DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH
NATIONAL LIBRARY OF MEDICINE

MINUTES OF THE BOARD OF REGENTS
September 16-17, 2015

The 170th meeting of the Board of Regents was convened on September 16, 2015, at 9:00 a.m. in the Donald A.B. Lindberg Room, Building 38, National Library of Medicine (NLM), National Institutes of Health (NIH), in Bethesda, Maryland. The meeting was open to the public from 9:00 a.m. to 3:30 p.m., followed by a closed session for consideration of grant applications until 4:00 p.m. On September 17th, the meeting was reopened to the public from 9:00 a.m. until adjournment at 11:30 a.m.

MEMBERS PRESENT [Appendix A]**:**
Mr. Eric Dishman, Intel Corporation
Dr. Robert Greenes, Arizona State University
Ms. Sandra Martin, Wayne State University
Dr. Esther Sternberg, University of Arizona
Ms. Gail Yokote [Chair], University of California, Davis

EX OFFICIO AND ALTERNATE MEMBERS PRESENT:
Mr. Christopher Cole, National Agricultural Library
Dr. Joseph Francis, Veterans Health Administration
RADM Scott Giberson, Office of the Surgeon General, PHS
Col. Helen Hootsmans, United States Air Force
Ms. Kathryn Mendenhall, Library of Congress
Dr. David Neri, United States Navy
Dr. Dale Smith, Uniformed Services University of the Health Sciences

CONSULTANTS TO THE BOR PRESENT:
Dr. Jill Taylor, Wadsworth Center, New York State Department of Health
Dr. H. Kenneth Walker, Emory University School of Medicine

SPEAKERS AND INVITED GUESTS PRESENT:
Ms. Sharon Chiang, Rice University
Dr. Francis Collins, Director, National Institutes of Health
Dr. Joshua Denny, Vanderbilt University
Ms. Terrie Reed, Food and Drug Administration
Dr. Lawrence Tabak, Deputy Director, National Institutes of Health

MEMBERS OF THE PUBLIC PRESENT:
Mr. Glen Campbell, Friends of the National Library of Medicine
Ms. Lesley Macherelli, Friends of the National Library of Medicine
Dr. Barbara Redman, Friends of the National Library of Medicine

Dr. Elliot Siegel, Consultant
Mr. Thomas West, Krasnow Institute

FEDERAL EMPLOYEES PRESENT:
Ms. Betsy Humphreys, Acting Director, NLM
Dr. Milton Corn, Deputy Director for Research and Education, NLM
Dr. Michael Ackerman, Lister Hill Center, NLM
Ms. Dianne Babski, Division of Library Operations, NLM
Ms. Joyce Backus, Division of Library Operations, NLM
Dr. Seo Baik, Lister Hill Center, NLM
Mr. Todd Danielson, Office of the Director, NLM
Ms. Darlene Dodson, Office of the Director, NLM
Mr. Ivor D'Souza, Office of Computer and Communications Systems, NLM
Dr. Kathel Dunn, Division of Library Operations, NLM
Ms. Gale Dutcher, Division of Specialized Information Services, NLM
Dr. Michael Feldgarden, National Center for Biotechnology Information, NLM
Dr. Valerie Florance, Division of Extramural Programs, NLM
Dr. Dan Gerendasy, Office of Health Information Program Development, NLM
Dr. Zoe Huang, Division of Extramural Programs, NLM
Dr. Michael Huerta, Office of Health Information Program Development, NLM
Ms. Christine Ireland, Division of Extramural Programs, NLM
Ms. Janice Kelly, Division of Specialized Information Services, NLM
Mr. Paul Kiehl, Office of the Director, NLM
Dr. George Komatsoulis, National Center for Biotechnology Information, NLM
Ms. Lisa Lang, National Information Center for Health Services Research and Health Care Technology, NLM
Dr. Robert Logan, Office of Communications and Public Liaison, NLM
Dr. Clement McDonald, Lister Hill Center, NLM
Mr. Dwight Mowery, Division of Extramural Programs, NLM
Ms. Becky Baltich Nelson, NLM Associate Fellow, Division of Library Operations, NLM
Ms. Kim-Loan Nguyen, NLM Associate Fellow, Division of Library Operations, NLM
Mr. Tyler Nix, NLM Associate Fellow, Division of Library Operations, NLM
Dr. Arthur Petrosian, Division of Extramural Programs, NLM
Dr. Steven Phillips, Division of Specialized Information Services, NLM
Dr. Barbara Rapp, Office of Health Information Program Development, NLM
Dr. Hua-Chuan Sim, Division of Extramural Programs, NLM
Dr. George Thoma, Lister Hill Center, NLM
Dr. Alan VanBiervliet, Division of Extramural Programs, NLM
Dr. Fred Wood, Office of Health Information Program Development, NLM
Dr. Jane Ye, Division of Extramural Programs, NLM
Dr. Deborah Zarin, National Center for Biotechnology Information, NLM

I. OPENING REMARKS

Ms. Gail Yokote, NLM Board of Regents Chair, welcomed Dr. Jill Taylor, Director of the Wadsworth Center, New York State Department of Health in Albany, NY, who is soon to be a new Regent, alternates, and guests to the 170th Board meeting. She then introduced RADM Scott Giberson to present the report from the Office of the Surgeon General.

II. REPORT FROM THE OFFICE OF THE SURGEON GENERAL (OSG), PHS

RADM Scott Giberson reported on leadership transitions. He said RADM Boris Lushniak, Deputy Surgeon General, officially retired in September 2015, and joined the Uniformed Services University of the Health Sciences faculty. RADM Sylvia Trent-Adams was recently appointed Deputy Surgeon General. She is a former Army nurse who will be coming on board October 1, 2015.

This fall, the OSG is on heightened alert for storms, is preparing for the Papal visit, and is continuing to respond to Ebola in Africa. The good news is the absence of new Ebola cases in recent days. In the early days of the Corps' work in Africa, there were about 80 new cases of Ebola a day and the Corps had required about 1000 volunteers a day to provide help. RADM Giberson personally spent time in the hot zone – a space no bigger than 4 times the size of the Boardroom with more than 100 Ebola patients receiving treatment.

On September 9, Surgeon General Murthy issued his first Call to Action on Promoting Walking and Walkable Communities at the Kaiser Center for Health. He distributed information about the positive impact that walking and wheelchair rolling can have on one's health. RADM Giberson asked the Board to encourage walking in their work environment. He said he schedules walking meetings weekly and employees are in a better mood when they do so.

RADM Giberson praised NLM's launch of a traveling exhibition on violence against women, an issue of concern to the new Surgeon General as well. The Surgeon General also wants to tackle mental and emotional health issues and chronic disease, use social media to a maximum, and will take on controversial issues.

Dr. Robert Greenes asked RADM Giberson if the Surgeon General was a political appointment. RADM Giberson responded that he was appointed by the President and confirmed by the Congress for a 4-year term.

Dr. Esther Sternberg discussed the importance of the including the impact of the built environment on the public's health and well-being. Working with the General Services Administration (GSA), she has found that the physical design of the work environment can have an impact on physical health and wellness. She noted that agencies across the federal government should work together to develop building standards beneficial to public health and wellbeing. RADM Giberson agreed that GSA's attention to the work environment is definitely welcome.

Dr. Greenes asked if the GSA or the OSG has information on the benefits of standing versus sitting at a desk. Dr. Sternberg said that one of the things that they found while working with the

GSA is that the design of the workplace is important for health and requires the support of the leadership to accommodate such opportunities and encourage walking.

III. REPORT FROM THE NIH DIRECTOR

Dr. Francis Collins said it was a pleasure to report to the Board in the officially renamed Donald Lindberg Room. He thanked Betsy Humphreys for her work as the Acting Director and said that the search for her replacement is underway.

Dr. Collins said that the Board would hear about the NIH Strategic Plan from Dr. Tabak later in the day and that they would also hear about informatics aspects of NIH's Precision Medicine Initiative tomorrow from Mr. Eric Dishman and Dr. Joshua Denny.

Dr. Collins said that NIH has a mission to conduct science in pursuit of fundamental knowledge about the nature and behavior of living systems to extend healthy life and reduce illness. NLM, he said, plays a very significant role in that mission— serving as the window for the public to see what is going on at NIH. He discussed several new NIH initiatives: The Brain Initiative, a 12-year plan involving 14 Institutes, to learn what the cells in the brain do; and The Precision Medicine Initiative, announced in the President's State of the Union Address on January 20, 2015. Learn more at: braininitiative.nih.gov or nih.gov/precisionmedicine.

The Precision Medicine Initiative (PMI) takes advantage of a number of recent events. First, increasingly patients want to be involved in their own health care. Second, the evolution of electronic healthcare records, and third the development of new technologies that track in real time many aspects of the body's performance, like the Fitbit and an iWatch he is wearing. Lastly, genomics allows us to look at what is going on at an individual level and to work with very large data sets.

There are two parts to the PMI. First, NIH needs to apply the tenets of PMI to cancer. NCI has already begun NCI-Match to find out what is going on at the molecular level for targeted therapeutics, to test combination therapies, and to understand and treat drug resistance. The other part of PMI is the very ambitious development of a National Research Cohort—more than a million US citizens. They will come from other funded cohorts, from community health centers, and through direct volunteers. The volunteers will be "partners" and will wear health trackers—a new model for scientific research. We will be able to use the data to reclassify disease categories and test pharmacogenomics to find the right drug at the right dose, and study factors contributing to disease resistance/resilience, among other things.

The PMI will bring about a big data issue. BD2K is underway through Centers of Excellent nationwide. NLM is a critical component of the NIH with respect to big data. NIH's Advisory Committee to the Director (ACD) compiled a report that found that NLM is the most visible face of the NIH. Its future must build on its successes and evolve to remain a leader in assimilating and disseminating accessible and authoritative biomedical research. NLM, the intellectual epicenter, should lead the NIH effort to catalyze open science, data-sharing. BD2K needs to live at NLM and will bring about a large increase in NLM's extramural program. NLM also needs to preserve the historical record of biomedical research and continue its important role in

informatics research. New NLM leadership will have to evaluate what talent and resources will be needed because a robust NLM is vital. NIH has a search committee for a new NLM director headed by Eric Green (NHGRI), and Jon Lorsch (NIGMS). Dr. Collins encouraged Board members to send names to the committee and to him.

Dr. Greenes asked about the representation of informatics expertise on the Search Committee. Dr. Collins indicated that ACD member Russ Altman brought that perspective. Dr. Greenes also asked about the role of informatics research in the BD2K initiative. Dr. Collins said that "informatics is the 2" (i.e., to) in BD2K.

Dr. Sternberg said that her work with the GSA to link environmental variables in real time fits well with the PMI. Asked if he would be encouraging volunteers from NIH, Collins said they will market the opportunity and NIH employees can volunteer but it would not be a requirement of their employment. Dr. Sternberg suggested that folks wear fitness devices.

Dr. Collins indicated that the Congress seems supportive of PMI right now.

Dr. Jill Taylor said she was interested in PMI because of the new definitions for disease and wellness. She said there are groups who are proposing concepts of wellness and constant monitoring of characteristics. She asked Dr. Collins if this has a place in PMI. Dr. Collins indicated that the intention was to collect data on environment risk and self-reporting from the PMI cohort to learn more about wellness.

IV. MAY 2015 MINUTES AND FUTURE MEETINGS

The Regents approved without change the minutes from May 12-13, 2015 meeting. The February 2016 meeting will take place on February 9-10, 2016, the 2016 spring meeting will take place May 3-4, 2016, and the Board approved holding the fall meeting September 13-14, 2016.

V. REPORT FROM THE NLM ACTING DIRECTOR

Acting Director Betsy Humphreys said that, in addition to the FY 2015 budget summary provided in the Board book, NLM had received an additional $200,000 in 2015 for HIV funding for the Lister Hill project that is screening HIV positive patients for tuberculosis in Kenya, discussed at the last Board meeting.

As to personnel, Ms. Humphreys said that NLM is under a partial hiring freeze to provide hiring flexibility for the next NLM Director. She noted the vacancy for the position of NLM Director and asked Board members to encourage highly qualified candidates to apply. The recruitment will remain open until filled, but the Search Committee will review applications received shortly after October 20, 2015.

Ms. Humphreys announced the upcoming retirement of Dr. Steven Phillips, Associate Director of Specialized Information Services (SIS). Steve came to NLM in 1994 to serve on its Board of Regents at the request of Senator Harkin. Dr. Phillips later served as the chair of this Board, as

the Deputy Director of Research and Education, and since 2007, as the Associate Director of SIS.

Ms. Humphreys said that Mr. Jerry Sheehan, NLM's Assistant Director for Policy Development will be on a 6 to 12 month detail at the President's Office of Science and Technology where he will be serving as the Assistant Director of Scientific Data and Information and will coordinate government-wide efforts to increase free access to government funded research results, both publications and data.

Ms. Humphreys then introduced Dr. Seo Baik who recently joined the Lister Hill Center. He is working with Dr. Clem McDonald. He received his Ph.D. in statistics from the University of Pittsburgh. He has rich experience with the evaluation of large databases, especially Medicare's clinical and administrative data. Also new to NLM is Dr. George Komatsoulis. He first came to NLM on detail from the NCI and now has been appointed Senior Bioinformatics Specialist at the NCBI where he will support the development of advanced capabilities for managing large-scale data and the usage of new models of computing.

Ms. Humphreys also encouraged the Board to review the backgrounds of several new Fellows and Visiting Scientists that have joined both the Lister Hill Center and the NCBI, provided in the Board book. Lastly, Ms. Humphreys called on Dr. Kathel Dunn to introduce NLM's new Associate Fellows: Ms. Becky Baltich Nelson who, received her MLS from the University of Maryland in 2015; Ms. Kim-Loan Nguyen who received her MLS from the University of Maryland in 2015; and Mr. Tyler Nix who received his MSLS degree from the University of Kentucky in 2015.

Next, Ms. Humphreys noted that with respect to the 2016 Budget, little is known, and we will start the year under a Continuing Resolution. She noted that the House-passed 21st Century Cures Act is now pending consideration in the Senate.

Ms. Humphreys discussed a recently released proposed revision to the "Common Rule," the federal policy to protect human subjects in research that was released on September 8, 2015. There are two goals for updating the Common Rule – to make things better for research participants and to cut red tape for researchers. The major reforms will calibrate oversight to level of risk, enhance respect for research participants, facilitate broad participation in research, simplify consent documents, and streamline the IRB review. She encouraged all those interested in this topic to read the Rule and provide comments before December 7, 2015. [NOTE: The deadline for public comments was later changed to January 7, 2015.] The proposed Rule will cover some clinical trials that are not currently subject to Federal regulation, – estimated to be 1,399 trials in 2016. There are also exclusions for low-risk research involving information originally collected for purposes other than the proposed study when the information is either publicly available or de-identified and low-risk research that has independent controls (e.g., is subject to HIPAA or Paperwork Reduction Act requirements) among others. There will be a higher bar for waiving consent, and the proposed revision would establish broad consent elements that will facilitate the PMI. IRBs, rather than research institutions, will be held responsible. The effective date will be 1 year after the publication of the final rule.

Dr. Greenes asked if there is any effort to consider issues surrounding consent management and electronic health records as we integrate information from many sources. Ms. Humphreys said that this will likely to be considered as part of the PMI.

Dr. Joseph Frances said that one of the issues for NLM is the use of electronic health data. He said IRBs aren't certain whether they should be considering individual risk, organizational risk, or reputational risk, for example, with loss of data. Sometimes, it is more difficult to do health services research than it is to do a trial with toxic drugs. Ms. Humphreys said that one of the best features of the proposed Cures Act is the inclusion of health services research under the definition of health care operations.

Ms. Humphreys said that computer security is a time-consuming issue for NLM. While NLM is doing a good job, cyber-attacks continue. NLM and NIH systems have to be available at all times. An in-depth review of security practices is underway, prompted by the recent breach of OPM data. Adherence to security procedures, following up on security audits, etc. is requiring increasing amounts of staff time and other resources

Ms. Humphreys briefed the Board on the American Customer Satisfaction Index (ACSI) results -- good news for NLM. The report, based on the first quarter of 2015, was issued in May 2015. More people are now using handheld devices, and it is more tedious to fill out the brief customer satisfaction survey on a smartphone. Foresee, the company collecting the data, therefore recently decided to ask handheld users to provide an email address to which the survey could be sent. This violates the agreement that allows government agencies to use ACSI to assess satisfaction with their sites – so the latest results for the 2nd quarter do not include smartphone users. Because the survey is voluntary, Dr. Greenes asked if it is a violation. Ms. Humphreys said in general that NLM does not collect information from web site visitors. Whether NLM, HHS, and OMB eventually get comfortable with giving email addresses to a privately owned company is yet to be seen. But, at present, OMB has approved the survey as is, not with the collection of an email address.

Lastly, Ms. Humphreys said NLM will host a lecture September 17, 2015 by Catherine Jacquet, PhD, Louisiana State University, entitled *From Private Matter to Public Health Crisis: Nursing and the Intervention Into Domestic Violence* to launch a traveling exhibition and web site on *Confronting Violence: Improving Women's Lives*.

VI. NIH STRATEGIC PLAN

Dr. Lawrence Tabak, Principal Deputy Director of the NIH, introduced his talk by asking Board members to provide feedback on NIH's strategic plan which he would outline. He noted that NIH is obligated by law to develop a strategic plan.

Dr. Tabak said that the NIH strategic plan should be a living, forward-looking document that identifies major trans-NIH themes to advance biomedical research over the next five years. It should not describe what NIH will not do in the future, nor address individual Institute priorities.

The development of the Strategic Plan has involved the NIH senior leadership and an IC working

group that includes an NLM representative. The Advisory Committee to the NIH Director (ACD) that met and emphasized the interconnected nature of the research. Dr. Collins is monitoring the plan's progress.

The plan's overview includes NIH's mission and its current research landscape in spite of lost purchasing power. The plan identifies areas of opportunity that apply across biomedicine: fundamental science, health promotion/disease prevention and treatments and cures. In fundamental science, we will highlight that consequences are unpredictable. An example of fundamental science would be questions about microbial diversity. Scientists make unpredictable discoveries like the role of the gut microbiome in immune system development and disease.

With regard to health promotion/disease prevention, Dr. Tabak said that the NIH plan would emphasize the importance of studying healthy individuals and advances in prevention, like NIH's leadership role in vaccine design and development.

In terms of treatments and cures, that the emphasis will be that there are opportunities based on molecular knowledge which have broken down traditional disease boundaries. As an example, cancer researchers have found commonalities in the pathways and processes that lead to abnormal tissue growth in various cancer types, resulting in breakthroughs in cancer immunotherapy.

The final portion of the strategic plan will be a set of unifying principles that are very important to stakeholders and policymakers alike. These will come under two categories—how priorities are set at NIH and how stewardship of the public trust and funds are enhanced. For each of the unifying principles, the plan will describe the current status and emerging opportunities, highlight specific examples of recent breakthroughs, and align them with the HHS Strategic Plan.

In setting priorities, NIH will incorporate disease burden as important factor – but not the only factor, follow scientific opportunity, and consider the value of permanently eradicating a pandemic. In enhancing stewardship, NIH will recruit an outstanding research workforce, enhance diversity and innovation, optimize approaches to inform funding decisions, ensure rigor and reproducibility, reduce administrative burden and employ risk management strategies. The Accelerating Medicines Partnership is an example of enhancing stewardship.

NIH issued a request for information (RFI) which closed on August 16. There were 460 responses received, mostly positive about the broad framework. Three webinars were held as well. Questions for discussion are, "What are the benefits and drawbacks of the framework structure and content?" "Is the framework compatible with the broad scope of the NIH mission?" "Are there any trans-NIH themes that have not been captured?" "Are there future opportunities or emerging research needs that should be included?"

Ex-officio member Col. Hootsmans asked if the strategic plan's mission is tied to a vision as well. Dr. Tabak responded that as part of the mission statement there is a lot about the vision. The stakeholder base for this is very diverse and NIH is trying to strike a balance. Congress is

one stakeholder. Patients, investigators, and patient advocates are as well. NIH needs to address concerns in a way all can understand.

Col. Hootsmans asked if there would be strategic goals in the vision statement. For example, when Dr. Tabak is talking about building a workforce, are you talking about recruitment and retention as one of your strategic goals? Dr. Tabak agreed.

Dr. Greenes liked the shift to wellness. But, he asked how NIH intends to address issues that fail to be addressed by other agencies. Where does that fit into the strategic plan? Dr. Tabak responded that part of the challenge is to stay within the NIH framework. NIH wants to frame this within the overall context of HHS so we can delineate the things that are squarely within the NIH mission and distinguish between what NIH does and our sister operating divisions do. Dr. Greenes asked if Dr. Tabak could see partnerships between CMS and others.

Ms. Humphreys said that many sister agencies, like CMS, have been making more of their data available to NIH grantees and to our NIH intramural community as well. Dr. Tabak said that NIH has some great partnerships with the CMS, CDC and FDA and others and we need more of them. Hopefully, the strategic plan will help redefine the importance of those types of relationships. Dr. Greenes asked if it would be possible to add to the vision statement the need to partner with more implementation-oriented groups, not just science-related groups. Perhaps the NIH plan should explicitly identify where those bridges need to be built. Dr. Tabak agreed and later commented that in essence the deliverable from NIH research is new knowledge that becomes available for use. In order for some types of knowledge to be used effectively, you have to partner with other agencies or the private sector because ultimately they are the ones that make the pill or whatever the intervention is.

Dr. Ken Walker said he chaired a strategic plan at Emory in 1995. The last strategic plan prior to the 1995 plan had been developed in 1945 and nothing had happened after the plan. It would be useful if NIH were to specify the tools that would be necessary to implement the NIH plan. Dr. Tabak said that the last time the NIH tried to do a trans-NIH strategic plan was in 1991 under then Director Bernadine Healy and it was never issued. He was told that it did not go anywhere because it tried to do all things for all people. Dr. Tabak said that NIH cannot use this document to fundraise, but in terms of tools, if we harmonize how we make decisions, across Institutes, that will go a long way towards achieving goals. In terms of science, NIH is emphasizing a global approach between all the Institutes in order to achieve required progress. This will complement and not usurp the individual Institute and Center plans. NIH does not want to overwhelm anyone with a long report that will never be read. NIH wants to make the point with compelling examples and then link to further detail, if desired.

Dr. Francis said that his office is responsible for VA performance metrics. He said that he would not even attempt to count “discovery” as a metric. But there is a lot that can be measured in terms of the enabling, coordination, and facilitation of research. The stakeholders from the communities you serve would have a lot to comment on that.

Dr. Valerie Florence asked if open access is a part of the plan. Dr. Tabak said it was. Ms. Yokote said that there were two unifying themes. One theme is that the infrastructure would be

trans-NIH and support open access. How can this strategic plan encourage that particular theme? The second theme was one of coordination of effort across the NIH Institutes and Centers with the goal of reproducibility and transparency for how trials are conducted and for how research results are disseminated. Is there a way to make these two themes more prominent? Dr. Tabak said that she underscored the issue that NIH is struggling with. Rather than state the obvious, they are trying to use this as a way to call attention to things that will be useful to policymakers and stakeholders.

Ms. Humphreys said that discussion of infrastructure makes some in the NIH-funded community nervous because they fear you are talking about is a reduction in funding for investigator-initiated research. Dr. Tabak said he hopes people don't go there. Ultimately, he said, all will benefit and NIH should have the same, if not more, money for the investigator-initiated research. But the word "standardization" does make some people nervous.

Dr. Corn asked Dr. Tabak what he anticipates from the interest groups, Congress, and others who always ask about "disease burden?" Dr. Tabak said that to be silent on the issue just begs the question and he would rather state it up front.

Ms. Humphreys commented about NIH publishing priorities for HIV/AIDS funding. She said that was a difficult issue that was handled very well. Communities affected felt that if we have good science and opportunities in those areas then the NIH should fund it – not by an arbitrary formula. Dr. Tabak agreed and said it is precisely the model that should be used going forward.

VII. PRESENTATION OF REGENTS' AWARD

The Regents' Award for scholarship or technical achievement was presented by Ms. Gail Yokote to Dr. John Wilbur, a senior investigator in the Computational Biology Branch of the National Center for Biotechnology Information, for his outstanding and pioneering work in applying natural language processing and text mining methodologies for improving the retrieval of biomedical information. Dr. Wilbur is the original developer of algorithms underlying the "Related Articles" (now called "Similar Articles") in PubMed among other heavily used PubMed features.

VIII. NLM/FDA MEDICAL DEVICE INFORMATION PARTNERSHIP

Mr. Ivor D'Souza, Director of NLM's Information Systems, noted that on May 4, 2015, the NLM, in partnership with the Food and Drug Administration (FDA) launched a website that hosts the Global Unique Device Identification Database (GUDID). He introduced Ms. Terrie Reed, Senior Advisor for UDI Adoption at the FDA Center for Devices and Radiological Health, to provide the background and overview of the establishment of a unique device identification (UDI) system and the role NLM plays in supporting the adoption of UDI as part of an inter-agency agreement with FDA.

Ms. Reed explained that medical devices cover a vast range of products – implants, CT scanners, surgical instruments, contact lenses, wheelchairs, and blood glucose test devices, to name a few. Until recently the ability to clearly identify a device has been hampered both by the lack of a

unique identifier that distinguishes one product from another and the absence of a publicly available reference catalog to provide key data associated with such identifiers. The absence of these key components means that it is easier to identify recalled consumer products like milk or peanuts than it is to identify specific recalled medical devices. As a response to this gap in our healthcare system, Congress authorized FDA to establish a unique device identification system designed to adequately identify devices through distribution and use. In 2013, FDA released the final UDI rule that requires device labelers (most commonly device manufacturers) to 1) label their device with unique device identifiers (UDIs) in both plain-text and machine readable form and 2) submit device identification information to the FDA-administered Global Unique Device Identification Database (GUDID) – information that is made publicly accessible on AccessGUDID through the inter-agency agreement between FDA and NLM.

Once fully implemented, the UDI system will provide the basic device identification information to achieve a range of benefits including:

- Providing a foundation for a global, secure device supply chain, improving ordering efficiency, helping to address counterfeiting and diversion, and preparing for medical emergencies;
- Facilitating more rapid and accurate adverse event reporting and recall management;
- Generating device benefit-risk information to help practitioners and patients make better informed health care decisions; and
- Serving as the cornerstone of FDA's National Medical Device Postmarket Surveillance System, a far-reaching strategy launched in September 2012 for gathering and analyzing real world data collected as part of routine clinical and patient experience to identify poorly performing devices, to characterize and disseminate information about the real-world performance of medical devices on the market; and to facilitate the clearance and approval of new devices, or new uses of existing devices.

Dr. Sternberg asked if the FDA will scan the device UDI before it is implanted. Or is the FDA planning to have implantable radio transmitters? What happens if the bar code was not scanned before an artificial hip was implanted. Will your system then be able to pick up information from the actual device? Why rely on somebody scanning it in the operating room? Why not also have it transmitted?

Dr. Francis said that the FDA should be able to track these devices easily. We owe that to patients. The VA has an initiative under way to do that – to interrogate devices with a transponder basically.

Dr. Greenes said another partner is the Center for Medical Interoperability, a consortium of about 50 hospital organizations that are trying to create inventories of all of their devices. These are not necessarily implantable devices. He said this would be another source that FDA might want to work with because they are trying to get devices registered as well. He also mentioned that there are a lot of fitness devices that might be FDA approved. Is there any intent to regulate such devices?

Ms. Reed said the public thinks such devices are regulated and that it is only when something bad happens to them with an implantable device that they realize it is not tracked very well.

Patient empowerment is an important strategic FDA objective.

Dr. Francis said he was not surprised that patients think such devices are regulated. How long did it take for the grocery industry to put UPC numbers on things?

IX. PREDICTING SMOKING RELAPSE THROUGH A BAYESIAN MODEL FOR FMRI BIOMARKER IDENTIFICATION

Ms. Sharon Chiang introduced herself as a participant in the NLM biomedical informatics training program at Rice University's Department of Statistics. Working with functional Magnetic Resonance Imaging (fMRI) data, she discussed a specific model she developed to predict smoking relapse.

Despite the fact that cigarette smoking is the leading preventable cause of death in the U.S., only 6% of smoking cessation attempts are successful after six months. An fMRI, Ms. Chiang noted, may be able to show why some smokers are more likely to relapse than others. An fMRI is a non-invasive neuroimaging method used to measure brain activity by detecting changes in blood flow. The goal of her research was to figure out how brain activity is altered in smoking relapse and to be able to predict relapse risk for individual patients.

Ms. Chiang said there are a few theoretical contributors to smoking relapse. One of them is the physical withdrawal symptoms faced in the days immediately following smoking cessation. Another contributor to smoking relapse involves the mental cravings that can persist for weeks after the unpleasant withdrawal symptoms fade. For example, seeing a smoking buddy or engaging in an activity that is associated with smoking can trigger relapse. This is thought to be due to drug-induced internal changes and how the brain reacts to cigarette-related cues.

Her fMRI experiment was designed to show patients cigarette-related cues and scan their brain to see how their brain activity responded to these cues. She looked at data from a double-blind, placebo-controlled randomized clinical trial. For 55 smokers, their fMRI brain activity was recorded for different cigarette and neutral cues at baseline and through 12 weeks. They were treated with a variety of drugs and a placebo. We recorded their smoking status 6 months later to determine whether or not they quit smoking or relapsed. She discussed her novel Bayesian statistical model that simultaneously identified neuroimaging biomarkers for smoking relapse, and predicted the risk of smoking relapse on an individual patient level. The model achieves high prediction accuracy and identifies several brain regions as potential fMRI regional biomarkers of smoking relapse.

As a proof of concept, this model has been tested on simulated data. The model was found to out-perform current methods for predicting smoking relapse. Patients with increased activity in certain regions were 1.7 times more likely to relapse. This was very interesting because the fMRI data markers she saw are actually involved in motor planning. This research is able to give us a better understanding of circuits that can possibly be targeted by treatment. It can help us identify patients who may benefit from behavioral therapy.

Dr. Greenes said that sometimes hypnotism works well in treating smoking. Also, some people

use reminders or coaching on their smart phones to assist in smoking cessation. Through the research you are doing, can you tell which of these kinds of methods might work best for people who want to quit smoking?

Ms. Chiang said they do not have data right now on whether these other treatments and smoking cessation aids are effective for certain people. However, we can incorporate these methods into our model to see if a certain subsets of patients might benefit from these particular treatments.

X. EXTRAMURAL PROGRAMS REPORT

Extramural Programs Director Dr. Valerie Florance said that NIH takes rigor and responsibility seriously. There is now a Web site relating to that topic (http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research). Also, NIH Director Dr. Francis Collins and Deputy Director Dr. Lawrence Tabak wrote a commentary in the January 2014 issue of *Nature*, discussing actions that NIH planned to take to address this issue.

They state that research using animal models is an area that is susceptible to problems of reproducibility. Possible explanations include the fact that different animal strains were used or the work was done in different lab environments, with subtle changes in the protocol. Some irreproducible reports are probably the result of statistical problems. And then there's publication bias.

Drs. Collins and Tabak also mentioned that in 2014 NIH had launched PubMed Commons. Acting NLM Director Betsy Humphreys mentioned that the site has so far attracted a relatively small number of people—several thousand—who provide helpful comments about participants' ongoing research. People do address things that would affect reproducibility. To increase interest, NCBI has encouraged journal clubs to go on PubMed Commons and make comments.

In June 2015, NIH issued a "Guide Notice," to "clarify and revise application instructions and review criteria to enhance reproducibility of research findings." It is expected that these policy guidelines will apply to all research and career transition applications received after January 25, 2016. The guide covers four areas:

(1) Scientific Premise: The applicant is expected to describe the general strengths and weaknesses of prior research, based on a literature review and also a possible critique of rigor of research in a particular area.

(2) Rigorous Experimental Design: The applicant needs to address how he/she is going to achieve robust and unbiased results when describing experimental design and proposed methods, and provide reviewers with sufficient information to determine that.

(3) Consideration of Sex and Other Biological Variables: Sex, age, weight, and underlying conditions are often critical factors in predicting health or disease. As a biological variable, sex will be factored into research designs, analysis, and reporting and in both animal and human studies. Anyone not planning to do this must furnish a rationale as to why not.

(4) Authentication of Key Biological or Chemical Resources: If these substances are part of the research being done, there needs to be an assurance that their quality and validity for the study are sound. Dr. Florance said this information would need to appear as appendices to the application.

These new requirements have implications for training programs like NLM's. Scores could be lowered if there is no evidence of a good, strong plan to ensure that people know how to do rigorous, reproducible research by the end of their training.

The Collins-Tabak article said that lack of reproducibility is prevalent in preclinical research, but what about bioinformatics research? Should we ask the same kind of questions about the research that we support? Obviously, scientific premise perfectly fits into our field. However, the experimental design question—how one can assure the unbiased and reproducible results—might require additional thought. What documentation goes with the software that is developed?

Dr. Florance has explored applying the NIH Guide Notice to training programs with American Medical Informatics Association (AMIA) leadership. She encouraged Board members to contact her if they had questions about the policy.

XI. RESPONSES TO NIH RFI TO ASSIST NLM WORKING GROUP

Dr. Barbara Rapp gave background on the Advisory Committee to the NIH Director (ACD), charged with making recommendations for the future of the NLM.

From February 13 to March 13, 2015, the public was invited to respond to a request for information (RFI) issued by NIH on behalf of the ACD working group. There were 649 respondents. (The questions are listed at Tab 7 in the Board Book.) The basic structure was, "What are the current NLM elements that are the most or least valuable?" to four groups: the research community; health professionals; patients and the public; and publishers, librarians and developers. The content of the responses covered more than 200 specific NLM products. Librarians comprised the largest group of responders, although responses were received from a wide range of users of NLM services. Comments were extremely positive. For value to the researcher, PubMed topped the list. Respondents also offered many suggestions that generally fell into these categories: expand, continue to support, promote.

Comments on biomedical informatics focused on supporting research and training the workforce. Recommendations to increase funding were plentiful, with at least one person using the phrase "grossly underfunded" to characterize the current situation. Emphasis was placed on a research portfolio that is both broad and deep, fundamental and applied, and balanced to include clinical and public health informatics. Some suggested making NLM the home for all NIH informatics research.

With regard to big data, comments emphasized building and hosting repositories, enforcing data transparency, implementing standards, developing protections against fraud, and requiring data management plans.

In clinical data analysis, comments emphasized support for the secondary analysis of clinical data, creating a central repository and developing online navigation tools for browsing genome data, creating common reporting standards for various forms of health-related data as an important prerequisite for meta-analysis.

There were many comments regarding vocabulary and other standards, praising NLM's leadership but noting continuing great need in this area. The words "collaborate" and "partner" figure strongly. Three specific areas of need were noted: drug allergy, adverse drug effects and biotechnology-derived pharmaceuticals. The "bridge to knowledge" was viewed as important for clinical informatics, the need to fund clinical decision support systems that would be integrated with the EHRs.

There was a plea to retain the NLM print collections, and to digitize as much as possible from the modern and historical collections. Suggestions were made for the History of Medicine Division to take on large-scale acquisitions for pre-1920 medical records and 3D scanning projects for human anatomical collections.

Support for continuing and expanding open access with free full-text articles available to all was strong throughout. There were requests to facilitate access for public health workers, school nurses, as well as unaffiliated health professionals. There were also recommendations to make links to full-text articles more seamless.

On the information provider side, the tension of who does what came up again in determining the relative roles in the publishing and article access process. Publishers raised issues of copyright, access to use measures, linking to the full-text articles and taking a collaborative approach to the data sharing policies.

Support for NLM's toxicology emergency response and disaster-related resources was strong. Respondents noted the importance of social media in times of disaster, and that NLM should work with the disaster preparedness community to set up a model for national use of social media with roles and responsibilities assigned. A suggestion was made to develop an online certification program to equip people with knowledge about how to respond to safety incidents in rural areas too. Finally the need to develop an infectious disease information service similar to those for radiation and chemical events was described.

In summary, the responses to this RFI conclusively proved that we have a highly engaged user community. They provided thoughtful, useful input with relevance across NLM. Dr. Rapp welcomed Board members' thoughts and reactions.

Board member Sandra Martin asked whether the findings of the RFI would be shared with all respondents. Ms. Humphreys thought that Dr. Rapp's overview would let them know how their piece fit in with the overall findings. These results will feed into the next strategic planning sessions, once the new NLM Director is appointed.

Dr. Greenes asked whether there were comments about knowledge bases, especially computable knowledge bases. We have scattered places where these reside now and there is no authoritative,

or even peer-reviewed, process managed by some entity—public, private or by NLM—that could house these. The question comes up so often, especially with meaningful use: Where should these live? Is this a role for NLM? Dr. Rapp did not recall seeing that concept mentioned.

Mr. Dishman said the health information exchanges, which are an important national resource, are facing challenges. The PMI, and the development of the NLM's strategic long-range plan, offer both promise and problems to solve. As every individual software service provider, medical provider, is starting to handle patient data, it's becoming increasingly difficult for people to gain access to their own data. People's access to data should be the goal, said Mr. Dishman.

Ex-officio member Dr. Dale Smith said that about half of the recommendations are about new records of knowledge, and new formats. To plan, we need to know who needs these new records of knowledge, what do they need, and how will they be used?

How do you summarize all of the data so that it presents a meaningful picture to the person or to the healthcare provider about the health status of a patient? If NLM achieves a much larger extramural budget, that area clearly needs more R&D, said Ms. Humphreys.

XII. PRECISION MEDICINE INITIATIVE: INFORMATICS IMPLICATIONS

Dr. Joshua Denny from Vanderbilt University shared a brief history of the PMI. It was first announced at the State of the Union address on January 20th and then, 10 days later, President Obama announced the initiative as a goal with two parts: one, to treat cancer and another, to form a national research cohort with at least 1 million individuals to accelerate medical science in this country and the world. The President's proposed budget for 2016 included $215 million dollars, most of which would go to the NIH but this inter-agency initiative also includes components at the Food and Drug Administration and the Office of the National Coordinator. The breakdown of funding for NIH includes $70 million for the PMI oncology component and the rest to establish a national research cohort study of a million or more Americans. The goal is to establish a new way of doing research that fosters, open, responsible data sharing, patient privacy, and that puts engaged participants at its center.

An ACD PMI working group was established in March, to develop a vision for how to harness the advances in technology, scientific understanding, and participant engagement to develop a platform for precision medicine research. Dr. Denny is a member, as is Board of Regents member Eric Dishman. That diverse body of 19 includes representation from the private sector, academia, and patient advocates. The group has held several workshops, to obtain input from a wide variety of experts and interested parties, including one at Vanderbilt in May.

The group explored what we could use such a large cohort for. There were also two NIH- based RFIs, looking at existing biobanks and the strategies we could use to engage patients. We looked at different cohort models in an effort to capture diversity nationwide across a number of criteria. The Working Group's final report to the ACD is to be released today.

Thinking about quantitative assessments of environmental exposures, genetic factors, gene environment interactions and so on, such a large cohort will allow us to do many things not

previously available to us. Pharmacogenomics was seen as an early target for this, examining drug exposures and response. An Institute of Medicine report on precision medicine talked about our taxonomy of diseases and its evolution over time, and how more detailed and refined classifications may be possible using molecular data.

Mobile technologies and sensor technologies are a possible big win, too. We wanted to rethink the model of engagement with participants—not just subjects but truly participants. We need to rely on participants giving us data.

Having this rich store of data allows us to think about doing more targeted clinical trials involving relevant subsets of the PMI cohort; we get that capability by being able to contact participants to ask if they will participate in specific studies.

Why now? Much faster, cheaper methods for sequencing genomes; smartphone use across all socioeconomic boundaries; more ubiquitous EHRs; and increased computing power and techniques for data mining.

Key attributes include the free longitudinal access to data, biospecimens, and the ability to re-contact people. Those were the cardinal points that we valued as a working group.

We discovered a number of models to enable enrollment. We felt that it was important to leverage existing relationships with healthcare provider organizations because we know these have been successful in the past, with many large, EHR-related biobanks; these have collected genomic data for hundreds of thousands of people in maybe more limited engagement models than what we hope for, but they show the possibility of this kind of research being done with a lot of success.

The working group looked at the possible diseases that could be studied if we had a million person cohort. Dr. Denny showed data projected from a cohort of 200,000 individuals at Vanderbilt. As would be expected with a million individuals statistical thresholds would be 5,000-10,000 people to do disease-gene studies of statistical significance. You would need 10,000 individuals to look at a gene-by-environment interaction and then a pharmacogenetics study. With a million person cohort, there will be sufficient people for a number of different diseases.

The working group talked a lot about different data sources. The principle was to think about diverse data classes from the beginning, maybe starting with a more limited set that we can collect initially, but expecting that to grow. We want to tap into the rich detail and data that we can get and not be limited to a core dataset. Dr. Denny reviewed the categories of data of interest. Self-report measures are going to be important, especially things like diet, substance use and mood assessments.

We talked a lot about how to organize data. The model of having core data that could be centrally available arose as a tenet because that would enable us to do faster queries. But it is not sufficient for answering many questions so we will also need to be able to query additional data on the participants stored in other locations. Some research queries could be executed entirely

within some degree of core data, which could scale to potentially hundreds of thousands of queries. We looked at the types of data we will need, for use in either Boolean logic or machine learning approaches to get highly accurate algorithms.

So how do you collect EHR information? If you are a large healthcare system, you have a lot of these data and a research data warehouse, and you can restructure this data and probably send it forward to a PMI coordinating center. We can put certain standards and technology around .these transfers. From individual participants, though, we need new technologies and approaches to enable them to share their data. All of the standards that we need around this don't exist yet. So we came out with this idea of "sync for science," as an evolution of the "view, download and transmit" protocol. Sync for science would be a broader tool that would link or sync someone's health care system data potentially to a *research* enterprise, but it could also extend to any sort of clinical enterprise. The idea would be that it would be whole EHR data including structured and unstructured data; we would need to think about elements and metadata to support this.

The working group valued secure computing environments, the Centers for Medicare and Medicaid Services enclave being one example. Data security and privacy are of course very important; we expect the PMI data store to be a target, and we need to think about computational approaches to make it secure as possible. Also de-identification of patient data is critical. Work should be done on de-identified data except when there is a use case that needs identification including whole language—natural language narrative text.

A key principle is that participants should have access to their data, starting with their access to clinical data.

Dr. Sternberg hailed the new initiative and its promise of progress, but asked how it would be possible to measure a million people with only $200 million. That sum is the fiscal year 2016 budget, replied Dr. Denny, or the down payment, as Mr. Dishman noted. It takes a lot of money to develop an algorithm, said Dr. Sternberg. I think it has to be done with private-public partnerships, and I don't think it's possible to do it any other way. This equivalent of a medical "moon shot," with the goal of real-time molecular biomarkers, is another long shot.

Consultant Dr. Kenneth Walker asked for a rough timeline of the milestones for the project. Mr. Dishman remarked that, when a project is this widely known, people are excited about it and there's pressure to get started. However, there's a lot of heavy lifting initially, building both the cohort recruitment infrastructure and the scientific infrastructure, then the technical infrastructure. It does take time.

Ms. Humphreys asked about possible concerns on the part of prospective enrollees. They might be all right sharing their EHR information, having some contact with PMI participants and maybe giving an occasional sample. But they may object to recording health data on their smart phone all the time. They may not want their activities, or their vital signs, constantly recorded and shared. Mr. Dishman agreed, saying PMI hopes to learn from people who have studied certain communities where very different recruitment, education and maintenance strategies were put in place, to keep people in the cohort.

Dr. Francis asked whether there was a level of effort to develop the right data model, looking towards the future. The VHA has a high performance computing (HPC) environment for the tens of millions of veterans that it sees. It was quickly brought to its knees, unfortunately, because of the kinds of questions we are asking. Dr. Denny said that the Working Group has given this point a lot of thought. He admitted that he had brought the system at Vanderbilt, with about two million participants, to its knees many times, too.

Mr. Dishman reported that discussions are already underway with the Department of Energy and others, about using their HPC knowledge and others to try and figure out these challenges. We did some calculations for the sake of PMI and said if we sequenced all of the 1.65 million new cancer patients and added the other clinical data types that we're actually talking about, you would generate a dataset which is 400,000 times the digitization of the Library of Congress. It would take $58 million of electricity a year to run the analytics on this and 1,500 million server hours. This gives you a hint of the kind of scale of this project.

Dr. Francis said that, although you must do the heavy lifting computationally or mathematically, sometimes, in the end, it's the simple stuff that makes the difference. A longitudinal study requires genealogists ensuring follow up because the differential loss to follow up, biopsy results. It's hugely important to make sure patient identifiers are kept consistent over time. Although mundane, those are the things that are our biggest challenges in data models.

Ms. Terrie Reed from the FDA Center for Devices said that her agency is at a point where regulation for implantable device information has been completed. While not specifically mentioned in the PMI, she thought that capturing device data, too, would be important and offer good possibilities for data analysis.

Finally, Mr. Dishman commended Dr. Denny for his commitment and his many contributions to the Working Group, saying that he gave most of the group members a Ph.D. course on the subject matter in the course of their five months of collaboration.

XIII. PATHOGEN SEQUENCES UPDATE

Dr. Michael Feldgarden from NCBI said that his presentation would be on antimicrobial resistance (AMR) informatics. Today, microbial genomics is commonly used as an epidemiological tool. To solve the riddle of these AMR genes and organisms and how they spread, we can pose some simple questions, such as, do two isolates belong to the same outbreak? Have we ever seen this isolate in another part of the country? So, if I find evidence of salmonella in peanut butter in California and another case in New York, is that because the source was the same processing plant or is it just bad luck in two different places? We can also ask, if we see signs of a contaminated plant, are sickened people showing up at the local hospital?

One advantage of this approach is that it's faster and it also provides more resolution. But microbial genetics also provides much more information about the organism itself. That allows us to answer a very important question, about the nature of antimicrobial resistance. We used to be one drug class away from having untreatable organisms. Unfortunately, we now have

untreatable organisms—a serious problem. At NCBI, we asked ourselves, how can we help combat AMR?

We can provide database resources. We can help improve the identification and annotation of resistance genes. Finally, NCBI can help standardize resistance gene terminology, so biologists across disciplines have a common language to use.

Earlier this year, the White House released an action plan for combatting antibiotic resistance bacteria. One charge was to develop a national sequence database of pathogens—something like GenBank. The basic research goal was to understand the relationship between antibiotic resistance phenotypes and their underlying genome, their genotypes. This is as an opportunity to build an infrastructure base for collecting and presenting antibiograms, that pattern of resistance and sensitivity for a given bacteria that are associated with any bacterial genome.

Dr. Feldgarden discussed NCBI's progress to date. These new resources are now available. In three months we received over 700 antibiograms associated with genomic data from a variety of sources, including NIAID genome sequencing centers, private institutions and partner government agencies. People currently have the ability to find genomes that have these antibiogram data if they want to do an analysis. To make the submission process simpler, NCBI has developed data dictionaries, allowing us to standardize the inputs as well as minimize data drifts.

The pathogen detection pipeline is an important element. We've developed the ability to take data from the short-read archive (SRA), which people submit—this is the raw sequencing data. We can then build genome assemblies with that data using a two-phase process. We yield an improved assembly, a combined assembly, and then we annotate. We identify the genes on that genome and then can turn that into a report that makes sense to a researcher or a clinician.

So after annotation, what do we do then? We built a database that has over 3,600 resistance proteins. This set of proteins is subjected to hidden Markov models and BLASTs, to identify resistance genes in the genome. Then we generate the report.

This database has been constructed with multiple sources of input. We have domain experts, who are the people who literally publish on "this is what you should call this gene." We've also incorporated data from several groups that have large databases, such as the FDA Center for Veterinary Medicine, a key partner.

We have also developed a standardized descriptive nomenclature for these genes, which is important because the first step in figuring out how to go from a genotype to a resistance phenotype is figuring out what the proteins might do.

In trying to predict antibiotics susceptibility, one point to note is that various clinical groups and agencies are starting to use sequence to predict phenotype. Dr. Feldgarden is working with clinical groups to get their raw sequence data. He has two data sets. One is "known truth"—finished genomes that have been characterized. He said they know every single nucleotide in that genome. This is our positive and negative control for seeing how well we've done. The other is

Illumina data. It's not the top-of-the-line type of data. But we have it for a bunch of strains where we have both antibiograms as well as this data. If you work on antimicrobial resistance, it is difficult to assemble this part of the genome. It's essentially like doing a jigsaw puzzle where you have multiple, identical pieces. And there is no box cover with a photo of what to look for.

Dr. Taylor thanked Dr. Feldgarden for his presentation calling it a "moon shot for labs." Many people are doing important work on AMR, but we need to coordinate it all. This is the preparatory work to develop the algorithm so eventually there will be a tool for physicians to say, "With this genome, and with this patient's drug history, these are the drugs your patient is likely to benefit from." But this is the incredibly important preparatory work to get us to that point.

Ms. Humphreys said that strategically planning and dealing with greater standardization in terminology aligns well with NLM's expertise.

Dr. Walker said that his greatest worry is the urgency of this situation. Planning and standardization need to happen now. The CDC is doing an enormous amount of sequencing. Otherwise, we will have a mess to deal with, in multiple formats.

Dr. Walker asked whether this might be used with agricultural products, such as, "Where did this E. coli in this cucumber come from?" Call it forensic genomics. Yes, replied Dr. Feldgarden. A big customer in the pathogen detection pipeline is the Genome Tracker Project, headed by FDA. They plan to sequence 8- 10,000 isolates this year that are associated with foodborne contamination. It's the forensics.

Ms. Humphreys announced a special program following the Board meeting, on the history of nurses' involvement in highlighting and working to treat and prevent violence against woman. It marks the opening of a new display, Web site and traveling exhibition, *Confronting Violence: Improving Women's Lives*. There will also be a webinar presenting information on the PMI. Board Members have dial-in information and the proceedings will be published.

XIV. ADJOURNMENT

Ms. Yokote officially adjourned the meeting, at 11:30 a.m.

ACTIONS TAKEN BY THE BOARD OF REGENTS:

- Approval of the May 12-13, 2015 Board Minutes
- Approval of the September 13-14, 2016 Future Meeting Dates

Appendix A - Roster - Board of Regents

I certify that, to the best of my knowledge, the foregoing minutes and attachment are accurate and complete.

Betsy L. Humpheys, M.L.S.
Acting Director, National Library of Medicine

Gail A. Yokote, M.S.
Chair, NLM Board of Regents