Meeting of the Board of Scientific Counselors, Office of Infectious Diseases
Centers for Disease Control and Prevention
Tom Harkins Global Communication Center
Atlanta, Georgia

November 9, 2011

A one-day, open public meeting of the Board of Scientific Counselors (BSC), Office of Infectious Diseases (OID), was held on November 9, 2011, at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia. In addition to Board members and CDC staff, the meeting was attended by representatives of several public health partner organizations.

The focus of the meeting was to generate ideas on how CDC laboratories can maintain core capacities and provide leadership and support to state and local laboratories at a time of rapid change and limited resources. Break-out discussions on this topic were held following opening remarks, updates, and panel presentations on current and recent issues affecting infectious disease laboratories.

I. OPENING REMARKS

BSC Chair Dr. Rich Whitley called the meeting to order and was joined by Dr. Rima Khabbaz, CDC Deputy Director for Infectious Diseases and Director OID, in welcoming participants and facilitating introductions. Dr. Whitely stated that three BSC members, including himself, will have completed their terms of office before the next board meeting in May. The other two retiring members are Dr. Matt Boulton and Dr. Ron Stall. Dr. Khabbaz thanked retiring members and particularly Dr. Whitley for his long-time leadership of the BSC.

A request for names of individuals to be considered for nomination to the BSC to replace these three retiring members will be published in the Federal Register in December. The BSC is currently awaiting final approval from HHS on its 2011 nomination package for five new members.

II. UPDATES

Antimicrobial Resistance Working Group

Dr. Beth Bell, Director, National Center for Emerging and Zoonotic Infections Diseases (NCEZID) reported on an NCEZID proposal to establish a working group to advise CDC on implementation of CDC-led components of the 2011 *A Public Health Action Plan to Combat Antimicrobial Resistance*, which was issued in August by the Interagency Task Force on Antimicrobial Resistance (ITFAR) (http://www.cdc.gov/drugresistance/pdf/public-health-action-plan-combat-antimicrobial-resistance.pdfwebsite). The terms of reference and structure of the OID/BSC Antimicrobial Resistance (AR) Working Group would be similar to those of the BSC/OID Food Safety Modernization Act (FSMA) Surveillance Working Group, whose membership includes two BSC members who serve as co-chairs (Dr. Boulton and Dr. James Hadler) and other scientific experts and stakeholders.

Discussion of the proposed AR Work Group:

- In response to a question about the composition of the AR Working Group, Dr. Bell stated that (as with the FSMA Working Group) membership would include representatives from NIH and other federal agencies.

- Dr. Bruce Gellin, HHS National Vaccine Program Office (NVPO), commented that HHS would welcome "big-picture" advice from an OID/BSC AR Working Group. He also noted that antimicrobial resistance is a major priority for WHO.
- In response to a question about the BSC's responsibility in overseeing the AR Working Group, Dr. Khabbaz noted that working groups will report back to the BSC and may bring draft proposals and recommendations back to the BSC for vote.

The BSC **approved** the motion to form an AR Work Group.

Food Safety Modernization Act Surveillance Working Group (FSMA WG)

Dr. Dale Morse, Associate Director for Food Safety, Division of Foodborne, Waterborne, and Environmental Diseases (DFWED) and NCEZID Office of the Director, provided an overview of the 2011 Food Safety Modernization Act (FMSA). FMSA emphasizes disease prevention and response, increasing FDA authority to inspect food production and processing facilities and to recall contaminated foods. Its major themes are prevention and enhancing partnerships; inspection, compliance, and response; and import safety. Implementation funds have been authorized, but no appropriations have been made.

CDC's responsibilities under FMSA include improving foodborne disease surveillance and establishing "Food Safety Integrated Centers of Excellence" (see below). In addition, CDC is providing guidance on food allergy prevention and assisting FDA with a range of activities, including establishment of performance standards related to food contaminants; conducting a study of the food processing sector; development of produce safety regulation; development of a food safety research plan; identification of high risk foods; and review and enhancement of state and local capacity to combat foodborne disease.

CDC's core work related to foodborne disease surveillance includes coordinating and integrating federal, state, and local foodborne illness surveillance systems; increasing participation in national networks; facilitating timely sharing of information; developing improved epidemiologic and laboratory tools; and improving attribution of illness to specific foods. Several challenges are outlined as follows:

- Surveillance systems are underfunded, understaffed, often backlogged and suffer incomplete participation
- Critical partners at state and local health departments have suffered huge job losses (16,000 at the state level and 29,000 at the local level) between 2008 and 2011.
- The increasing use of non-culture diagnostics may weaken or undermine existing detection systems for foodborne disease, including PulseNet (http://www.cdc.gov/pulsenet/) and FoodNet (www.cdc.gov/foodnet/); see also pages 10-11.

First Meeting of the FSMA WG. Dr. James Hadler, BSC member and co-chair of the OID/BSC FSMA WG, reported on the group's first meeting, which was held Nov 7-8, immediately prior to the OID BSC meeting. Attendees included representatives from federal, state, and local government, academia, and industry (manufacturing, retail, and food testing), as well as three consumer groups: the Center for Science in the Public Interest, the Center for Foodborne Illness Research and Prevention, and the Pew Charitable Trusts. The agenda included providing guidance to CDC in the following three areas:

1) ***Selection Criteria for the Centers of Excellence.*** The FSMA Integrated Food Safety Centers of Excellence will be public-private partnerships that 1) are led by state health departments, 2) partner with one or more academic institutions, and 3) collaborate with FoodNet, the Foodborne Diseases

Centers for Outbreak Response Enhancement (FoodCore), and other existing surveillance systems. Specific aims include the following:

- Providing technical resources to frontline health professionals for improving routine surveillance and outbreak investigation
- Analyzing timeliness and effectiveness of foodborne disease surveillance and outbreak response
- Supporting training at the state and local levels that advances a streamlined and standardized approach to outbreak investigations
- Conducting research that supports outbreak activities (e.g., on prevention effectiveness and risk communications)

The FSMA WG recommended that organizations selected as centers of excellence have documented expertise in project management and coordination, performance measurement, training, leadership and mentoring, information systems, and research. They also recommended that the centers of excellence conduct the following:

- Provide strategic leadership and coordination that goes beyond state borders
- Be a network of centers rather than a group of stand-alone centers
- Have ongoing engagement with a range of stakeholders, including stakeholders from industry, agriculture, and consumer groups
- Build on existing resources
- Identify and address public health gaps
- Provide regional coverage so that all parts of the country benefit

Subject to the availability of funds, the anticipated posting date for the funding opportunity announcement (FOA) for the FMSA Integrated Food Safety Centers of Excellence is March-April 2012, with a submission date of May 2012, and an anticipated award and start date of August 1, 2012. The budget period length would be 12 months, and the project period length would be 5 years.

2) ***Interagency Food Safety Analytics Collaboration (IFSAC) Strategic Plan.*** IFSAC was established by CDC, FDA, and USDA to improve coordination of federal food safety responsibilities, including food safety data collection, analysis, and use. IFSAC is developing a Strategic Plan for Attribution that will allow public health officials to estimate the percentage of foodborne illness in the United States associated with specific foods and settings. That information will allow policy-makers to focus disease prevention efforts in areas where they can have the greatest impact. At the FSMA WG meeting, scientists from CDC presented a short-term (1-2 year) plan for developing point estimates based on data from outbreaks and a long-term (3-5 year) plan for providing refined estimates with ranges.

FSMA WG members recommended that CDC:

- Simplify the information in the strategic plan so that it can be understood by a wider audience
- Generate estimates within the short-term timeframe, because the long-term timeframe is too long to be useful
- Ensure that the attribution information is made available for public use

A public meeting on the IFSAC Strategic Plan for Attribution will be held on January 31, 2012, in Washington, DC.

3) ***Enhancement of foodborne disease surveillance.*** CDC's FSMA WG is also charged under FMSA with providing advice and recommendations on the following:
   - Priority data needs of partners related to foodborne illness and its causes

- How to improve the effectiveness, coordination, and integration of foodborne disease surveillance
- How to improve timeliness of data collection and access to surveillance data
- Overcoming barriers to improving surveillance and disease prevention
- Identifying capacities needed for automatic electronic searches of surveillance data
- Identifying specific actions to improve foodborne disease surveillance, with measurable objectives, timeframes, and resource needs.

Discussion:

- In response to a question about how FMSA provisions address disease risk related to imported food, Dr. Morse noted that 16% of U.S. food is imported, including 84% of fish and shellfish and 32% of fruits and nuts. CDC has been involved in a growing number of outbreaks related to imported foods, including the recent multistate outbreak of *Salmonella* associated with Turkish pine nuts. An important challenge is to improve access to data from partner agencies and routinely include these data in our public health surveillance systems (e.g., data on whether contaminated foods are imported or home-grown).
- In response to a question about advising states with limited resources on prioritizing food safety efforts, Dr. Morse suggested that the estimates developed by the IFSAC group might help by identifying high-risk foods and processing methods. He noted that the FSMA WG considered how to assist states with fewer resources and less likelihood of being selected as sites for centers of excellence. One approach is to expand FoodCore, whose goal is to improve outbreak investigation and build capacity in states.
- In regard to a question about building on existing resources, Dr. Morse noted that training is a major role of foodborne disease surveillance networks and of many foundations (e.g., the Robert Wood Johnson Foundation). CDC and partners should make an inventory of the distance-learning courses on foodborne disease offered by those networks. Dr. Hadler agreed that many valuable training tools already exist, although there is some duplication and insufficient dissemination.
- In response to a question on measuring progress in reducing foodborne illness over time, Dr. Morse agreed that it is difficult to compare data from different states because of different reporting measures. He noted that FoodNet provides harmonized data from 10 states that cover about 15% of the U.S. population. Dr. Bell emphasized that the primary objective of the IFSAC attribution plan is to track disease data—and the impact of regulatory interventions— in a way that informs policy. It is important, for example, to measure the impact of the Egg Safety Rule (http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/EggSafety/EggSafetyActionPlan/ucm170615.htm) on rates of *Salmonella* infection as well as the impact of FDA's new authorities under FMSA. Because disease rates fluctuate from year to year, it may be best to have a 3-year rolling average of national foodborne disease estimates.
- In regard to a question about expanding collaboration with Canada and Mexico on foodborne surveillance, Dr. Morse mentioned recent joint investigations by Mexican and U.S. health authorities, and Dr. Bell noted that PulseNet Canada has helped CDC identify and investigate cross-border disease clusters.
- In response to a question about regulatory coverage of food produced on farms (e.g., poultry and eggs), Dr. Morse noted that FSMA provides FDA with increased authority to inspect food processing facilities, but not farms, which are inspected by USDA. However, studies on foodborne disease attribution (which is a major concern for both the public health system and the agricultural industry) require farm and animal data. It is important that the Integrated Food Safety Centers of Excellence have access to expertise in agriculture and animal health issues.

OID UPDATES

Dr. Khabbaz opened her update with remarks about the recently released *CDC Infectious Disease Framework* (http://www.cdc.gov/oid/framework.html), which focuses on three critical elements: strong public health fundamentals, high-impact interventions, and sound health policies. The document incorporates comments on an earlier draft discussed during the December 2010 BSC meeting, additional program input, and other ideas raised at the May 2010 BSC meeting on transitioning disease prevention programs at time of changes in healthcare and economic challenges. She stated that CDC will be looking to the BSC for input on ways to best implement the *Framework* actions. Today's break-out discussions will focus on several of the laboratory issues described in Element 1 of the *Framework* (strong public health fundamentals).

Additional updates provided by Dr. Khabbaz included the following:

- ***New appointments:***
  - Wendi Kuhnert, Associate Director for Laboratory Science, NCEZID
  - Sonja Rasmussen, Deputy Director, Influenza Coordination Unit
  - Ron Rosenberg, Associate Director for Global Health, NCEZID
  - Steve Solomon, Director, Office of Antimicrobial Resistance, DHQP, NCEZID
  - David Swerdlow, Associate Director for Epidemiologic Science, NCIRD
  - Benedict Truman, Associate Director for Science, NCHHSTP

- ***Recent Awards:***
  - Kenneth Castro, Director, Division of TB Elimination, NCHHSTP, was honored as a public health hero in the October 22 issue of the Lancet.
  - Kevin Fenton, Director, NCHHSTP, received the 2011 Root Award, as one of the 100 most influential African Americans.
  - At the IDSA annual meeting, Umesh Parashar, CDC epidemiologist, received the Oswald Avery Award for Early Achievement for his efforts contribution to investigation and control of emerging diseases and Larry Pickering, Senior Advisor, NCIRD, gave the Edward H. Kass Lecture on vaccines.
  - On the media front, Janine Cory and Susie Childrey, NCIRD, received the 2011 Blue Pencil and Gold Screen Award of the National Association of Government Communicators for their poster, *Who Needs a Flu Vaccine –You*, and NCHHSTP's work with MTV on the *Get Yourself Tested* campaign received the 2011 Beacon Award for Integrated Communications by the Association of Cable Communicators.

- ***Budget news****:* CDC's budget decreased by 11% ($740 million) between FY 2010 and FY 2011. The Senate proposal for FY2012 contains a 2.5% increase in the CDC budget that includes increases for NCIRD and NCHHSTP; continued funding of the ACA Prevention and Public Health Fund (PPHF); and elimination of block grants to the states. The proposed House bill contains a 13% decrease in the CDC budget (including decreases for all ID centers); elimination of PPHF; and funding of the block grants at a low level ($100 million). Under either budget, it will be challenging for state and local health departments to provide basic public health services.

- ***CDC Grand Rounds, Winnable Battles, Vital Signs, and Special Issue MMWR:*** Dr. Khabbaz briefly mentioned CDC's Public Health Grand Rounds (http://www.cdc.gov/about/grand-rounds/index.htm) and several of the infectious disease topics included in these highly popular series. She also described progress made in CDC's "Winnable Battles" on food safety, HIV prevention, and reduction of healthcare-associated infections (HAIs), and highlighted recent CDC

Vital Signs publications (http://www.cdc.gov/VitalSigns/) on these topics. She cited two recent special issue MMWRs describing 1) major public health achievements over the past decade; and 2) 50 years of MMWR at CDC—both of which highlighted significant infectious disease issues.

- ***Expert Panels and Reviews***: In addition to several recent external program reviews, Dr. Khabbaz described a cross-cutting blue ribbon panel held in June 2011 which focused on bioinformatics in CDC's infectious disease laboratories. The panelists reviewed the status and range of bioinformatics activities across OID and provided comments and feedback on gaps and short-and long-term recommendations for addressing them. Next steps include possibly bringing in a senior bioninformatics consultant for a short-term assignment to help identify priority activities.

- ***Recent domestic and global infectious disease achievements***: Dr. Khabbaz next briefly described several notable issues and program accomplishments in infectious disease prevention domestically and globally:
  - In October, ACIP issued new recommendations on wider administration of vaccines against human papillomavirus (HPV) and hepatitis B virus (HBV; http://www.cdc.gov/vaccines/pubs/acip-list.htm).
  - PPHF-supported investments in FY 2011 included $100 million allocated for improving immunizations coverage among children, adolescents, and adults.
  - Major 2011 global achievements in immunization included progress in polio eradication and the introduction of new vaccines against rotavirus, pneumococcal pneumonia, and bacterial meningitis.
  - Results from The Prevent TB Study have shown a shorter combination drug regimen is safe and as effective as current standard treatment with isoniazid. CDC has convened expert consultation to begin working on new U.S. TB treatment guidelines.
  - A supplement on H1N1 was published in June 2011 by the *American Journal of Obstetrics and Gynecology*.
  - The November issue *EID* is focused on the Haiti cholera response.
  - New multi-year estimates on HIV infection showed relatively stable overall incidence, but alarming increases among young, black MSM. CDC's new high impact approach to HIV prevention funding for health departments is designed to better align resources with the geographic burden of the epidemic
  - Despite its severity, the multi-state outbreak of listeriosis linked to whole cantaloupes showed rapid action on the part of local, state, and federal partners.

Dr. Khabbaz concluded the OID updates by mentioning ICEID 2012, which will take place in at the Hyatt Regency Atlanta, March 11-13.

During the discussion that followed, BSC members commended Dr. Rana Hajjeh, NCIRD, and her group for advancing global implementation of the pneumococcal conjugate vaccine. CDC's global leadership on the development and use of rotavirus vaccine was also noted.

Follow-up questions from BSC members and other meeting participants along with responses from panelists are summarized as follows:

- In regard to a question about revising CDC guidelines on 1) preventing heterosexual transmission of HIV/AIDS and 2) HIV/AIDS treatment, Dr. Hazel Dean, Deputy Director, NCHHSTP, confirmed that both efforts are underway but stated that no publication date has been announced.
- In regard to a question on CDC's efforts to improve compliance with HIV prevention interventions (which also prevent other STDs and TB), Dr. Khabbaz noted that CDC is working with HRSA to

evaluate strategies for testing and linkage to care, with increased focus on keeping people in care and monitoring their progress.

- In regard to a question on whether directly observed therapy (DOT) has been considered for HIV, Dr. Dean said that CDC has considered that approach and is working with HRSA to learn from the TB experience with DOT.
- In regard to a question about CDC's capacity to conduct cost-benefit analyses (i.e., to identify potential high-yields from major investments), Dr. Anne Schuchat, Director, National Center for Immunization and Respiratory Diseases (NCIRD), noted that analyses of childhood vaccine programs indicate that for every dollar spent, $10 dollars is gained in direct and indirect savings. CDC is conducting similar analyses for adolescent and adult immunizations, including the economic impact of seasonal influenza immunization. Dr. Schuchat and Dr. Bell agree that cost-benefit analyses are an important component of CDC's future work.

III. PANEL DISCUSSION: THE CHANGING LANDSCAPE FOR INFECTIOUS DISEASE LABORATORIES

Following the opening presentations, a laboratory-focused panel session was held. Presentations included an overview of infectious disease public health laboratories, perspectives from a state public health laboratory, and three examples of CDC's infectious disease laboratories in action (foodborne diseases, influenza, and tuberculosis). Dr. Jan Nicholson, OID Senior Advisor for Laboratory Science, served as panel moderator and noted that the presentations included three outbreak stories that describe laboratory challenges for discussion during the break-out sessions.

1. Overview of Infectious Disease Public Health Laboratories

Dr. Steve Monroe, Director, Division of High-Consequence Pathogens and Pathology, NCEZID, noted the close relationship between clinical medicine—which focuses on the individual patient— and public health—which focuses on communities and populations. He reviewed the 11 core functions of state public health laboratories identified by APHL (http://www.aphl.org/AboutAPHL/publications/Documents/COM_2010_CoreFunctionsPHLs.pdf) and described the three layers of the "Public Health Laboratory Pyramid":

- Clinical and sentinel laboratories—the base of the pyramid—focus on patient health, providing routine diagnostic services and ruling out common diseases.
- State and local public health laboratories—the middle of the pyramid—focus on community health, conducting confirmatory testing and subtyping, and conducting outbreak investigations and emergency responses.
- CDC's reference laboratories—the top layer of the pyramid— focus on national and global health, conducting specialized diagnostic testing, confirmatory testing, and subtyping. CDC also develops new tests and reagents when new pathogens emerge, conducts diagnostic and proficiency training, and facilitates tech transfer to public health laboratories.

Dr. Monroe offered the story of the detection of 2009 influenza A (H1N1) as a "textbook case" of how the three components of the laboratory pyramid interact to protect the public's health. The initial detection of the H1N1 2009 virus was made by a clinical laboratory using an investigational diagnostic device that identified the pathogen as a strain of influenza A that did not match existing circulating subtypes. The clinical laboratory notified the San Diego Public Health Laboratory, which confirmed that the virus was an unsubtypable strain of influenza A. CDC received the H1N1 specimens from San Diego and determined that the virus was "swine-origin" influenza A (H1N1).

Dr. Monroe reviewed the unique roles of the CDC infectious disease laboratories in the following areas:

- **Serve as national diagnostic reference laboratories:** Identifying and characterizing new and unusual organisms; working with highly dangerous pathogens that require BSL-4 containment; developing and evaluating diagnostic tests, reagents, and methods; and providing quality assurance, standards, guidelines and proficiency testing for public health laboratories.
- **Serve as global diagnostic reference laboratories:** Providing technical support for global disease surveillance networks (e.g., for influenza and polio), and serving as WHO Collaborating Center laboratories that address a range of microbial threats, including viral hemorrhagic fevers, plague, shigellosis, tularemia, viral hepatitis, meningitis, influenza, rabies, smallpox, polio, viral gastroenteritis, arboviral diseases, rickettsial and *Bartonella*-associated diseases, and drug-resistant bacterial diseases.
- **Conduct cutting-edge public health research:** Advancing knowledge of disease detection and prevention; microbial genomics and proteomics; microbial biology and physiology; reservoir and vector ecology; and immunology (including host response, correlates of protection, vaccines). Dr. Monroe cited CDC's development of the first PCR test for HIV in the late 1980s as an example of cutting-edge public health research.
- **Support state and local public health laboratories:** Providing laboratory support and reference testing for outbreak investigations, including multi-state investigations; developing diagnostic methods, guidelines, and recommendations; and providing diagnostic reagents, training, and laboratory quality assessment.

The major challenge facing public health laboratories is maintaining a highly skilled and flexible workforce in the face of significant job losses due to the current economic downturn. This challenge is exacerbated by the retirements of long-time, highly skilled laboratory personnel and by the promotion of experienced laboratory staff to non-laboratory positions.

Other challenges confronting public health laboratories include:

- **An information challenge:** How to ensure timely integration and communication of laboratory and epidemiologic data ("information for action"). Data exchange and information flow require advanced and standardized electronic tools, as well as powerful analytical tools, like the pulse field gel electrophoresis (PFGE) analysis tools available to PulseNet. Data exchange involves staff at the three levels of the public health laboratory pyramid, as well as epidemiologists at CDC, state and local health departments, and hospitals.
- **A technology challenge**: How to adapt to rapid technologic change. Laboratory personnel must have expertise in both biology and bioinformatics in order to manage, analyze, and store the huge amounts of diagnostic sequence data generated by second-generation DNA sequencing technology. These activities require advanced computational hardware, advanced analysis algorithms, and improved computer security. As a result, bioinformatics costs are rising at a time of decreased resources. At the same time, culture-based diagnostic and typing methods like PFGE are being replaced by rapid PCR tests (see also pages 10-11).
- **The "one-health" challenge**: How to integrate public health data with veterinary and environmental health data.

2. <u>Perspectives from a State Public Health Laboratory</u>

Dr. Joanne Bartkus, Director, Public Health Laboratory Division, Minnesota Department of Health, gave a brief history of U.S. public health laboratories and their roles, which include diagnostic testing, infectious disease research, water-testing, and the development of diagnostic tests, vaccines, antitoxins, and antimicrobial agents. Minnesota established the first chemical hygiene laboratory in 1873, and New York City established the first public health bacteriology laboratory in 1893.

Today, the roles of public health laboratories are evolving, balancing traditional roles (e.g., testing for chemicals and pathogens of public health and environmental concern) with modern roles that support disease surveillance, reference testing, and outbreak response. Dr. Bartkus referred to the 11 core functions of a modern public health laboratory identified by APHL (also described by Dr. Monroe), and noted that public health research—an important part of good public health practice—is often overlooked, underfunded, and under-appreciated.

Dr. Bartkus stated that the story of the detection of a case of inhalational anthrax in Minnesota illustrates the importance and utility of laboratory methods developed and deployed to the states by the Laboratory Response Network (LRN; www.**bt.cdc.gov**/lrn). The patient was found to have been exposed to naturally occurring anthrax.

Laboratories at all three levels of the public health laboratory pyramid were prepared to detect and diagnose anthrax and other select agents:

- CDC had developed and deployed LRN methods to the states for detection of anthrax in clinical and environmental samples. CDC had also trained personnel at the LRN reference laboratories.
- The public health laboratory of the Minnesota Department of Health had trained LRN sentinel laboratories throughout the state (including hospital laboratories), established a laboratory communication system, and held regional LRN conferences that included laboratory workshops.
- The clinical laboratory conducted routine testing and participated in the LRN workshops.

Due to this preparation, all of the laboratories were able to respond rapidly:

- The clinical laboratory recognized a possible case of anthrax and sent the suspected anthrax isolate to the state public health laboratory.
- The state health laboratory confirmed the identification, notified the CDC Select Agent Program, shipped the isolate to CDC, and tested environmental samples.
- CDC conducted antimicrobial susceptibility testing and genotyping and provided guidance on environmental sampling.

Both the state and federal laboratories played critical roles in the investigation. The state public health laboratory conducted confirmatory testing for a rare and potentially dangerous agent; conducted environmental sampling and testing; and complied with the Select Agent Regulations. CDC provided subject matter expertise, genotyping, and susceptibility testing. Fortunately, the patient survived.

Dr. Bartkus reviewed other important public health laboratory activities, including:

- **Monitoring the performance of commercially available diagnostic tests**. For example, the Minnesota public health laboratory has assisted CDC with evaluations of rapid tests for West Nile virus, *Cryptosporidium*, and *Campylobacter* infections.
- **Investigating unusual cases of disease**. In April 2009, a clinical laboratory in Minnesota isolated an enterovirus from a person with an apparent case of paralytic polio and sent it to the state laboratory, which identified it as poliovirus by serotyping and then as a vaccine strain by sequencing. The CDC Polio Laboratory sequenced the full genome and determined that it had reverted from an attenuated vaccine strain not used since 2000.
- **Subtyping isolates of foodborne pathogens.** All state laboratories participate in the PulseNet subtyping system, which facilitates detection of outbreaks involving a small number of cases that are geographically and temporally dispersed. Clinical laboratories typically make the initial identification and send isolates or specimens to the state laboratory, which conducts PFGE subtyping and communicates the results to the PulseNet database hosted by CDC. A recent PulseNet investigation involved a multistate outbreak of *Salmonella* serotype I 4,[5],12:i:- spread via frozen rodents sold at pet stores as food for pet snakes.

Today, funding reductions are resulting in decreases for PulseNet activities. Some states only conduct PFGE testing on certain *Salmonella* serotypes, and Nebraska no longer conducts PFGE subtyping on *Salmonella* isolates. CDC currently assigns PFGE pattern designations to only the 10 most frequently reported *Salmonella* serotypes, rather than to the top 25, which might result in delayed outbreak detection for some serotypes.

Dr. Bartkus concluded by describing other challenges faced by public health laboratories. Examples include the following:

- Decreased state and federal financing, leading to layoffs, closing of county and regional public health laboratories, laboratory consolidation, and discontinuation of some testing services
- Increased reliance on commercial reference laboratories, resulting in less timely and less complete reporting and difficulties in obtaining samples for additional testing
- Increased use of non-culture diagnostic methods, leading to inability to obtain isolates for subtyping and susceptibility testing
- Workforce issues, including retirements and inability to attract qualified candidates
- Regulatory issues, related to compliance with FDA, CLIA, HHS, and DHS rules
- Political challenges, including a government shutdown in Minnesota and the state legislature's refusal of federal grants provided to state laboratories under the Affordable Care Act

Strategies to address these challenges include

- Exploring the use of shared or centralized services
- Identifying new sources of funding (e.g., fee-for-service testing)
- Promoting an increased focus on translational research (see: http://www.aphl.org/AboutAPHL/publications/Documents/COM_July2011_TranslationalResearchPaper.pdf)
- Identifying laboratory efficiencies (see information on the CDC Laboratory Efficiencies Initiative, pages 17-18).
- Forging public/private partnerships that keep laboratory testing current and relevant and help maintain capacity for "high-stakes testing" to identify unknown pathogens

3. CDC's Infectious Disease Laboratories in Action

A. CDC's Foodborne Disease Laboratories

Dr. John Besser, Deputy Chief, Enteric Diseases Laboratory Branch, DFWED, NCEZID, reviewed the role of public health laboratories in ensuring food safety and outlined key threats and opportunities facing laboratory-based enteric disease surveillance and outbreak investigation. Each year, 1 out of 6 Americans (or 48 million people) get sick and 3000 die of foodborne diseases. Dr. Besser quoted HHS Secretary Katherine Sebelius, who stated in a recent speech that this is an unacceptable price to pay for contaminations that are mostly preventable.

PulseNet, the nation's molecular subtyping network for foodborne disease surveillance, has become an integral component of our food safety system. It includes 85 laboratories throughout the country and uses standardized subtyping methods to identify clusters of disease that may be geographically or temporally dispersed. Every year, PulseNet triggers about 1500 state or local investigations and 250 multi-state or national investigations. Outbreak investigations have led to safer production and distribution practices in a wide range of food industries, including those related to peanut products, processed foods ("ready to eat" and "ready to cook"), eggs, beef, spices, tree nuts, flour, melons, poultry, and leafy greens, sprouts, and other vegetables.

Nevertheless, CDC experts believe that the foodborne disease outbreak detection and investigation systems are currently operating at only a fraction of their true potential. It is likely that many foodborne disease outbreaks are not solved because of absent, incomplete, or non-standardized information; lack of timeliness of disease reporting; and/or inadequate environmental analyses of the sources. CDC and partners are working to develop rapid and standardized methods for collecting data on exposures, new analysis software, and improved environmental assessments.

PulseNet is affected by declining state and local resources and competing public health priorities. Another major near-term challenge is the probable decrease in availability of microbial isolates for PulseNet subtyping, due to diminished use of culture-based diagnostics. The rise of rapid "non-culture" diagnostics may improve the availability, speed, and cost-effectiveness of testing. However, the use of rapid tests will lead to a lack of isolates for public health subtyping and susceptibility testing.

Examples of other foodborne disease surveillance and response programs that depend on data provided by these isolates include

- CDC programs such as FoodNet, OutbreakNet, and the Foodborne Diseases Centers for Outbreak Response Enhancement (FoodCore)
- The FDA Coordinated Outbreak Response and Evaluation (CORE) Network
- The Predictive Analytics tools of the USDA Public Health information System (PHIS)
- The CDC/FDA/USDA National Antimicrobial Resistance Monitoring System (NARMS)

Dr. Besser stated that without a way to preserve these culture methods, we will lose the ability to detect wide-spread, low-level outbreaks of foodborne and waterborne diseases. We will also lose our ability to assess trends in disease patterns and measure the efficacy of prevention measures. Potential solutions include:

- Implementing changes in laboratory practice, reimbursement policies, or regulatory requirements that will allow culture-based methods to be preserved
- Creating sentinel surveillance systems that monitor changes in drug susceptibility. An example is the Gonnoccoccal Isolate Surveillance Project (GISP), which monitors antimicrobial susceptibilities in *Neisseria gonorrhoeae* isolates obtained at dozens of STD clinics in the United States. GISP data have led to significant changes in the 2010 STD Treatment Guidelines.
- Developing culture-independent subtyping methods (e.g., PCR-based single-pathogen assays, single-cell sequencing methods, or "random shotgun" metagenomics). New laboratory technology for subtyping and susceptibility testing can facilitate faster, better outbreak investigations, better understanding of disease causation, and more accurate assessment of trends in disease patterns (see tuberculosis story below).

B. The CDC Influenza Laboratory

Dr. Michael Shaw, Associate Director for Laboratory Science, Influenza Division, NCIRD, reviewed CDC activities to improve laboratory preparedness for an influenza pandemic in the aftermath of the 2009 influenza H1N1 pandemic. He noted that a common assumption for pandemic planning before 2009 was that the pandemic virus would emerge in Asia, providing lead time for diagnostic test development and deployment before the pandemic virus arrived in the United States. Although this was not the case in 2009, fortunately, by the time H1N1 was detected in California and Mexico, CDC had already received FDA approval for a new platform for rapid influenza A subtyping. As a result, CDC was able to ship H1N1 tests kits to the states under an FDA Emergency Use Authorization 16 days after the identification of the new pandemic strain.

CDC actions to improve diagnostic preparedness for a pandemic include working with state and local partners to

- Develop new diagnostic tests for subtyping influenza
- Implement proficiency testing on their use
- Develop policy and regulatory preparedness to use new tests
- Increase laboratory surge capacity
- Improve access to viral isolates and test reagents
- Provide guidance to clinicians
- Improve virologic surveillance

CDC's diagnostic preparedness activities—begun in the 2000s and intensified during the H1N1 response—have been expanded further in these areas. Examples include the following:

- **Virologic Surveillance.** The CDC Influenza Laboratory has increased equipment, reagents, and reporting capacity for detection of new influenza strains. CDC has also partnered with APHL to expand domestic and international laboratory training to enhance virologic surveillance worldwide.
- **New Diagnostic Tests.** The CDC Influenza Laboratory is preparing reagents and performance data to ensure rapid approval and deployment of new tests when new strains appear.
- **Antiviral Resistance Testing.** The CDC Influenza Laboratory has increased capacity for resistance testing and has partnered with state laboratories to establish additional reference laboratories
- **Monitoring Viral Evolution.** Increased capacity for whole-genome sequencing of influenza isolates has enhanced CDC's ability to detect viral subpopulations and monitor virus evolution during a pandemic. CDC is also evaluating commercially available, "next-generation" sequencing technologies.
- **Serologic Testing.** Serologic testing to determine transmission and range of disease severity remains a technical and logistical challenge. CDC is evaluating commercially available, rapid point-of-care and high-throughput tests that are based on serology as well as new methods for cell-free microneutralization assays. H1N1 seroprevalence surveys are underway.
- **Evaluation of commercial diagnostics assays.** CDC is developing a program to evaluate commercial diagnostic assays that will review new and existing influenza tests. The aims are to ensure that the assays are able to detect new subtypes and variants as viruses emerge or drift and to provide testing guidance for clinicians.
- **Public Health Laboratory Assessment and Performance Evaluation.** CDC is also establishing a new voluntary laboratory assessment program to monitor capacity to isolate viruses and use WHO test kits, PCR kits, and microneutralization assays.
- **Information Flow, Management, and Analysis.** The CDC Influenza Laboratory and other CDC infectious disease laboratories are reaching out to partners to help improve bioinformatics at CDC and to implement the APHL Public Health Laboratory Interoperability Project (PHLIP), whose goal is to improve integration of laboratory and epidemiologic data and electronic data-sharing among CDC laboratories, state laboratories, sentinel providers, and international partners.

Dr. Shaw concluded by describing current efforts to develop "right-size" influenza virologic surveillance at a time of increased needs and reduced resources. CDC is working with APHL, CSTE, ASTHO, NACHHO, IDSA, and other partners to

- Define core capabilities for influenza virologic surveillance to inform policy decisions and disease prevention efforts
- Maximize available resources by redirecting funds when necessary and building new capacity
- Create a scalable approach to meet laboratory surge capacity needs.

C. The CDC Tuberculosis Laboratory

Dr. Michael Iademarco, Chief, Laboratory Branch, Division of Tuberculosis Elimination, NCHHSTP, reviewed ongoing efforts by the National TB Laboratory to increase clinical access to molecular diagnostic testing, improve diagnostic accuracy, and reduce delays in starting effective therapy. During the 1990s, there was limited evidence of the cost-effectiveness of nucleic acid amplification (NAA) tests for the detection of TB. NAA tests were expensive and in low demand, and are classified as FDA class III —requiring a high level of regulatory control to provide a reasonable assurance of safety and effectiveness; there are no FDA-approved molecular tests for the detection of drug resistance. However, the situation is changing. By 2009, the CDC TB Laboratory was performing molecular testing on about 14% of U.S. patients with suspected *M. tuberculosis* infection. In 2011, WHO endorsed the GeneXpert MTP/RIF assay, which detects *M. tuberculosis* and associated rifampin resistance. (FDA has not yet approved this assay.)

Dr. Iademarco offered a story about a patient with extremely drug resistant TB (XDR TB) to illustrate how molecular TB testing has improved ability to detect and treat drug-resistant TB and to prevent its spread. The story involved a 24-year-old immigrant about to enter graduate school who had an abnormal chest X-ray. He had been treated for TB two years earlier but currently had no symptoms. He was started on standard therapy with four drugs (i.e., rifampin, isoniazid, pyrazinamid, and ehambutol) but instead of improving began to feel ill.

The hospital laboratory isolated drug-resistant *M. tuberculosis* in culture—a test that took 16 days. This result was reported to the state public health laboratory, which submitted an isolate to CDC's Molecular Detection of Drug Resistance (MDDR) service. Within 24 hours, the MDDR service confirmed that the patient had XDR TB and provided laboratory results to facilitate guidance on second line treatment. The rapid results benefited the patient, who began to get well, and helped the public health department conduct contact investigations to avert disease spread.

The MDDR test is an example of how public health laboratories might move from culture-based to molecular subtyping and resistance-testing methods. Based on PCR amplification and DNA sequencing, the MDDR test was implemented in September 2009 after 1½ years of applied research. Test development included identification of mutations associated with TB drug resistance and a comparison of genotypic and culture-based data to ensure accuracy. MDDR testing typically provides results within 2 days, while culture-based drug susceptibility testing takes up to 33 days.

To deploy the new test, the CDC TB laboratory worked with APHL and state laboratories to establish clinical protocols, validate methods, and develop new reporting procedures. Educational efforts included developing a guidance document and web-based instructional materials and organizing a webinar for public health laboratories. State-level deployment efforts were supported by the TB cooperative agreement program. CDC issued new TB testing guidelines in 2009, based on the policy recommendations of the Federal TB Task Force and the Advisory Council for the Elimination of Tuberculosis (ACET). In June 2011, an FDA advisory panel recommended reclassification of the MDDR test to class II.

At the present time, the MDDR service is capturing an estimated 50% of MDR TB in the United States. The current challenge is to maintain momentum by enhancing workforce training and bioinformatics capacity, establishing electronic data exchange between clinicians and laboratorians, and harmonizing policy requirements on the use of data from different sources (e.g., clinical, laboratory, and surveillance data) to meet the needs of clinicians, public health practitioners, and researchers.

In conclusion, Dr. Iademarco stated that the "three R's" of an effective national TB Laboratory program are *Relationships* (e.g., with APHL, public health laboratories, other HHS agencies, and other partners), *Research* (applied, translational, and operational), and *Reference Services and Consultation***.**

Follow-up comments from BSC members and other meeting participants, along with responses from panelists, are summarized as follows:

- A recent APHL survey on public health, agriculture, and environmental laboratories emphasized the need for succession planning and for increasing the number of persons in the public health laboratory pipeline who can replace those who leave or retire. Dr. Bartkus noted that these issues are important for clinical as well as public health laboratories. Laboratory training programs at universities have been discontinued, and it is difficult to attract qualified people, in part because of poor salaries and lack of opportunities for advancement. In Minnesota, the recent government shut down has also had a negative impact on applicants for employment.
- Public health laboratories might generate new revenue streams by accepting Centers for Medicare and Medicaid Services (CMS) reimbursement for diagnostic testing, especially in view of closures or reductions in services by hospital laboratories. Dr. Bartkus noted that Minnesota does not allow state laboratories to receive CMS reimbursements, although many other states do. The NYS Wadsworth Center has suggested that public health laboratories accept co-pays for laboratory testing services, in addition to CMS reimbursement.

IV. BREAKOUT GROUP DISCUSSIONS

During lunch and continuing into the afternoon, BSC board members and participants from partner organizations met in two groups to consider 1) How to ensure that CDC infectious disease laboratories maintain capacity to serve as national and global reference laboratories; and 2) How CDC laboratories can provide leadership and support to state and local laboratories during an era of rapid change and limited resources.

Group 1: The CDC perspective: *How to ensure that CDC infectious disease laboratories maintain capacity to serve as national and global reference laboratories.*
Participants:

- ***BSC Members***: Carol Baker, Luciana Borio (attending on behalf of Jesse Goodman), Bruce Gellin, John Gittleman, Shannon Jones, Mathu Santosham, Robert Sautter, Julio Sotelo, Bob Tesh (group leader), Mary Wilson, Rich Whitley
- ***Partners and Guests***: Harry Keyserling, AAP; Ruth Lynfield, IDSA; Howard Njoo, PHAC; Christy Phillips, PIDS; Andy Pavia, Department of Pediatrics, University of Utah School of Medicine
- ***CDC Co-leader***: Allison Mawle, NCIRD
- ***CDC Participants***: Roberta Carey, Alexandra Levitt, Tonya Martin, Beverly Metchock, Steve Monroe, Mark Pallansch, Shambavi Subbarao, Kathy Tatti, Patty Wilkins

Members of Group 1 observed that their discussion about maintaining laboratory capacity at CDC was intricately linked to maintaining laboratory capacity in states and localities. As state laboratories have lost jobs and capacity, they have come to rely even more on CDC.

Group 1 recommended that CDC convey to the public and to Congress the critical importance of laboratory-based disease surveillance and emphasize the need to1) address workforce and training issues; 2) ensure continued availability of ID isolates for subtyping and analysis of drug susceptibility; 3) preserve CDC capacity to serve as a national and global reference laboratory; 4) make better use of advances in bioinformatics and diagnostic technology; 5) assist state public health laboratories at a time

of increased demands and reduced resources; 6) address regulatory issues that affect the use of diagnostic tests during emergencies; and 7) balance global and domestic ID priorities. Issues discussed under each of these seven areas are outlined as follows:

- **Address workforce and training issues**
  - State and local laboratories face multiple workforce issues, including
    - Public health laboratories have fewer microbiologists and medical technicians, due to cuts in funding
    - Two-thirds of the public health laboratory workforce will retire in the near future
    - Public health laboratories have significant retention issues, due in part to the lack of opportunities for advancement in laboratories (referred to as the "pyrex ceiling")
    - Public health laboratories are cutting back on culture-based testing due to financial costs (including specimen transport costs) and lack of personnel. Nevertheless, culture-based testing remains the major method for drug-susceptibility testing.
  - CDC can help by
    - Promoting training in microbiologic techniques that are needed at CDC, public health laboratories, and clinical laboratories
    - Promoting the use of bioinformatics and next-generation diagnostic technologies (see below)
    - Providing guidance on succession planning

- **Ensure the continued availability of ID isolates for subtyping and analysis of drug susceptibility**
  - Trends that are leading to fewer available isolates include
    - Use of rapid PCR tests and DNA sequencing procedures that do not require growing pathogens in culture
    - Physicians may not order tests for viral diseases for which there is supportive therapy but no specific treatment
    - Hospitals and other partners do not have facilities or incentives to save or store samples.
    - The need to comply with select agent rules may discourage some diagnostic laboratories from growing unidentified viruses that might turn out to be on the select agent list (e.g., laboratories may no longer culture encephalitis viruses, because EEE and JE are classified as select agents). There is also declining capacity to use animal testing to isolate viruses.
  - CDC might consider establishing regional reference laboratories where states could send unidentified specimens or specimens that might contain microbes that state laboratories no longer have the capacity to grow or identify. These laboratories would both characterize and store isolates (see related item on regional laboratories under the next bullet).

- **Preserve CDC capacity to serve as a national and global reference laboratory**
  - CDC must retain capacity to do what other laboratories cannot do (e.g., detect new pathogens, identify new forms of drug resistance, and work with dangerous agents that require high-level biocontainment)
  - To improve capacity to detect new pathogens, CDC should consider
    - Supporting sentinel sites that discover new pathogens through investigation of unusual cases of disease and unusual deaths (like the former Unexplained Deaths Project).
    - Supporting regional laboratories that test unidentified specimens submitted by clinical laboratories that have received training in specimen recognition and transport. A regional laboratory network for identifying unknown pathogens might be modeled on (or partner with) the LRN network, which focuses on select agents.
    - Adopt next-generation diagnostic techniques (see next bulleted section)

- **Make better use of advances in bioinformatics and diagnostic technology**
  - Bioinformatics goals include
    - Achieving rapid information flow among laboratories (at CDC, state and local health departments, and clinical laboratories) and among epidemiologists (at CDC, state and local health departments, and hospitals)
    - Improving capacity to detect new agents
  - Four laboratories at the CDC Roybal Campus currently participate in an advanced biocomputing network that exchanges data with external research partners.
  - CDC should
    - Implement the recommendations of the blue ribbon panel on bioinformatics in the infectious disease laboratories, held at CDC in June 2011.
    - Consider using sequencing assays at the front end of a laboratory investigation, in order to characterize unidentified specimens as rapidly as possible. This approach may become economically feasible as sequencing costs go down. A less costly approach might be to use PCR arrays as an initial screen. Each array might include a panel of DNA sequences from all known pathogens that cause a particular syndrome (e.g., respiratory, gastrointestinal, or encephalitic disease). In either case, the process might be streamlined by sharing the samples with many CDC laboratories after they have been sequenced or screened, rather than sending them sequentially from laboratory to laboratory.
    - Review commercially available diagnostic platforms, including platforms considered commercial "winners" or that have interesting features
    - Improve capacity to manage large amounts of data, which will require new expertise and new equipment
    - Address legal and privacy issues that may arise if new sequencing techniques generate DNA on patients as well as microbes
    - Transfer bioinformatics expertise and technology to state and local partners (e.g., via the Epidemiology and Laboratory Cooperative Agreement), providing proficiency testing and training in the interpretation of diagnostic sequencing data.

- **Assist state public health laboratories at a time of increased demands and reduced resources**
  - The goal of the CDC Laboratory Efficiencies Initiative (LEI) is to reduce laboratory costs without losing capacity (see pages 17-18). CDC must be ready to assist the states when state laboratories are unable to do testing, due to lost capacity.
  - CDC should
    - Provide guidance on laboratory consolidation and regionalization, taking into account that capacities and resources vary from state to state
    - Help states plan for the future by taking stock of priority testing needs, personnel, and equipment
    - Consider opportunities for pooling interagency resources to address priority ID issues. Precedents include interagency efforts to address food safety and antimicrobial resistance (e.g., PulseNet, FoodNet, and NARMS)

- **Address regulatory issues that affect the use of diagnostic tests during emergencies**
  - The influenza testing platform used during the H1N1 pandemic had already been approved by FDA before the pandemic began. However, use of unapproved tests is often a major problem during emergencies.
  - CDC develops tests that are not of interest to commercial developers (e.g., tests to detect new pathogens). CDC also helps public health partners and the private sector by evaluating commercially available tests and providing guidance on their use.

- FDA is developing new guidance on emergency use of unapproved diagnostic tests, recognizing that development of tests for public health purposes is different from commercial test development.
- CDC currently has an FDA liaison who is learning about these processes

- **Balance global and domestic ID priorities**
  - CDC has an intrinsic global perspective because of work conducted on global diseases, many of which also affect U.S. health (e.g., influenza, measles, TB)
  - CDC needs to be aware of new pathogens that arise anywhere in the world
  - CDC plays a role in health diplomacy (i.e., building public health capacity as part of U.S. development efforts in resource-limited countries)

In summary, major challenges for CDC identified by Group 1 include

- Prioritizing internal CDC lab work and helping states streamline and prioritize their laboratory services, recognizing activities and expertise that may no longer be available.
- Improving data exchange in both directions between state laboratories and CDC
- Improving understanding by Congress and the general public of public health needs

Group 2: <u>The state and local perspective</u>: *How CDC infectious disease laboratories can provide leadership and support to state and local public health laboratories during an era of rapid change and limited resources*

Participants:

- ***BSC Members***: Ruth Berkelman (group leader) , Matt Boulton, Frank Cockerill, Rainer Engelhardt, Larry Granger, James Hadler, Carole Heilman, Edward Hook, Duane Hospenthal, Tracy Lieu, Steve Ostroff
- ***Partners and Guests***: Joanne Bartkus, Minnesota Department of Health; Eric Blank, APHL; Harry Chen, Commissioner, Vermont Department of Health; Joseph Hilinski, PIDS; Lilly Kan, NACCHO; LaKesha Robinson, CSTE; Kathy Talkington, ASTHO
- ***CDC Co-leader***: Wendi Kuhnert, NCEZID
- ***CDC Participants***: Bill Bellini, Kristin Brusuelas, Stephen Hadler, Tom Hearn, Renée Ned, John Ridderhof, Jane Seward, Julie Villanueva

<u>CDC Laboratory Efficiencies Initiative</u>

Dr. May Chu, Director, Laboratory Science Policy and Practice Program Office (LSPPPO), CDC Office of Surveillance, Epidemiology, and Laboratory Services (OSELS), provided Group 2 with an overview of the CDC Laboratory Efficiencies Initiative (LEI), whose goal is to help public health laboratories across the country to achieve long-term sustainability by adopting high-efficiency management practices and system-wide savings. Options considered by LEI include:

- **Regionalization of testing services** (e.g., newborn screening conducted by multi-state consortia)
- **Consolidation of laboratories** (e.g., mergers between public health and environmental or agriculture laboratories)
- **Contractual services**
- **Adoption of cost-saving technologies and harmonized testing platforms** (e.g., lab instrumentation)
- **Procurement discounts achieved through joint purchasing** (e.g., mechanisms to leverage volume discounts)
- **Generation of new revenue streams** (e.g., providing reimbursable immunization services)

CDC plans to issue LEI recommendations and guidance for state and local public health laboratories in 2013.

In regard to a question about specimen storage, Dr. Chu noted that the CDC repository in Lawrenceville, Georgia, contains about 6 million specimens. CDC is in the process of determining which isolates should be kept and what can be done in the future to ensure that isolates are available for sharing (e.g., for calibrating diagnostic tests).

Group 2 Discussion.
Comments and suggestions for CDC included providing technical and financial support to state and local public health laboratories in the following areas:

- **Incorporating new diagnostic technologies**
  - CDC should continue to work with industry to evaluate and validate new tests and provide guidance on their use. (During the H1N1 pandemic, for example, CDC provided guidance on evaluation of commercially available rapid tests for influenza.)
  - Caution may be needed when new commercial tests are introduced. For example, clinicians may need guidance on proper use of a new EIA test for syphilis that does not distinguish between active and past infection.

- **Promoting electronic data-sharing and better public health use of bioinformatics**
  - CDC should
    - Make use of best practices and model systems for electronic reporting developed by the states (e.g., for reporting notifiable diseases)
    - Provide sustained support for the Public Health Laboratory Interoperability Project (PHLIP), which aims to establish electronic laboratory data exchange between state public health laboratories and CDC (http://www.aphl.org/aphlprograms/informatics/collaborations/phlip/pages/default.aspx).
    - Work with industry to design laboratory data systems that are useful for public health purposes, including data analysis, data storage, and research
    - Address obstacles to electronic data-sharing and public health use of bioinformatics, including
      - State-level reporting and privacy laws that differ among jurisdictions. These laws impact efforts to collect multi-state data and regionalize disease surveillance efforts.
      - Lack of public health expertise on the use of bioinformatics for integrating data sets and analyzing data

- **Ensuring an adequate pipeline of well-trained laboratory staff**
  - To help increase the number of persons in the public health laboratory pipeline, CDC should consider
    - Offering a larger number of CDC laboratory fellowships
    - Providing incentives for students to take laboratory training courses and enter public health
    - Providing direct assistance for training public health laboratorians (i.e., using CDC personnel, equipment, and facilities to provide training). Direct assistance is effective but may be too expensive as a long-term solution.
  - CDC should help ensure that the public health laboratory workforce is trained in bioinformatics by
    - Identifying appropriate training courses at universities and in training networks
    - Working with academic partners to develop continuing education programs in bioinformatics for public health laboratorians
    - Placing CDC staff trained in bioinformatics at state health departments to promote technology transfer and build capacity

- Public health laboratory training in diagnostics and bioinformatics should be
  - Competency-based, emphasizing knowledge, skills, and attitudes that correlate with performance and can be measured against well-accepted standards
  - Conducted in collaboration with academic partners
- CDC and/or state laboratories should partner with academic institutions to provide
  - Laboratory certification and education programs, like those offered by the Wadsworth Center of the New York State Department of Health (http://www.wadsworth.org/docs/mission.shtml)
  - Succession planning, as the members of the baby boomer generation retire
  - Information on the cost-effectiveness of contracting out laboratory services.

BSC members also discussed the need for healthcare workers to have a basic understanding of microbiologic testing. They recommended that CDC and partners work with schools of medicine and nursing and accreditation agencies to

- Ensure that physicians, nurses, and other healthcare workers receive training in laboratory medicine
- Promote CME courses in microbiology, since many current medical school graduates received no training in laboratory skills

- **Advance public health research at state and local public health laboratories**
  - CDC should emphasize to Congress and the public that generation of new knowledge is an important part of the public health laboratory mission
  - Priorities include
    - Development of drug-susceptibility tests, subtyping tests, and diagnostic tests that identify new pathogens
    - Research that translates new scientific discoveries into practical public health and healthcare applications
  - CDC should continue funding its extramural ID program and identify additional research funding opportunities for state and local public health laboratories, working in partnership with
    - Universities and medical centers
    - Other federal agencies, including NIH and USDA
    - Foundations like the Robert Wood Johnson Foundation, whose Public Health Practice-Based Research Networks (PBRN) Program supports a research network of about 20 institutions that study the comparative effectiveness, efficiency and equity of public health strategies (http://www.publichealthsystems.org/pbrn).

Group 2 also recommended that CDC continue to provide guidance to state and local partners on LEI issues, including:

- **Regionalization**
  - Regionalization of laboratory functions (e.g., testing for vaccine-preventable diseases) should be driven by states with guidance from CDC.
- **Standardization and harmonization of testing and results-reporting** (e.g., through adoption of standard health IT codes)
- **Emergency response issues**
  - Achieving emergency surge capacity (e.g., access to high-throughput testing) is especially difficult when resources are limited.
  - Public health laboratories might consider triaging testing during an emergency if surge capacity is insufficient.

V. DISCUSSION WITH CDC/OD

Dr. Ileana Arias, Principal Deputy Director, CDC/ATSDR, brought greetings from CDC Director Thomas Frieden and invited the BSC members to provide feedback on how CDC can assist state and local laboratories.

Dr. Whitley noted that the CDC *ID Framework* describes many of the challenges faced by state and local health departments as we look to the future. He noted that the OID/BSC has established two working groups that address cutting-edge and over-arching public health issues: food safety and antimicrobial resistance. Both of these issues are related to the interface of public health with agriculture and with other health issues in other countries.

Other comments from BSC members included the following:

- **Workforce issues**
  - Workforce issues need more attention, both because of decreases in funding and because of attrition.
  - Clinical and public health laboratories face the same workforce issues: training opportunities are decreasing, recruiting is difficult, salaries are low, and retention is poor.
  - CDC has a long history of providing direct assistance by assigning people to state health departments.

- **Training issues**
  - More laboratory fellowships are needed at laboratory training networks and public health schools—many of which have lost laboratory training capacity.
  - The University of Alabama at Birmingham public health program is one of only a few that still provide courses in public health laboratory skills.
  - CDC should work with medical schools to emphasize the importance of microbiology training in adult and pediatric ID training programs.

- **CDC/CMS Liaison**
  - The CDC liaison to CMS may help address such issues as decreased reimbursement for diagnostic tests of public health importance and lack of training for physicians and nurses in microbiology.

- **Harmonization of Laboratory Services**
  - At a time of decreased resources for laboratory services (both public and private), CDC should take the lead in developing a standardized, cost-effective approach to laboratory testing and disease reporting—harmonizing the diverse approaches used by different states—to save money and facilitate the effective use of IT.
  - Dr. Larry Granger, BSC member from USDA/APHIS, noted that his agency is facing similar challenges and that CDC and USDA can work together to find solutions.

- **Research**
  - CDC should emphasize to Congress and the public that the generation of new knowledge is integral to the core mission of public health departments and that research funding is an investment in the nation's health.

- **CDC Laboratory Capacity**
  - CDC must maintain its core laboratory functions—especially functions for which the capacity does not exist elsewhere. This is important for the United States and for the world.
  - CDC is the reference laboratory of last resort—a role that is more important than ever, as state laboratories must do less and less because of funding constraints.
  - CDC must continue to employ cutting-edge scientists who can identify new pathogens and generate new knowledge.

VI. CLOSING REMARKS

BSC members made the following suggestions for future meeting topics:

- Use of bioinformatics to integrate laboratory, epidemiology, veterinary, and environmental data. The BSC meeting could include consideration of ways to implement the specific recommendations made by the CDC Blue Ribbon Panel on future strategies for bioinformatics.
- The impact of budget cuts on state and local health departments and on private clinical laboratories.
- Enhancing cost-effectiveness research at CDC to ensure accountability and facilitate prioritization.
- Achieving "right-size" disease surveillance, taking into account current factors such as the adoption of electronic laboratory reporting by hospitals and the decrease in diagnostic ID tests.

Dr. Khabbaz concluded the meeting by thanking Dr. Whitley for his long-standing service as BSC chair. The next BSC meeting will take place in May 2012.

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I hereby certify that to the best of my knowledge, the foregoing minutes of the proceedings of the meeting of the Board of Scientific Counselors, Office of Infectious Diseases, on November 9, 2011, are accurate and complete.

_____ _____

Robin Moseley, MAT, Designated Federal Officer Date