeniable,

Internet? Who would’ve known the dawn of the genome? We want continuous dawns,” she concluded. “We don’t want twilights of our future and our future opportunities...No matter where I go, no matter what I do, I’m going to continue to be your advocate all the way up to my last hours in the U.S. Senate, and then after that, I’ll find a way to have my say...You can count on that. I will never ever forget you.” **R**

Ubel

CONTINUED FROM PAGE 1

A doctor's recommendation often influences a patient's treatment choice, so the clinician has a huge moral responsibility to recommend well, said Dr. Peter Ubel, a physician and behavioral scientist who teaches public policy and business at Duke University. He led an animated, thought-provoking discussion about shared decision-making among doctors and patients at a bioethics lecture Mar. 22 in Lipsett Amphitheater.

"People want to be heard and understood. That, to me, is what shared decision-making is; that's what partnership is," said Ubel, who helps prepare business students for jobs in health care. "What we need to do as clinicians is to get better at eliciting those patient preferences. [Clinicians should tell patients]: 'I'm the expert on medical facts, but you're the expert on you.'"

Ubel used the example of a patient with low-grade prostate cancer who was trying to decide between surveillance or surgery and radiation. Whether he chose the passive or active approach, the survival rate was the same. But with waiting comes anxiety, and with the medical procedures, he'd run the risk of incontinence and erectile dysfunction.

In this case, how worried was the patient about those side effects? What were his life goals? Asking these kinds of questions can help determine the best course of action. In

a similar case, a patient said he preferred the watch-and-wait approach, that he could more easily pursue active treatment after he retired in a couple of years.

"All else equal, the treatment people receive should have something to do with what they care about and these baseline preferences," said Ubel.

The doctor also should consider the patient's reaction when delivering the diagnosis, said Ubel. In a urology office, a doctor told a patient he had slow-growing cancer, then tossed out a lot of convoluted, vague information. The doctor may think it's not an aggressive case so it's not bad news, but the patient probably only heard, "you've got cancer" and tuned out the rest.

People need time to recover from bad news before making an informed decision. Ubel warned that information overload reduces comprehension and retention, and ultimately affects the patient's choice.

"I think in part because of the way we're taught in medical school about informed consent and patient autonomy, there's this big emphasis on information," said Ubel. "We inform the hell out of patients in jargon they can't understand at a time when they're not ready to take on complex information."

If we have too many choices and too much information to process, Ubel said, people disengage. And patients might just ask for the doctor's advice without really understanding the diagnosis and treatment alternatives.

"One of the problems with shared decision-making and promoting patient autonomy is that thorough communication is not always good communication," he said. "Good communication takes time; it takes time to deliver it well and it takes time for the patient to absorb the information."

In one survey, urologists said they only dispensed advice after gauging which way the patient was leaning. The urologists usually asked whether the patient had normal sexual function, but only 12 percent asked whether sexual function was important to the patient. And, astoundingly,

only 13 percent said this preference should factor into deciding the right treatment. Look beyond age and test results, said Ubel; consider what patients care about.

Furthermore, doctors should admit their biases, said Ubel. In one survey, most urologists said they'd choose surgery over radiation, but the radiation oncologists said they'd choose radiation. These opinions affect patient choice and doctors should explain their reasoning.

Another point to consider is that we often make different choices for ourselves than we'd make for others. Ubel surveyed a healthy group, giving them the hypothetical scenario of having colon cancer. They could choose between 1 of 2 surgeries, both with an 80 percent cure rate. The first treatment had low-probability side effects, including permanent colostomy and chronic diarrhea, while the second option had no side effects but a 20 percent chance of death.

Some 40 percent of doctors said they'd choose the surgery with the higher death rate for themselves, but only 25 percent said they'd recommend that option to their patients. Meanwhile, most patients surveyed said they'd prefer the treatment with the unpleasant side effects, but in the survey, half actually picked the surgery with the higher death rate.

Ubel said more doctors should employ "teach-back," a technique taught in medical schools in which the doctor explains a concept, asks the patient to explain it back and can then clarify misperceptions.

"I think we can learn a lot by hearing our own explanations through our patients' voices," he said.

Medical schools should have a broader curriculum that includes teaching communication skills and the psychology of decision-making, he suggested.

"I think many physicians today think of informed consent or shared decision-making or respecting patient autonomy as meaning an [obligation to] impart a tremendous amount of information to patients so they can be fully empowered to make a choice." But Ubel says that strategy doesn't always work.

When a patient asks, "What treatment would *you* choose," Ubel said doctors should ask probing questions and, when recommending a particular treatment, fully explain why. **R**



Ubel takes questions from the audience after his talk in Lipsett.

PHOTOS: JEFF ELKINS

NINDS Holds Summit to Prioritize ADRD Research

BY SHANNON E. GARNETT

Dementia—a debilitating condition that impairs memory, thought processes and functioning—affects as many as 47.5 million people worldwide, with 7.7 million new cases occurring each year, according to the World Health Organization. Although Alzheimer's disease accounts for most cases of dementia, about 20 to 40 percent of cases are caused by other, lesser-known forms often referred to as Alzheimer's disease-related dementias (ADRD).

NINDS recently sponsored a 2-day ADRD summit at Natcher Conference Center to bring together internationally recognized experts, investigators, physicians, non-profit groups and patient caregivers to discuss advances in the field as well as challenges and opportunities for future research on these disorders, which include frontotemporal, Lewy body, mixed and vascular dementias.

The goals of the meeting were to build on progress from the 2013 research recommendations, refine and add new recommendations based on recent scientific discoveries, solicit input from stakeholders and update priorities and timelines.

"This is an example of what makes NIH a great place," said NINDS director Dr. Walter Koroshetz. "In this process, patient advocates, scientists and government officials come together for this bottom-up approach to develop a plan for how to fight these terrible disorders. The process is now in its second phase. The first phase was quite successful as it was incorporated into the bypass budget, which returned a significant increase in funding to NIH for work in Alzheimer's disease and ADRD."

Dr. Ronald Petersen, professor in the department of neurology at the Mayo Clinic College of Medicine and chair of the Advisory Council on Alzheimer's Research, Care and Services for the National Alzheimer's Project Act (NAPA), gave an overview of the NAPA plan.

NAPA, signed into law in January 2011, is a plan to overcome Alzheimer's disease and related disorders by 2025. To help carry out the plan, in 2012 NIA held a summit to create a multidisciplinary research agenda for Alzheimer's disease and in



At left, summit audience members provide feedback on ADRD recommendations. At right, NINDS director Dr. Walter Koroshetz addresses the 2-day meeting.

PHOTOS: BILL BRANSON

2013 NINDS held the ADRD workshop to set initial research priorities. This year's summit built on progress since those priorities were created.

"These meetings are not just academic exercises but, in fact, they have real impact on the process and, at the end of the day, dollars and cents," said Petersen. The summits, he explained, determine the direction of research questions that translate directly into funding opportunities.

NINDS organized the summit in collaboration with NIA, NIH's Office of Disease Prevention, the Foundation for the NIH, Alzheimer's Association, Accelerate Cure/Treatments for Alzheimer's Disease, American Heart Association/American Stroke Association, Association for Frontotemporal Degeneration, Axovant Sciences, BrightFocus Foundation and LEAD Coalition.

In preparation for the meeting, more than 80 top dementia researchers, physicians and other experts in the field worked together for 6 months to refine earlier recommendations. They also were charged with evaluating progress and proposing new priorities and timelines based on current science.

Topics included multiple etiology dementias, ADRD health disparities, Lewy body dementias, frontotemporal lobar degeneration and vascular contributions to cognitive impairment and dementia. New this time were sessions on the role of non-governmental disease organizations and on the importance of standardizing dementia terminology.

Dr. David Holtzman, scientific chair of the summit,

presented three main themes that cut across all sessions: genetics, environment and aging. Understanding the genetic pathways that contribute to the disorders is going to be critical, especially for developing diagnostics and therapeutics, he said.

Another common idea was the need to develop better disease biomarkers—both pre-clinical and clinical as well as those for people in midlife.

At the end of the meeting, Holtzman and the session chairs fielded final questions from the audience and received feedback regarding the research priorities and the way forward.

"What is it that can be done practically within a timeframe?" stressed Dr. Rod Corriveau, an NINDS program director and summit program lead, encouraging researchers with dementia-related ideas to apply now for investigator-initiated grants and not to wait for funding announcements to be released.

Summit recommendations will be presented to NINDS's advisory council in September and then to the NAPA Council in October.

"The testimonies we have heard over the last 2 days are evidence that we all are just one big community trying to solve our problems and they are all important problems. To call everybody a part of your team and get everybody engaged in your problems are probably the best solutions," said Koroshetz in closing. "These recommendations have a tangible impact for ADRD research and funding. We are ahead of the ballgame."



Participants include (from l) summit scientific chair Dr. David Holtzman, summit lead Dr. Roderick Corriveau, Dr. Ronald Petersen of the National Alzheimer's Project Act and Koroshetz. At right, session panel members field questions from attendees.

Study Finds Factors That May Influence Flu Vaccine Effectiveness

The long-held approach to predicting seasonal influenza vaccine effectiveness may need to be revisited, new research suggests. Currently, seasonal flu vaccines are designed to induce high levels of protective antibodies against hemagglutinin (HA), a protein found on the surface of the influenza virus that enables the virus to enter a human cell and initiate infection.

New research conducted by scientists at NIAID found that higher levels of antibody against a different flu surface protein—neuraminidase (NA)—were the better predictor of protection against flu infection and its unpleasant side effects. Neuraminidase, which is not currently the main target antigen in traditional flu vaccines, enables newly formed flu viruses to exit the host cell and cause further viral replication in the body.

The findings, from a clinical trial in which healthy volunteers were willingly exposed to naturally occurring 2009 H1N1 influenza type A virus, appeared online Apr. 19 in the open-access journal *mBio*.

“Each year, between 3,000 and 49,000 people in the United States die as the result of seasonal influenza and its complications,” said NIAID director Dr. Anthony Fauci. “Annual vaccination against seasonal flu continues to be the most effective way to protect against infection, and this new study provides some interesting clues about how we might improve the level of protection that flu vaccines provide.”



Women live longer in areas with more green vegetation, says new NIEHS-funded research.

Greenness Around Homes Linked to Lower Mortality

Women live longer in areas with more green vegetation, according to new research funded by NIEHS. Women with the highest levels of vegetation, or greenness, near their homes had a 12 percent lower death rate compared to women with the lowest levels of vegetation near their homes. The results were published Apr. 14 in the journal *Environmental Health Perspectives*.

The researchers found the biggest differences in death rates from kidney disease, respiratory disease and cancer. The scientists also explored how an environment with trees, shrubs and plants might lower mortality rates. They showed that improved mental health and social engagement are the strongest factors, while increased physical activity and reduced air pollution also contribute.

“It is important to know that trees and plants provide health benefits in our communities, as well as beauty,” said NIEHS director Dr. Linda Birnbaum. “The finding of reduced mortality suggests that vegetation may be important to health in a broad range of ways.”

The study examined greenness around the homes of 108,630 women in the long-term Nurses’ Health Study. The scientists consistently found lower mortality rates in women as levels of trees and plants increased around their homes. This trend was seen for separate causes of death, as well as when all causes were combined.

New Role Identified for Scars at Site of Injured Spinal Cord

For decades, it was thought that scar-forming cells called astrocytes were responsible for blocking neuronal regrowth across the level of spinal cord injury, but recent findings challenge this idea. According to a new mouse study, astrocyte scars may actually be required for repair and regrowth following spinal cord injury. The research was funded by NINDS and published in *Nature*.

“At first, we were completely surprised when our early studies revealed that blocking scar formation after injury resulted in worse outcomes,” said Dr. Michael Sofroniew, professor of neurobiology at the University of California, Los Angeles, and senior author of the study. “Once we began looking specifically at regrowth, though, we became convinced that scars may actually be beneficial. Our results suggest that scars may be a bridge and not a barrier towards developing better treatments for paralyzing spinal cord injuries.”

Neurons communicate with one another by sending messages down long extensions called axons. When axons in the brain or spinal cord are severed, they do not grow back automatically. For example, damaged axons in the spinal cord can result in paralysis. When an injury occurs, astrocytes become activated and go to the injury site, along with cells from the immune system, and form a scar.

Scars have immediate benefits by decreasing inflammation at the injury site and preventing spread of tissue damage. However, long-term effects of the scars were thought to interfere with axon regrowth.

“This important research provides further evidence about the complexity of the brain and spinal cord’s injury response,” said NINDS program director Dr. Lyn Jakeman. “It shows that scar-forming astrocytes

support axon growth and suggests that therapeutics directed only at blocking these cells may not enhance regeneration of the injured spinal cord.”

Trauma leads to spinal cord injury in about 12,500 people in the U.S. each year. It is estimated that 276,000 individuals in the country suffer from long-term effects of spinal cord injury. The ultimate goal of spinal cord injury research is to enable connections to develop that cross the level of injury and rewire the normal cord below.



Another study lauds a diet rich in fruits, vegetables and whole-grain foods.

Healthy Diet May Reduce High Blood Pressure Risk after Gestational Diabetes

Sticking to a healthy diet in the years after pregnancy may reduce the risk of high blood pressure among women who had pregnancy-related (gestational) diabetes, according to a study by researchers at NIH and other institutions. The study was published in *Hypertension*.

“Our study suggests that women who have had gestational diabetes may indeed benefit from a diet rich in fruits, vegetables and whole grains and low in red and processed meats,” said the study’s senior author, Dr. Cuilin Zhang, a senior investigator in the Epidemiology Branch, NICHD.

In fact, a healthy diet was associated with lower risk for high blood pressure even in obese women. Obesity is a risk factor for high blood pressure. But obese women in the study who adhered to a healthy diet had a lower risk of high blood pressure, when compared to obese women who did not.

Approximately 5 percent of pregnant women in the United States develop gestational diabetes, despite not having diabetes before becoming pregnant. The condition results in high blood sugar levels, which can increase the risk of early labor and a larger than average baby, which may result in problems during delivery. For most women with the condition, blood sugar levels return to normal after birth. However, later in life, women who had gestational diabetes are at higher risk for type 2 diabetes and high blood pressure.

The current study is the first to show that adopting a healthy diet—known to reduce high blood pressure risk among the general population—also reduces the risk among women with prior gestational diabetes.

Thambisetty Wins 2016 Geschwind Prize

Dr. Madhav Thambisetty of NIA's Intramural Research Program in Baltimore has been awarded the 2016 Norman Geschwind Prize in Behavioral Neurology by the American Academy of Neurology. The academy presented the award Apr. 19 in Vancouver at its annual meeting.



Dr. Madhav Thambisetty

Thambisetty was recognized for his outstanding achievements in behavioral neurology research. Chief of the unit of clinical and translational neuroscience in NIA's Laboratory of Behavioral Neuroscience, he explores disease mechanisms that operate in Alzheimer's disease and seeks to identify novel biomarkers predictive of the disease prior to the onset of clinical symptoms. He has been at NIA since 2007.

In addition to his research, Thambisetty is a practicing neurologist, evaluating and caring for patients with memory disorders at the Johns Hopkins Bayview Memory and Alzheimer's Treatment Center.

Former Diversity Program Manager Laster Mourned

BY LINDA MORRIS

Osler H. Laster, better known within the NIH community as "O.H.," died Apr. 4 at Howard County General Hospital from complications of a heart condition. He was 90.

A former high school teacher and Peace Corps volunteer who served in several African nations, Laster was born in Monongah, W.Va. He came to NIH in 1972 as a training officer for the National Cancer Institute, but in more than four decades of service, he touched many facets of life at NIH.

Just as Laster will be remembered for his signature straw hat, he will also be remembered for wearing many hats throughout his NIH career.

In 1972, Laster served on the NIH child development committee that was responsible for implementing plans for the first NIH day care center. In addition to developing and recommending training programs to enhance the upward mobility of NCI employees, Laster coordinated special observances focusing on minorities, women and employees with disabilities for NIH. In the early 1990s, he became a diversity program manager in the Office of Equal Opportunity in the



"O.H." Laster, in 2002, with Dr. Yvonne Maddox

Office of the NIH Director, predecessor of the Office of Equity, Diversity, and Inclusion. Laster was responsible for bringing such noted guest lecturers as the late Julian Bond, Martin Luther King III, several members of Congress and other notable personalities to speak on sustaining a culture that allows every NIH employee to reach his or her full potential.

"O.H. had strong skills in community advocacy and organization that facilitated his skill in creating programs to bring history alive," recalled Vince Thomas, Small Business Innovation Research Program manager, NIMHD.

Laster was a founding member of the NIH chapter of Blacks in Government and later served a term as its president. He worked with Coretta Scott King on the committee to create the Dr. Martin Luther King Holiday. A strong proponent of cross-cultural communication, Laster made every effort to include the various races and ethnicities represented in the NIH workforce in his programs.

Although he officially retired from NIH in 2000, Laster continued to consult agency leaders on diversity and minority employment issues and on planning and development of such special emphasis programs as the King Day and African-American History Month observances, as well as Take Your Child to Work Day activities.

He received many awards and commendations over the span of his 42-year career at NIH, one of which was presented by Dr. Yvonne Maddox, former NIH acting deputy director, shortly after his retirement. In the ceremony held to present Laster with a marble plaque, Maddox observed that, "NIH owes O.H. a tremendous debt of gratitude for his many years of hard work, creativity and commitment to the advancement of equal opportunity issues."

Upon learning of Laster's passing, Maddox said, "O.H. Laster was a dedicated, unselfish supporter of the many NIH diversity programs. He devoted personal time on weekends and after work to do whatever the agenda required to ensure that our NIH racial/ethnic cultural events continued from year to year. O.H. was well known for this passionate devotion and highly respected for it."

Laster was a resident of Columbia, Md., and was active in his local community. He served on the board of the Howard County Center for African-American Culture. He hosted the organization's annual Men in the Kitchen dinner, its primary fundraiser. Laster planned an annual Juneteenth program for the county in which he dramatized the horrors of slavery with a character he created, "James Too," an emancipated slave. An avid physical fitness advocate, Laster became a certified trainer and exercise instructor, most recently in Zumba, after retirement.

Laster's NIH colleagues, past and present, and friends mourn his loss along with his son and daughter-in-law, Charles and Dianne Laster of Monongah, his brother Rudy Laster of Buffalo, N.Y., and many other relatives around the country. [R](#)

Have a question about some aspect of working at NIH? You can post anonymous queries at <https://nihrecord.nih.gov/> (click on the Feedback tab) and we'll try to provide answers.

Feedback: At the intersection of Old Georgetown Rd. and Center Dr., I have witnessed conflicts over the right of way for bikers and pedestrians crossing at the crosswalk at the NIH entrance, versus cars turning left with a left turn arrow from southbound Old Georgetown Rd. I believe the source of the confusion is that there is no pedestrian walk signal at that crosswalk, hence individuals on the sidewalk cannot tell that there is a left turn arrow for cars entering NIH. This leads to dangerous confusion about right of way. Can something be done to remedy this situation, such as a walk signal for pedestrians and bikers?

Response from the Office of Research Facilities: The Maryland Department of Transportation (MDOT) investigated the pedestrian signal situation at the intersection of Old Georgetown Rd. and Center Dr. They identified tree leaves slightly blocking pedestrian signals on the southwest corner, a malfunctioning pedestrian push button on the southwest corner and some light-emitting diode (LED) bulbs burnt out. As part of their maintenance responsibilities, MDOT is in the process of making these repairs.

Additional improvements will be made as part of the MD 187/Cedar Ln. construction project, to include modifications to the Center Dr. and Old Georgetown Rd. intersection. This project includes audible pedestrian signals, sidewalk and sidewalk ramps for Americans with Disability Act compliance and new traffic signal heads with brighter LEDs for greater visibility. Presently, the project engineering team is not able to provide a more precise estimated completion date for these items other than the current estimate of late summer 2016.

As work progresses this spring and summer, MDOT and the State Highway Administration project engineering teams will continue to keep us updated with a more precise timetable.

Until all intersection improvements for the project are complete, NIH employees who feel unsafe in terms of vehicles not yielding the right of way to pedestrians and others should contact Montgomery County Traffic Enforcement at (240) 773-5581.



ABOVE: NCI's Dr. Christian Hinrichs (I) tells guests about his work, including a clinical trial of HPV-targeted tumor-infiltrating T cells for patients with HPV+ cancers, which has demonstrated that this treatment can mediate complete regression of cervical cancer in some patients.

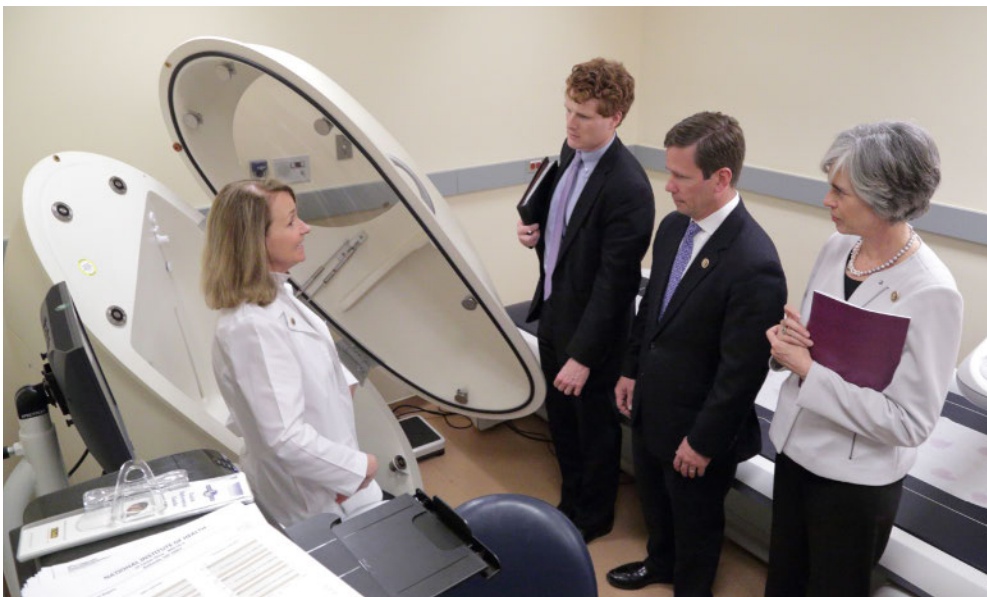


U.S. Representatives Visit NIH

PHOTOS: ERNIE BRANSON

Five members of Congress spent the afternoon of Apr. 12 at NIH, meeting agency leadership and visiting labs at NCI, NIDDK and NINDS. At left, the members include (from l) Reps. David Valadao (R-CA), Susan Brooks (R-IN), Robert Dold (R-IL), Katherine Clark (D-MA) and Joseph Kennedy (D-MA).

Below, NIDDK's Dr. Monica Skarulis (l) shows off the "bod pod" in the metabolic clinical research unit.



NIH director Dr. Francis Collins and NIDA director Dr. Nora Volkow at the recent summit on marijuana/cannabinoids

NIH Hosts Marijuana Research Summit

NIH hosted Marijuana and Cannabinoids: A Neuroscience Research Summit on Mar. 22-23, sponsored by several institutes and centers. Held at Natcher Conference Center, the event focused on the neurological and psychiatric effects of marijuana, other cannabinoids and the endocannabinoid system.

Given the rapidly shifting landscape of marijuana use and legalization, the summit was held to ensure evidence-based information is available to inform practice and policy. More than 2,000 people—including 60 international participants—attended the event in person and via videocast.

Speakers included NIH director Dr. Francis Collins, National Drug Control Policy Director Michael Botticelli, FDA commissioner Dr. Robert Califf, as well as researchers who presented on the cannabinoid system as well as the adverse and potential therapeutic effects of marijuana.

Attendees from around the world were able to pose questions to the researchers via Twitter during the event. The summit also included a poster session with 126 participants showcasing their research.