



Minutes from the July 17, 2015

CDC Advisory Committee to the Director

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Table of Contents

Advisory Committee to the Director: Record of the July 17, 2015 Meeting 3
Welcome and Introductions..... 3
Director’s Update 3
External Laboratory Safety Workgroup Update 4
CDC Update on Progress Addressing Internal Laboratory Safety 9
Public Comment.....11
Closing Comments; Meeting Adjourned12
Certification13
Attachment #1: Meeting Attendance14
Attachment #2: Acronyms Used in this Document.....17

Advisory Committee to the Director: Record of the July 17, 2015 Meeting

The Centers for Disease Control and Prevention (CDC) convened a meeting of its Advisory Committee to the Director (ACD) on July 17, 2015 via conference call from the Arlen Specter Headquarters and Emergency Operations Center in Atlanta, Georgia. The agenda included the Director's update and presentations by the External Laboratory Safety Workgroup (ELSW) pertaining to their site visit and evaluation of the Food and Drug Administration (FDA) Laboratory Safety Program; and a CDC update on progress toward addressing internal laboratory safety.

Welcome and Introductions

Dr. Alan Greenberg (ACD Chair) called the ACD meeting to order at 1:30 p.m. EDT. Those present introduced themselves. An attendance roster is appended to this document as Attachment #1. A quorum of ACD members was present, and quorum was maintained throughout the duration of the meeting. Dr. Greenberg welcomed FDA colleagues who were in attendance. The following ACD members disclosed conflicts of interest:

- Dr. Georges Benjamin: The American Public Health Association (APHA) has a cooperative agreement with CDC, as well as a series of small grants.
- Dr. Nisha Botchwey: Georgia Tech receives CDC funding.
- Dr. David Fleming: Works for PATH, which receives some grants from CDC, none of which are allocated directly to him.
- Dr. Jewel Mullen: Connecticut Public Health Commissioner. They are CDC grantees. She is also the President of the Association of State and Territorial Health Officials (ASTHO), a recipient of CDC funding. She is on the board of the Public Health Accreditation Board (PHAB).
- Ms. Sara Rosenbaum: The Department of Health Policy and Management at George Washington University receives CDC funding.
- Dr. Alan Greenberg: His department at George Washington University indirectly receives funding from CDC through the DC Department of Health.

Director's Update

Dr. Thomas R. Frieden (Director, CDC) welcomed the ACD members and FDA representatives who joined the teleconference. He acknowledged the ELSW's hard work and offered special thanks to Drs. Kanabrocki and Berns, as well as everyone else who has worked with this group to offer feedback on the critically important issue of improving the culture of safety. That includes not only specific actions, but also communication with staff and benchmarking best practices with other parts of the government. He said he could not emphasize strongly enough how much he valued the input.

In terms of progress toward implementing the recommendations for CDC, there are several examples in terms of communications. A Laboratory All-Hands meeting was convened in July with over 500 staff members in attendance, and there was a very good discussion regarding the status of improvements in laboratory safety. A Laboratory Innovation Championship competition was also held, which allowed staff to vote in real-time for their favorite innovation idea to improve laboratory safety at CDC. The winning idea was creating a database to share information about best practices for safety across CDC. There is a lot on CDC's intranet about biosafety and biosafety training. The Laboratory Safety Champion Recognition Program is also continuing, which gives credit to staff who do more than expected to promote the best safety practices. This is a monthly feature.

Dr. Frieden stressed that he takes the issue of laboratory safety extremely seriously, and is involved in it multiple times each day. For example, unrelated to this meeting, today he had already engaged in a series of in-depth conversations and review of documents about multiple areas of safety. It is critically important to improve the agency's work in this area on a continuous basis. He assured everyone that he would do everything in his power to continue to do that. It is known that the best organizations continuously review and improve practices. CDC has world class scientists, and it is important to ensure that the agency has world class safety science as well.

He stated that he believes that the events over the past year plus have shown that there can be risks to laboratory science work, and that they must do everything in their power to get those risks as close to zero as possible. It is important to continue to minimize risks to the greatest extent possible, and clearly identify the benefits of the work being done in order to determine whether the benefits outweigh the risks.

External Laboratory Safety Workgroup Update

Dr. Joseph Kanabrocki (ELSW Chair) expressed appreciation to Dr. Frieden for all that he has done to support the work of the ELSW. He explained that the FDA site visit and review was the third major assessment under the ELSW's charge. The ELSW visited the FDA's White Oak campus in Silver Springs, Maryland, on May 11-13, 2015. This review was conducted at the request of Secretary Burwell, HHS, to examine and evaluate the organization of FDA laboratory and research safety programs in supporting scientific functions and to make proposed recommendations for improvements to these programs. The site visit was productive and well-organized. He expressed the ELSW's gratitude to Dr. Ostroff, Dr. Leiphart, Dr. DeGrasse, Mr. Matt Amann, Ms. Sarah Wiley, and Ms. Judith Talbot for their cooperation, diligent work and hospitality. He then presented for the ACD's consideration the following observations made during the ELSW's visit concerning FDA laboratory safety programs and associated proposals for improvements to these safety programs:

Observation: Organizational Structure of the Safety Program at the FDA

The FDA is a complex organization which operates facilities and programs across the country. Organizationally, the FDA is structured as a collection of large Centers [i.e., Center for Biologics Evaluation and Research (CBER), Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Tobacco Products (CTP), Center for Veterinary Medicine (CVM), National Center for Toxicological Research (NCTR)], and Office of Regulatory Affairs (ORA) each of which seems to operate primarily as an independent entity. In this environment, Centers have developed important aspects of the research safety program independently, with some safety programs more fully developed than others. Many of these programs are robust and appear to work well and efforts to re-organize and improve lab safety should be careful to not compromise the quality of programs that are working well. It is clear that the Agency is at a critical juncture as it relocates to a new campus and embarks upon the development of new lab safety programs and infrastructure [e.g., Institutional Biosafety Committee (IBC)] as well as expansion of existing programs. The timing of the move to a new campus coinciding with this safety program review presents a great opportunity for initiating programmatic improvements to laboratory and research safety.

Good laboratory safety programs usually employ aspects of a centralized program. This centralized approach promotes the establishment of institutional expectations in the realm of lab/research safety that are consistent across the Agency. Centralized programmatic elements provide opportunities for shared best practices and lessons learned. Finally, centralized programs provide economies of scale and can provide infrastructure (e.g. shared databases, IT elements) that promote visibility, efficiency and economical use of staff and other resources. However, good lab safety programs also contain elements of familiarity and specificity that are best delivered via local mechanisms and programs; these elements are essential to the mitigation of the real risks presented by specific experimental elements and specific experimental activities encountered in each Center and even in each lab. In an entity with broadly diverse experimental activities, site-specific programmatic elements such as training and auditing also must be developed. The ELSW observed that individuals at the FDA are demonstrably taking responsibility for laboratory safety and feel accountability to their home Center; this accountability should, however, extend to the Agency level. The major challenge for the FDA is, therefore, to establish a more robust centralized (headquarters) Environmental Health and Safety (EH&S) program while at the same time not losing or damaging local, Center and lab-specific, elements. The NIH Model where Central coordinated staff are deployed to Centers works well, based upon the observations made by the ELSW earlier in 2015. This Central Office model, with deployed safety staff reporting to a central line of authority, would provide consistency yet retain the independence of the safety staff needed to minimize potential conflicts of interest.

Proposed Recommendations:

1. An Agency-wide institutional vision for FDA lab/research safety programs needs to be more fully developed and the implementation of mechanisms for improvement must be strategic.
2. Agency leadership should focus on providing a common approach to the safety program and define desired outcomes. While safety challenges are varied across the Centers, as well as being specific to the labs within the Centers, institutional Agency-level leadership and oversight of laboratory safety is needed.
3. The Safety Officers should report to Institutional Headquarters rather than the Centers they oversee to avoid conflict-of-interest situations. In addition, the Responsible Official (RO) should be represented at the central Headquarters level and not be assigned at Center level as this also presents a potential conflict of interest.
4. This centralized model with deployed staff presents fiscal implications, in that funding for safety initiatives, programs and personnel should be derived from a Central budget.

Observation: Laboratory Safety Leadership

We are encouraged by the plan to elevate the status of the laboratory safety leadership within the FDA hierarchy.

Proposed Recommendations:

1. The responsibilities and authorities of this function must be strategic and need to be more fully developed and carefully considered, as well as the reporting structure, (e.g., Office of the Commissioner or the Office of the Chief Scientist).
2. Funding for this function should not be drawn from Center's budgets but rather from a central source. It is important that the Centers fully "buy-in" to the need for laboratory safety leadership. If the Center's budget is reduced to support the function, resentment may result and this will defeat the purpose for its establishment.
3. In addition, the roles & responsibilities of the headquarters of Environmental Health and

Safety (EH&S) going forward, including lines of authority, particularly in the context of the proposed new leadership model, should be better defined.

4. While it is commendable that the FDA has considered and understood the approach of the CDC to establish a laboratory safety leadership position, it is important to remember that these Agencies' missions are varied and different and that what may be the right approach for CDC is not necessarily the right approach for the FDA. What is important is that this leader must be cognizant of the health and safety status of staff and must have the ability to report directly to the Commissioner on these matters in a timely way.

Observation: Long-Term Role of the LSPPW

The discovery of the smallpox vials was well handled as were the follow-up actions taken. Most importantly, this incident demonstrated that FDA staff feels empowered to report incidents in spite of their potential negative impact and that leadership responded responsibly and promptly. In particular, the work of the internal Laboratory Safety Practices and Policies Workgroup (LSPPW) has been laudable. The commitment and leadership of Kristine Leiphart, Jeff DeGrasse and Matt Amann is quite evident on these issues.

Proposed Recommendations:

1. The LSPPW, chartered by the Commissioner, has performed its task extremely well and should continue moving forward as part of the institutional safety structure. They are a good leadership team and are clearly committed to seeing this process through, even though it is not there yet. The LSPPW should be continued and charged with the development of specific goals supporting the missions of the FDA.
2. Center level safety committees with represented membership on a Central Uber Safety Committee, with links to the IBC and Institutional Animal Care and Use Committees (IACUC), would be helpful. The LSPPW could play the role of the Central Uber Safety Committee; laboratory safety leadership could serve to chair this uber committee.

Observation: Inventory System

New efforts to link safety competencies and compliance to a performance evaluation program (e.g., as they are doing in the Hazardous Biological Agents and Toxins (HBAT) program) are excellent. New plans for inventory management in the HBAT program are also commendable. If they work as planned, they may be a model for other institutions. We were concerned, however, by some reports that not all components of the wide-spread FDA enterprise were committed to using a single electronic format for record keeping and monitoring of inventories.

Proposed recommendations:

1. The LSPPW should be charged with the implementation of the inventory system and auditing to assure that the system is maintained and updated to meet the need of the agency.
2. A single electronic system should be employed throughout FDA for this purpose.

Observation: Institutional Biosafety Committee

The FDA created an independent Institutional Biosafety Committee (IBC) in 2013. We applaud this effort and the commitment to implement the important risk assessment and risk mitigation activity at an institutional level via the IBC. The IBC membership is dedicated and takes their job very seriously. Similarly, we believe that the plan to consolidate IACUC is also a laudable effort. Our experience is that these institutional level committees provide consistency of risk assessments and safety expectations supporting FDA missions and

promote Agency-wide communication around research safety.

Proposed recommendations:

1. We believe that cross-representation across the IBC and IACUC should be considered.
2. As the NIH has done, we recommend that questions and discussion concerning Dual Use Research of Concern be incorporated into the PI's standard Risk assessment and IBC application for approval. The IBC Risk Assessment tool (IEC Application) could also be improved to elicit more information critical to the risk assessment process.
3. The FDA should monitor the pace of the IBC reviews. The FDA should consider adding people to the group to help speed things up. Another possibility is to consider providing incentives (financial or leave, etc.) for the IBC to work more hours to get things moving through the system.
4. We believe that efficiencies can be improved in the IBC review process by devoting more resources for pre-review by biosafety officers and that processes for expedited review be considered.

Observation: Occupational Health

There is not a clear view in the Centers of what staff should expect from Occupational Health. In addition, Occupational Health services available to ORISE Fellows do not seem to be equivalent to those available to Federal employees.

Proposed recommendations:

1. Clarify to employees what the Occupational Health Office does (and does not do). The central EH&S office should support the proposed development of databases that will track immunization, vaccine compliance etc.
2. ORISE Fellows and Federal employees who work in laboratories should have equivalent Occupational Health and Safety services.
3. Develop post-exposure follow-up procedures to be consistent throughout the institution and not Center-oriented.

Observation: Training

Multiple approaches to safety training have been developed, including on-line training and lab-specific training, but this effort is not standardized across the FDA. There seems to be ambiguity in the role of the FDA University versus the Centers in designing and delivering training.

Proposed Recommendations:

1. We recommend that the headquarters EH&S survey the Centers to find out where specific needs and gaps exist. For instance, in one Center, staff did not seem to know procedures for whom to call in emergency medical situations. The needs for CBER as compared to CFSA in terms of training, outreach, etc. are very different and it is likely that this is the case across the FDA.
2. There is a need for more granular information that focus groups can provide to understand the particular needs within the Center, as well as the baseline views of the scientists and employees there. It would also be valuable to have more concrete data assembled every year on accidents. How many accidents exactly have occurred in each Center, each year? What were the patterns? What steps have been taken to reduce them in the coming year? This information should be tracked over time to demonstrate progress. The NIH has a good model for tracking incidents.
3. We would encourage the FDA to report near-misses and disseminate lessons learned to other scientists as a way to continuously improve quality.

4. A modular training model would help address site-specific safety needs while establishing consistency in training effort and content. Additionally, it appears that at some sites important training is not mandatory and that competency assessments (post-tests) are not performed. In addition to written competency assessments, technical competency in the lab should be assessed and documented.
5. Responsibilities for training should be clarified between the centers and the FDA University.

Observation: Communication:

We learned from leadership about many initiatives that are underway to improve lab safety programs; however, we also heard that staff are not aware of many of these initiatives. We believe that efforts to communicate these initiatives, their rationale and criticality to the FDA community can be improved. Specifically, the role of the Occupational Health Program and the availability of this program to FDA staff as well as contractor employees is not well understood by the FDA staff. More specifically, the feedback from CBER staff was different from CFSAN staff, perhaps reflecting the different safety cultures of the two Centers. In particular, the CBER group felt that the Safety Program they have works well for them and they are reluctant to see the safety function move to a “headquarters” office, not wanting to “break” a process that was working for them. CFSAN staff, in contrast, indicated a need for a stronger biosafety presence at CFSAN and felt they would benefit from more electronic training as well as more actual hands-on interactive training.

Proposed recommendations:

1. Increase the visibility of signs and phone numbers that people can use to call with any safety concerns. The FDA needs ways for those who feel the least empowered to easily call with concerns.
2. Improve communication around the Occupational Medicine Program. A sentiment that this program was reactive rather than proactive was also articulated.
3. Develop an institution-wide communication program that emphasizes the FDA-way of doing good science safely.

Discussion Points

Dr. Berns noted that the ELSW was very impressed by how assiduously FDA was working in this area, despite the fact that the leadership is currently in an acting capacity and that FDA recently moved to a new campus, and combined a significant number of activities.

Dr. Frieden said he was interested in trying to learn from the ELSW’s very comprehensive and thoughtful review of FDA, having conducted the CDC review first, whether there were findings from the FDA review that would help to inform additional advice the ELSW might give to CDC either on issues of centralization versus decentralization or best practices in various areas.

Dr. Berns replied that at the level of the problem of having a variety of different centers that have operated autonomously in terms of structure, the issues are similar to those at CDC. Essentially, he thought the ELSW’s recommendations for both agencies were comparable.

Dr. Kanabrocki agreed, noting that one thing the FDA is doing that could perhaps help CDC is in the area of safety committees. The FDA is now standing up its IBC, and is working to develop it in such a way that it is an institutional committee that oversees and conducts risks assessments from an institutional perspective for all of their research activities, whether recombinant or pathogenic organisms. This is a challenge for CDC as well. It is possible that CDC could glean

something from FDA's approach to this that would be beneficial. The diversity of what CDC and FDA must deal with is very much in contrast with NIH, whose mission is strictly research. There is a greater challenge for CDC and FDA.

Dr. Berns thought the recommendation that addressed these issues was having in situ safety officers in various locations who work with the individual centers, but report back to a more central office. This avoids the COI issue. That is a situation that is particularly sensitive in terms of the CDC.

Dr. Greenberg asked whether there was a recommendation that the more centralized biosafety committees communicate across these HHS agencies.

Dr. Berns thought that would be challenging on a regular basis; however, meeting once a year to discuss issues could be beneficial.

Dr. Kanabrocki agreed that this would be difficult to do organizationally on a regular basis, although an annual or semi-annual meeting among the leadership of the agencies might be feasible and beneficial.

Dr. Frieden responded that they are actually planning to do this, with the first meeting planned for the safety leads in each of the three agencies. He said he did not have much visibility into the size and scope of the FDA laboratories to understand the similarities and differences. He would appreciate receiving any readily available background materials that were shared with the ELSW.

Motion

A motion was made and seconded to approve the FDA recommendations of the ELSW. The motion passed unanimously with no abstentions.

Motion

A motion was made and seconded to approve the minutes of the ELSW conference calls from March through May of 2015. The motion passed unanimously with no abstentions.

CDC Update on Progress Addressing Internal Laboratory Safety

Dr. Michael Shaw (OID Senior Advisor for Laboratory Science) presented updates on the seven functional areas for which recommendations were specifically given to CDC on the basis of ACD deliberations and the ELSW. Regarding leadership, on May 5th Dr. Frieden announced to CDC staff that Dr. Steve Monroe would be serving as the Acting Associate Director for Laboratory Science and Safety (ADLSS) beginning on May 18th while the nationwide search continues for a permanent ADLSS. Dr. Monroe is the Deputy Director of the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID). He previously served in leadership positions such as Acting Director of CDC's Office of Advanced Molecular Detection (OAMD). He was Director of the Division of High Consequence Pathogens and Pathology (DHCPP), and Associate Director for Laboratory Science in the Division of Viral and Rickettsial Diseases (DVRD). As Acting ADLSS, Dr. Monroe will be establishing the office in the CDC Office of the Director (OD) and continuing the agency's focus on ongoing laboratory safety improvements.

On June 28th, Dr. Leslie Dauphin accepted the permanent position as Deputy Director of the Office of the Associate Director for Laboratory Science and Safety (OADLSS). She has played an instrumental role in leading the agency's laboratory safety and science improvement efforts over the past several months. She has very broad laboratory engagement experience. She has been Deputy Associate Director for Laboratory Science in NCEZID in the past, and worked as a bench scientist for many years working with select agents. Thus, she has great familiarity with the issues.

In terms of governance, the new Laboratory Safety Review Board (LSRB) that was charged to conduct safety reviews of laboratory procedures is currently collecting data for its first quarterly reporting cycle. Each of the branches that have laboratories conducting BSL-3 or BSL-4 work is providing a quarterly report to the LSRB that will then be submitted to the new OADLSS. The purpose of this report is to monitor adherence to CDC's procedures for transfer of biological materials from BSL-3 and BSL-4 laboratories to lower levels of containment, along with a risk assessment of the protocols that are being put in place.

Regarding more general risk assessments, during the last ACD meeting, an announcement was made that CDC has a new biological risk assessment course that was developed to teach staff how to identify and mitigate risks associated with laboratory work with biological agents. The course has now been finalized based on feedback from course participants, and courses have been offered to laboratory staff each month to meet demand, which has been very high. Enrollment has consistently reached the limit within 24 hours of posting course availability, so the number of courses being offered has been increased as a result. Most recently, the course was offered in June 2015 to Fort Collins staff.

In terms of more general laboratory safety training, there is the new Laboratory Leadership Service (LLS) fellowship program. The LLS Class of 2015 began their formal training on July 1, 2015. The course work is intended to focus on skills in biosafety, quality management systems (QMS), leadership, and public health. The instructors include subject matter experts (SMEs) from across and outside the agency. The fellows will begin serving officially in their assigned host laboratories on August 1, 2015. Recruitment has also been opened for the LLS Class of 2016. The application period began on May 18, 2015 and will remain open until August 17, 2015.

With respect to the culture of safety, proactive two-way communication and staff engagement continue to enhance the culture of safety at CDC. For example, on June 17th, the OADLSS disseminated the first issue of Lab Links. Lab Links is a monthly newsletter dedicated to keeping staff informed of science and safety news. This newsletter will be distributed via the laboratory listserv, which currently has over 1600 subscribers. As Dr. Frieden mentioned, he convened a Laboratory All-Hands meeting on June 19th that highlighted progress of all of the initiatives the agency has created to address laboratory safety and quality. Dr. Frieden also took that opportunity to thank the laboratory staff for all of their hard work and dedication. On June 23rd, the OADLSS conducted a staff engagement session to gather additional input on how to improve the utilization of camera systems in BSL-3 and BSL-4 laboratories. These were facilitator-led, interactive information gathering sessions, which have proven to be very useful over the past year. On July 27th, OADLSS will convene a focus group with laboratory staff representing all centers across the agency to acquire their input and recommendations for developing new programs for sharing best practices for laboratory safety and quality. Programs will continue that recognize staff who promote best practices in laboratory safety and quality.

Pertaining to biosafety, the Office of Safety, Security, and Asset Management (OSSAM) where the Environment, Safety, and Health Compliance Office (ESHCO) resides, has established a new leadership workgroup. This workgroup includes leaders from centers and laboratory programs that impact CDC's laboratories to represent the primary customers for the CDC safety office. Their purpose is to provide advice and guidance to strengthen and improve CDC's comprehensive safety program, with a specific aim of assuring the safest work conditions for the agency's employees and contractors.

Concerning progress reporting and laboratory accreditation, transparency continues to be promoted by sharing updates with staff and the public. CDC's website includes updates on progress toward recommendations from the laboratory-related incidents, and the ELSW receives regular updates on progress toward implementing the ACD's recommendations, most recently on July 14th. CDC is also making progress with its pilot project for external accreditation of International Organization for Standardization (ISO) standards in five infectious disease laboratories. During July through August, staff from each of these pilot laboratories are traveling to ISO-accredited federal and state laboratories to gather lessons learned from the process for CDC's own ISO accreditation and to inform decision-making for implementation at CDC. The benchmarking federal laboratories include FDA, the US Army Medical Research Institute of Infectious Diseases (USAMRIID), the Animal and Plant Health Inspection Service (APHIS), and the US Public Health Command. The public health laboratories include New York, Arizona, Arkansas, and Maryland.

Discussion Points

Dr. Greenberg emphasized that CDC has taken the recommendations very seriously, and has designed a very comprehensive response.

Dr. Frieden agreed that CDC could not possibly be taking this more seriously, and is implementing and tracking the progress toward the recommendations that they have been given. The agency is always seeking new and better ways to increase the safety of CDC's staff and procedures. It is encouraging to see the amount of interest and commitment from throughout the agency as progress continues to be made on this effort.

Dr. Berns asked about the potential to gain access to an appropriate physical facility in which to perform hands-on high-containment training. He wondered whether there was any follow-up on how that effort is going.

Dr. Frieden replied that consideration has been given to a few ways to have a dry laboratory for hands-on training. One idea is to build a laboratory facility, and requests have been made in the budget in an effort to acquire the resources to do that. Another idea is to rent space. While there is space at Emory University, it has not been fully functional currently. Therefore, CDC is engaged in discussions with Emory University regarding whether it makes sense to collaborate with them on that effort. Those discussions are still underway.

Dr. Shaw added that this effort is being investigated actively, because the agency wants to have something like this in place for training not only CDC staff but also visitors who come to CDC to learn the agency's procedures.

Public Comment

No public comments were offered during this meeting.

Closing Comments; Meeting Adjourned

Dr. Greenberg invited those present to share their final comments and ideas:

- ❑ Dr. Kanabrocki extended gratitude to the ACD, CDC staff, and the FDA for their support and cooperation throughout the process.
- ❑ Dr. Berns echoed Dr. Kanabrocki's comments. The task of the ELSW has been challenging and is very delicate with regard to the interaction with the agencies involved. He thought the support and interactions had been exemplary, and said he was very grateful. The ELSW will be visiting CDC again in October 2015 to observe what has occurred in follow-up to the ACD's recommendations. There will be an effort to monitor or at least receive reports periodically from the three agencies. Some of the agencies will have less to report about, in particular NIH. However, the ELSW has had some informal follow-up from that assessment. There is ongoing activity at CDC and FDA, so as long as the ELSW is in place, hopefully input will be provided to the workgroup regarding the various steps being taken.
- ❑ Dr. Frieden expressed sincere gratitude for all who have worked on this process. It has been extremely helpful to CDC, and the agency continues to be highly focused on implementing the recommendations. In terms of some of the specific efforts, he welcomed the LLS group earlier in the year and again when they first began their work in July and is very delighted by this effort. CDC would like for the LLS to become as respected and well known--in the laboratory safety and management area--as the Epidemic Intelligence Service (EIS) is. There was a recent incident with the Department of Defense (DoD), which CDC is involved in investigating. CDC's Division of Select Agents and Toxins (DSAT), which is part of the Office of Public Health Preparedness and Response (OPHPR), oversees and regulates such issues. The DoD investigation is ongoing, and the lessons from that investigation are going to relate to how protocols are followed, how certain tests are performed, how records are kept, and how procedures are conducted. CDC will be assessing all such incidents to try to enhance the safety of the work being done at CDC and elsewhere.
- ❑ Dr. Greenberg thanked everyone for their time and the ELSW for its excellent work and report.

With no further business posed or additional comments or questions raised, the meeting officially adjourned at 2:30 p.m.

Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the July 17, 2015, meeting of the Advisory Committee to the Director, CDC are accurate and complete.

Date

Alan Greenberg, MD, MPH
Chair, Advisory Committee to the
Director, CDC

Attachment #1: Meeting Attendance

ACD Members Present:

Georges C. Benjamin, MD, FACP, FNAPA, FACEP (E), Hon FRSPH
Executive Director
American Public Health Association

Kenneth I. Berns, MD, PhD
Distinguished Professor Emeritus
Molecular Genetics and Microbiology
College of Medicine, University of Florida

Nisha D. Botchwey, PhD, MCRP, MPH
Associate Professor, School of City and Regional Planning
College of Architecture
Georgia Institute of Technology

David W. Fleming, MD
Vice President, Public Health Impact
PATH

Alan Greenberg, MD, MPH
Professor and Chair
Department of Epidemiology and Biostatistics
Milken Institute School of Public Health
The George Washington University
ACD Chair

Joseph Kanabrocki, PhD, CBSP
Associate Vice President for Research Safety and Professor of Microbiology
The University of Chicago

Jewel M. Mullen, MD, MPH, MPA
Commissioner and State Health Officer
Connecticut Department of Public Health

Lynne D. Richardson, MD, FACEP
Professor and Vice Chair of Emergency Medicine
Professor of Population Health Evidence and Policy
Icahn School of Medicine at Mount Sinai

Sara Rosenbaum, JD
Harold and Jane Hirsh Professor
Milken Institute School of Public Health
The George Washington University
Department of Health Policy and Management

CDC Staff Present:

Ileana Arias, PhD

Principal Deputy Director

Katherine Lyon Daniel, PhD

Associate Director for Communication
Office of the Director

Thomas R. Frieden, MD, MPH

Director

Gayle J. Hickman

Committee Specialist, ACD
Advance Team, Office of the Chief of Staff

Michael F. Iademarco, MD, MPH (CAPT, USPHS)⁸

Director
Center for Surveillance, Epidemiology and Laboratory Services, OPHSS

Harold W. Jaffe, MD, MA

Associate Director for Science
Office of the Director

Vikas Kapil, DO (Representing Dr. Kenyon)

Center for Global Health

Keven Karem, PhD

Associate Director, Laboratory Science
Center for Global Health

Stephen C. Redd, MD (RADM, USPHS)

Director
Office of Public Health Preparedness and Response

Chesley Richards, MD, MPH, FACP

CDC Deputy Director for Public Health Scientific Services
Director
Office of Public Health Scientific Services

Anne Schuchat, MD (RADM, USPHS)

Director
National Center for Immunization and Respiratory Diseases

Michael Shaw, PhD

Senior Advisor for Laboratory Science
Office of Infectious Diseases

Carmen Villar, MSW

Chief of Staff
Designated Federal Officer, Advisory Committee to the Director

Sarah Wiley, MPH

Senior Advisor, Office of Infectious Diseases
Interim Designated Federal Officer, ELSW

CDC Foundation Participants:

Charlie Stokes

President and CEO

Chloe Knight Tonney

Senior Vice President for External Affairs

FDA Staff Present:

Mr. Matt Amann

Director, Employee Safety and Environmental Management

Dr. Jeff DeGrasse

Office of the Chief Scientist

Tara Goodin

Media Affairs Office

Dr. Kristine Leiphart

Deputy COO

General Public Present:

Stephanie Wallace

Medical & Scientific Writer/Editor

Environmental Scientist

Cambridge Communications, Training, & Assessments, Inc. (CCTA)

Attachment #2: Acronyms Used in this Document

Acronym	Expansion
ACD	Advisory Committee to the Director
ADLSS	Associate Director for Laboratory Science and Safety
APHIS	Animal and Plant Health Inspection Service
ASTHO	Association of State and Territorial Health Officials
BSL	Biosafety Level
CBER	Center for Biologics Evaluation and Research
CDC	Centers for Disease Control and Prevention
CDER	Center for Drugs Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFSAN	Center for Food Safety and Applied Nutrition
CGH	Center for Global Health
CTP	Center for Tobacco Products
CVM	Center for Veterinary Medicine
DFO	Designated Federal Official
DHCPP	Director of the Division of High Consequence Pathogens and Pathology
RO	Responsible Official
DoD	(United States) Department of Defense
DSAT	Division of Select Agents and Toxins
DVRD	Division of Viral and Rickettsial Diseases
EH&S	Environmental Health and Safety
EIS	Epidemic Intelligence Service
ELSW	External Laboratory Safety Workgroup
ESHCO	Environment, Safety, and Health Compliance Office
FDA	(United States) Food and Drug Administration
HBAT	Hazardous Biological Agents and Toxins
HHS	(United States Department of) Health and Human Services
IACUC	Institutional Animal Care and Use Committees
IBC	Institutional Biosafety Committee
ISO	International Organization for Standardization
LSPPW	Laboratory Safety Practices and Policies Workgroup
LSRB	Laboratory Safety Review Board
NCEZID	National Center for Emerging and Zoonotic Infectious Diseases
NCTR	National Center for Toxicological Research
OAMD	Office of Advanced Molecular Detection
OPHPR	Office of Public Health Preparedness and Response
OSSAM	Office of Safety, Security, and Asset Management
PHAB	Public Health Accreditation Board
QMS	Quality Management Systems
SME	Subject Matter Expert
USAMRIID	US Army Medical Research Institute of Infectious Diseases