



# CDC Advisory Committee to the Director (ACD)

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*Minutes from the April 21, 2016 Meeting*

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## Advisory Committee to the Director: Record of the April 21, 2016 Meeting

The Centers for Disease Control and Prevention (CDC) convened a meeting of its Advisory Committee to the Director (ACD) on April 21, 2016 at the Arlen Specter Headquarters and Emergency Operations Center in Atlanta, Georgia. The agenda included updates from the CDC Director; review and discussion of current issues, including the Zika response, the Global Health Security Agenda (GHSA), and CDC's Prescription Drug Overdose Guidelines; reports and discussion from ACD workgroups; an update on the response in Flint, Michigan; an update on CDC's laboratory safety efforts; and a discussion of future ACD agenda items.

### Welcome and Introductions

David Fleming, MD (ACD Chair), called the meeting of the Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC), to order at 8:40 a.m. He welcomed three new ACD members:

- Christopher Elias, MD, MPH
- LaQuandra Sherese Nesbitt, MD, MPH
- Wilma J. Wooten, MD, MPH

Those present and participating via telephone bridge or video conference 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. The following ACD members disclosed conflicts of interest (COIs):

- Dr. Fleming: PATH, his organization, receives funding from CDC, but he has no direct COIs.
- Dr. Elias: The Gates Foundation provides support to CDC's mission through the CDC Foundation, but he has no personal conflicts.
- Dr. Lynne Richardson: Her institution receives funding from CDC, but she has no conflicts.
- Dr. Lynn Goldman: Her university receives funding from CDC, but she has no conflicts.
- Dr. Nesbitt: The District of Columbia (DC) Department of Health receives funding from CDC, but she has no direct conflicts.
- Dr. Wooten: Her agency receives funding from CDC, but she has no direct conflicts.
- Dr. Tom Farley: His agency receives CDC grants, but he has no conflicts.
- Ms. Sara Rosenbaum: Her institution receives funding from CDC, but she has no conflicts.

Carmen Villar, MPH (Chief of Staff, CDC; Designated Federal Officer (DFO), ACD) offered some housekeeping points. Dr. Fleming directed ACD's attention to the minutes from the October 2015 meeting provided in their materials. The External Laboratory Safety Workgroup (ELSW) was disbanded during that meeting because its job was complete, but additional reports were provided regarding activities in that arena since October 2015.

### Director's Update

Thomas R. Frieden, MD, MPH (Director, CDC), reiterated his thanks to the ACD members for their attendance and for engaging with CDC to provide advice. He emphasized that no organization is perfect; no individual could not do a better job; and no program has ever been conducted perfectly—and even if it were, the world would change the next day and the program would need to adapt. ACD's feedback is crucially important and has been extremely helpful to the agency, not only as a whole group, but also because its workgroups and subcommittees

have provided direction to many areas of CDC and have helped the agency do more and serve better. Dr. Frieden provided updates on several key topics for CDC and encouraged ACD to engage in interactive discussion.

### ***Zika***

Zika is the single most complex public health emergency that Dr. Frieden has ever been associated with. Dr. Coleen Boyle and the National Center for Birth Defects and Developmental Disabilities (NCBDDD) are activated, as are multiple other parts of CDC, to respond to this unprecedented situation—the first time in which a pregnant woman can be bitten by a mosquito and as a result give birth to a child with a devastating malformation. CDC’s portion of the Congressional request to address Zika is \$828 million, which was revised downward. CDC hopes that there will be action in Congress soon. There are three critical parts of the Zika response:

- Emergency response in Puerto Rico (PR). PR is part of the US, and it has problems similar to other parts of the world. If Zika can be stopped in PR, then there will be important lessons for the world.
- Prevention of cases on the mainland and responding as needed.
- Support internationally through research, diagnostics, and control.

### ***Winnable Battles***

Over the past seven years, CDC has had a series of goals referred to as the “Winnable Battles.” Tobacco use is now at an all-time low. It remains the leading preventable cause of death, but progress has been made. Some types, but not all, of healthcare-associated infections (HAIs) have experienced declines. Teen pregnancy is at the lowest rate in US history. Regarding nutrition, physical activity, and food safety, there have been decreases in childhood obesity and in some, but not all, foodborne infections. Motor vehicle injuries dropped between 2007 and 2013, but that trend may not continue. Fewer and fewer people who are HIV positive are unaware of their infection. A great deal of progress has been made on these indicators. While CDC is not responsible for all of the progress, the agency has made important contributions to the progress. Identifying and defining areas for specific action and focused effort toward improvement makes a significant difference.

### ***CDC’s Worldwide Work***

CDC has made an impact in global health. The world is closer than ever to polio eradication. The Ebola response was the largest response in CDC history. The current political situation in Haiti is problematic, but tens of thousands of lives have been saved by a stronger public health system with improved vaccination, malaria control and elimination efforts, and HIV treatment. Global Health Security (GHS) is a major effort to build the world’s capacity to find, stop, and prevent health threats. The President’s Emergency Plan for AIDS Relief (PEPFAR) provides more than half of the world’s HIV/AIDS treatment. With efforts such as scaling up voluntary male circumcision and expanding laboratory systems, PEPFAR is the largest bilateral global health program in history. PEPFAR began under the George W. Bush administration, and the current administration has “carried the torch.” It remains important, and CDC is a crucial part of it. While not in the news of late, CDC staff have responded in countries with outbreaks of Middle East Respiratory Syndrome (MERS). There were two MERS cases in the US, which were not a threat to the general population.

### ***A Stronger, More Effective CDC***

Building a stronger, more effective CDC includes focusing on the Winnable Battles as well as emphasizing scientific rigor. CDC continues to hold all of its scientific activities to a higher level, whether they are publications, laboratory science, Public Health Grand Rounds, or other efforts. CDC also focuses on training future leadership. The Epidemic Intelligence Service (EIS) program is well-known and the Public Health Associate Program (PHAP) continues to grow, with hundreds for graduates. PHAP has the potential to rejuvenate public health if it continues for the next 10 years. Participants' experiences have been excellent with recruitment within the two-year clinic program and with placement after the program. The newest training program is the Laboratory Leadership Service (LLS), which was implemented as a result of a recommendation from the body of advisors assembled by CDC after a series of laboratory incidents. The goal of the LLS is to create a cadre of people with excellence in laboratory management, laboratory science, and laboratory safety. If this program works well, it should become an international model for building laboratory systems around the world as EIS has been. The first cohort of seven fellows had an excellent experience; in fact, they investigated a recent salmonella laboratory infection, rapidly identifying the source and helping to rapidly implement agency-wide policies that will prevent a recurrence. In 2009, the *Atlanta Journal-Constitution* asked Dr. Frieden about the "least-recognized aspect CDC," and he answered that it was CDC's laboratories. The laboratories allow the agency to speak definitively to so many issues. CDC is the reference laboratory of the world, and that stature must be maintained.

### ***Communication***

CDC's communication is timely, trusted, and accessible. New products have been launched, but the *Morbidity and Mortality Weekly Report (MMWR)* remains CDC's chief way of speaking with the public. The *MMWR* is indexed and a good way for CDC to ensure that information can be shared within 24 to 48 hours, if necessary. It not cleared or reviewed by anyone over the level of the CDC Director.

### ***Collaboration with Healthcare***

For many years, there was a sense that public health and healthcare are separate. Some parts of public health may still have the impression that healthcare is "messy and political," but there are many interactions between public health and healthcare, at many levels. CDC has made a great deal of progress in working with the Centers for Medicare and Medicaid Services (CMS). An EIS officer is stationed at CMS, and the two agencies have employed each other's staff members. CDC has assisted with CMS's grant programs as well.

### ***Emergency Operations***

CDC continues to optimize its emergency response capacity.

### ***Antibiotic Resistance***

The Fiscal Year (FY) 2017 CDC budget request includes additional funds to fight antibiotic resistance (AR). AR continues to be a significant problem. People continue to die from resistant infections that are acquired at hospitals. To really make a difference with this problem, the way that hospitals work will have to be reinvented. The amount of contamination in a hospital is close to infinite. The AR Initiative in Year 2 has additional goals.

### ***Prescription Drug Overdose***

The FY 2017 budget request includes an additional \$10 million to address prescription drug overdose (PDO). CDC recently released guidelines for prescribing opioids for chronic pain. The risk/benefit ratio is clear in this area. For chronic pain, opioids are proven to cause addiction and death and they are unproven to have any long-term benefit. In fact, data indicate that people who take opioids chronically are more likely to become sensitized to pain and to have decreased functionality and increased pain. States measure drug poisoning differently, but in terms of all drug poisonings, rates of these deaths have risen in the US and have skyrocketed in several states. Only two states experienced a decrease in death rates. We are not winning this war and there is good, bipartisan, cross-government, cross-society understanding that this problem is vast and more should be done. There is willingness to do more to inform industry that actively marketing drugs that kill people is not acceptable.

### ***Health and Wellness in Indian Country***

The FY 2017 budget request incorporates more work in Indian Country. The National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP) and the Office of State, Local, Territorial and Tribal Support (OSTLTS) have done tremendous work to improve CDC's efforts in Indian Country, but more should be done.

### ***Mental Health***

There is a \$30 million request in the FY 2017 budget to implement and evaluate comprehensive suicide prevention programs based upon promising models and partnerships with Injury Control Research Centers (ICRCs) and state health departments. These programs will address key risk factors for suicidal behavior, including substance abuse and mental illness, to reduce the likelihood that ideation leads to attempt and attempt leads to death. Few causes of death are increasing in the US. Suicide is one, hepatitis C is another, and drug overdose is third. To a great extent, all three are related to addiction and to early onset of exposure to alcohol, tobacco, and drugs.

### ***Global Health Security***

GHS is critically important, but is funded on a one-time allocation. Therefore, it is important to keep in mind the need for more funding in the future. CDC is now working on a Lassa Fever outbreak in West Africa. It affected one individual who was flown to Emory, a fact that was not mentioned extensively in the news—what a difference two years makes.

### ***The "6/18 Initiative"***

Regarding the healthcare-public health interface, Mr. John Auerbach, CDC's Associate Director for Policy, has worked to identify important areas for healthcare-public health collaboration. There are six areas, which partially overlap with the Winnable Battles, in which CDC shows public health benefit and that the healthcare system can save money:

- Tobacco use
- Blood pressure
- HAIs
- Asthma
- Pregnancy
- Diabetes

Clinical systems are shocked to take a denominator approach to view their excess costs associated with these areas. For instance, tobacco users cost systems large sums of money and HAIs represent a significant avoidable expense. CDC's AR Initiative will prevent 37,000 deaths and save \$7.7 billion in healthcare costs if it is fully funded. Public health can help healthcare change incentives to help patients and to help their bottom lines.

### ***Tobacco***

Tobacco remains the leading preventable cause of death in the US. There has been progress. The "Tips from Former Smokers" campaign is one of the efforts from the last seven years of which Dr. Frieden is most proud. The campaign is stories of real people and emanates from work in New York City which showed that people are motivated to change by seeing disfigurement and disability. Death does not motivate people to change, and positive messages do not motivate people to change. In his first year as CDC Director, Dr. Frieden visited with Senator Daniel Inouye who at the time was the Chair of the Senate Appropriations Committee and who has since passed. Dr. Frieden asked Senator Inouye how to garner more resources to help save lives overseas, and the senator replied, "Don't tell us the good things that will happen if we give you the money. Tell us the bad things that will happen to us if we don't give you the money." The cost-effectiveness of tobacco control efforts is astonishing.

### ***Heart Disease and Stroke***

Heart disease and stroke remain the leading killers in the US and globally. In fact, hypertension is the only thing globally that kills more people than tobacco. In the US, only 52% of Americans with high blood pressure have it controlled. Jerry Stamler outlined the idea of moving the population bell curve. This concept is important. If the bell curve moves, many lives are saved. Currently, many people with bad outcomes from hypertension are not in the range to be treated. Therefore, there is no way to save them without population-based intervention. Individuals with blood pressures of 120-140 over 80-90 are not likely to be treated, although a recent trial indicates that they are at high risk and should be treated. There are not many ways for an individual to reduce his or her blood pressure. Individuals who try find that it is extraordinarily difficult to consume a low-salt diet, because there is salt everywhere. Americans eat way too much sodium. It is estimated that globally, one million deaths per year could be prevented if sodium were reduced by approximately 15%. The efforts in this area focus on giving consumers more choice. Of the sodium that Americans consume, 80% comes from packaged foods such as breads and breakfast cereals. A healthier default would be a lower level of sodium in these foods. There have been claims that these decreases could then cause harm, but the evidence is very clear that that is not the case. There have also been debates regarding whether there is an association between sodium and outcomes. Science is challenging in this area, because it is not possible to randomize one million people to different diets and to follow them for 20 years. The study that tried to do this work found borderline significance, but it is difficult to conduct these studies. However, it is entirely clear that if sodium is reduced, blood pressure is reduced and that lower blood pressure is correlated with much better cardiovascular outcomes. Industry and some academics will insist that it has not been proven that lower blood pressure through sodium reduction results in improvements in mortality. There are examples of success in the real world, however. When the United Kingdom (UK) significantly reduced sodium through voluntary targets, there was a dramatic reduction in cardiovascular disease.

### ***CDC Facilities and Budget***

CDC has 188 buildings that must be protected. CDC also has facilities that are falling apart and that have experienced fires and floods. It has been challenging to secure funding for necessary repairs and improvements. The budget request reflects an overall decrease for CDC of \$194 million, but there are increases in AR, quarantine and migration, viral hepatitis, global health protection, the select agent program, health and wellness in Indian Country, drug overdose, gun violence prevention research (which has been requested in each of the past 20 years), and non-occupational noise and hearing loss. There is a growing theory that is supported by strong data that age-related deafness is no more inevitable than age-related hypertension, but is the product of cumulative noise toxicity. There is bipartisan support for the National Violent Death Reporting System (NVDRS). If the funding increase occurs, it will expand to the entire country. CDC facility and laboratory safety are also important focus areas for monitoring health.

### ***Polio Eradication***

The world is closer than ever to achieving polio eradication. Global polio cases have decreased from 350,000 cases per year to 72 cases per year. Polio only remains in Pakistan and Afghanistan. India got “over the finish line” and then Nigeria did as well. They also controlled the Ebola virus. Nigeria has the capacity to do great things. The challenges in Pakistan and Afghanistan are enormous, and the risk of not achieving eradication is substantial if polio is not eradicated in the near future. The opportunities of having a world free of polio are enthralling. So far, 13 million children have been saved from paralysis and 650,000 polio deaths have been prevented.

Dr. Frieden reflected on processes, outcomes, and the future in larger themes. Over the past seven years, CDC has shaped itself as an organization to fit the needs of the country and the world to protect people. New entities were created within CDC, and existing entities were joined in different ways. There is a new Center for Global Health (CGH) that did not exist before. It has allowed CDC to be more synergistic and to better partner with others. There is a new Deputy Director for State, Tribal, Local, and Territorial (STLT) Support. This structure has allowed CDC to increase the proportion and amount of funding going out to the front lines where CDC’s focus should be. CDC relies on scientific excellence, and the Deputy Director for the Center for Surveillance, Epidemiology, and Laboratory Services (CELS) ensures that excellence is maintained. The rapid road to progress is policy, so an Associate Director for Policy was created to address areas where CDC can make rapid progress, such as strengthening the agency’s relationship with CMS.

Science has also been strengthened at CDC through efforts such as the Public Health Grand Rounds, the *MMWR*, the VitalSigns™ publication, and the Advanced Molecular Detection (AMD) initiative. CDC has focused on staffing through efforts such as PHAP, and an enormous amount of work has been done in communication. CDC has developed linkages with other parts of the government, such as CMS, that allow CDC to extend what it can do. With some challenges, CDC has done reasonably well from a budgetary standpoint so that the agency is able to continue to protect Americans better. CDC has been able to increase laboratory safety work consistently with the staff and their commitment to excellence. These process improvements have led to a series of outcome improvements, such as success in the Winnable Battles, Ebola, polio, GHS, PEPFAR, MERS, H1N1, and other issues in which people are alive and/or healthy today who would not have been without the great work of the doctors, nurses, laboratory experts, and scientists at CDC and that partners that CDC supports to do so much.

CDC does a great deal behind the scenes as well. For instance, because CDC has such credibility, when the new US Department of Agriculture (USDA) “plate” method replaced the food pyramid for recommended food intake, CDC played a pivotal role in helping USDA with the completion of that movement. When the US Environmental Protection Agency (EPA) issued regulations that dramatically reduced PM<sub>2.5</sub> in the environment, CDC was able to determine what the health benefits would be to get that change through regulatory hurdles. CDC has been able to make a difference in people’s lives. Going forward, CDC and all of society have the responsibility and the opportunity to continue to support CDC’s technical work and its interaction with the healthcare system so that the agency can help the country achieve much more health value for the dollars that are spent. CDC has a pivotal role in GHS.

## Discussion Points

Dr. Fleming commented on the scope of what CDC does and the issues that the agency deals with on a day-to-day basis. He invited discussion and advice from ACD, particularly regarding the context of a change of administration. Are there things that can be done between now and the change to position the agency?

Dr. Anthony Iton thanked Dr. Frieden for the presentation and encouraged him to create an op-ed piece based on it to describe the progress that has been made across the Winnable Battles. The piece could serve as a “shot in the arm” to public health, illustrating that investing in these issues leads to change. Some may still labor under the assumption that things don’t change. Dr. Frieden’s presentation clearly illustrates that focused investment leads to measurable change. Whatever dissemination channel he chooses, Dr. Frieden can reach beyond the public health community to the broader community. Regarding causes of death in the US, rising trends have been observed in suicide and overdoses. There is not enough public awareness regarding the underlying causes of these issues. There is a concentration of increases in the Northeast and the Midwest. Dr. Iton wondered about correlates regarding, for instance, income inequality or unemployment, that align with these regional “hot spots” of overdose and suicide. Pointing out these correlates could help educate policymakers about some of the underlying consequences of dis-investing in strategies that provide a “safety net” for people.

Dr. Frieden pointed out that the HIV outbreak in Scott County, Indiana is a sentinel event. The community is poor, with low educational levels. The area has been locked out of economic opportunity. How society addresses these sentinel events is challenging. Public health’s role is first to “sound the alarm” and to serve as an honest broker for what is happening. Analyses of income inequality and unemployment have been generated more by economists than by public health professionals, and public health should do more of this work. The work does not necessarily fit well within CDC, but it is important. Public health’s second role is to support general change to reduce health inequalities and disparities. In his term as CDC Director, Dr. Frieden instituted a regular surveillance summary of health inequalities and disparities that will continue indefinitely at CDC until there are no more inequalities. Public health’s third role is to identify specific areas where a difference can be made. CDC identified teen pregnancy prevention as one such area where public health progress can make a significant difference on inequality. Overall, public health tries to avoid and reverse what is often called the “inverse care law.” That is, the people who need care the most receive it the least and vice versa. This concept is also true to a great extent with medications. Healthcare over-treats with antibiotics and opioids and under-treats for hypertension. These issues are not just about economic incentives. They are a broader cultural

issue that all of us have a role to do what we can to understand as individuals, as communities, as a society that some things take time. Sometimes the best solution is not the quickest solution.

Dr. Goldman added that the behavioral sciences are important because sometimes public health talks to people, but the messages are not received because public health is not speaking their language. Public health has not done the necessary behavioral science work to understand how to impact health behaviors across a more diverse set of population groups. This area, additional application of economics, and big data have potential for CDC. She noted the differential between this year's CDC budget request and previous requests and wondered what the agency is not doing and how, in the context of a constrained budget, CDC can address other unexpected challenges, such as the lead issues that are surfacing in Flint, Michigan and throughout the country.

Dr. Frieden said he hoped that Congress will have the wisdom to make choices that protect Americans. Some "games are played" in the budget. Some elements are proposed for cuts that Congress will not cut. The issue of responding to emergencies is very important. There should be a mechanism in place, a disaster relief fund for public health, such that CDC does not have to run to Congress when there is an emergency. Congress should set criteria so that the fund is only triggered under certain circumstances. Reporting will be required so that it is not a slush fund. Setting money and mechanisms in advance will minimize the need for emergency supplemental funding. When Ebola began, there was not enough money to buy airplane tickets to send staff to West Africa. US Agency for International Development (USAID) offsets provided \$3 million to support the basic activities of the response. CDC was scraping together money at the end of the fiscal year. There are jurisdictional issues to be resolved, but if there is a will, there will be a way.

Dr. Farley was pleased to see the investments in CDC's long-term health, with focus on the agency's processes and structures. He was impressed by how Dr. Frieden has managed to maintain CDC's independence and image of scientific credibility and reliability in a politically divisive time. He asked how ACD can help CDC in this area. Further, if a new CDC Director is placed next year, he wondered how CDC could maintain its professional scientific image in an environment that is likely to become more political in the future, and how the new CDC Director could avoid being "a political hack?" If CDC loses the sense that it is outside politics, it loses almost everything.

Dr. Frieden replied that as a Federal Advisory Committee Act (FACA)-chartered committee, ACD has a voice and can make its views known. More broadly, it is important that CDC's scientists understand that they work within a society, and their scientific integrity is not open for compromise. In any organization with over 20,000 people, some people will feel that something is wrong. Any complaint must be taken seriously. The most important thing for CDC to do is to continue its internal scientific excellence. If the agency is strong internally, then it can withstand any external pressure. Part of this internal strength and coherence as an organization includes ACD advising CDC and ensuring that the agency's vision is clear, and that the agency makes the best public health decisions based on the best, most objective, transparent evidence.

As a healthcare provider, Dr. Richardson expressed interest in moving forward on the identified priorities and in building on the groundwork that has been laid with the healthcare-public health collaboration. There is significant potential value in this collaboration, and a number of interesting ideas were generated by the ACD workgroup. Emergency medicine is an important part of the identified priority areas (blood pressure control,

suicide prevention, decreasing unintended pregnancy) and there are partners within healthcare that would welcome what CDC brings to these initiatives. Gathering data is very important, and the expansion of the NVDRS is to be applauded. What are the next action steps for making these collaborations real? The workgroup has built momentum, but it is not part of this meeting's agenda.

Dr. Frieden agreed that there is a great deal of momentum on the healthcare-public health collaboration within CDC. The work is led by John Auerbach. CDC is observing good progress different parts of the healthcare system, such as providers, systems, insurers, and CMS. For example, there is migration of public health officers within clinical systems and an awakening to broad possibilities. The public health-healthcare interface may be the most significant domestic challenge for public health over the next decade. It will be included on the next ACD agenda if time did not permit discussion of it during this meeting.

Dr. Joseph Kanabrocki noted that he and Dr. Kenneth Berns are pleased with CDC's progress in laboratory safety. The agency is on the right track, and these efforts can have a role outside the laboratory and research settings. His institution was named one of the hospitals to receive Ebola patients two years ago. In preparation, the hospital's infection control staff recognized that they needed help developing procedures and protocols for treating these patients, and they turned to the institution's biosafety staff, researchers, and high-containment laboratorians to develop training. Several hundred clinicians were trained to receive Ebola patients. Clinical staff expressed appreciation for the training, and many asked, "Why don't we already know this?" As nosocomial infections are a high priority, there is a role for the laboratory and research safety programs to inform infection control and clinical staff on safe procedures.

Dr. Dileep Bal agreed with ACD that Dr. Frieden has done an excellent job as CDC Director. During his tenure, Dr. Frieden has broadened the definition of population health very widely. The breadth of CDC's mission is somewhat humbling. CDC's portfolio has expanded to incorporate areas that population health needs to address, but has not always addressed. Congress has not seen fit to allocate resources to all of the needs. At some point, resources may be spread too thin. He asked, "Do you want to be a mile wide and an inch deep? Or, like in the old days, an inch wide and a mile deep?" Who knows what allocation of resources is to the greater good of the American people?

Dr. Frieden recalled Senator Inouye's comments and noted that CDC's message, which is honest and accurate, is that the agency works 24/7 protecting Americans from threats, whether the threats are domestic or from somewhere else in the world; whether they are intentional or natural; whether they are infectious or other. Regarding funding for non-communicable diseases (NCDs), nobody wants to fund a "non." There is greater possibility of support for stopping cancer, heart disease, stroke, or diabetes.

Dr. Jonathan Fielding commented on increased politicization over the last 30 to 40 years. CDC has an advantage being in Atlanta. As public health realizes that the greatest advances have come from changes in policy, the field must be close to politics. Dr. Frieden has done a wonderful job managing these issues. Going forward, it is important to have broad support for public health. The public must understand how essential the broad base of public health is in order to have the necessary degree of support in order for Congress to be convinced to do the right thing. Collectively, there should be messaging about what works in public health, what public health is,

and why people should care. A groundswell of popular support will be even more important in the future than it has been in the past.

Dr. Frieden agreed and commented on the challenge of telling the story of public health in a way that resonates with the public. Too often, public health speaks to itself. It is important to break out.

## Zika and GHSA Update and Discussion

Lyle R. Peterson, MD, MPH (Incident Manager, Zika Response; Director, Division of Vector-Borne Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC) and Coleen A. Boyle, PhD, MSHyg (Director, National Center for Birth Defects and Developmental Disabilities, CDC), presented updates and information regarding the CDC response to Zika. Rebecca Martin, PhD (Director, Center for Global Health, CDC) addressed ACD regarding the Global Health Security Agenda (GHSA).

Dr. Peterson explained that Zika virus is a single-stranded ribonucleic acid (RNA) virus of genus *Flavivirus*. It is related to the yellow fever (YF) virus. It is also closely related to the dengue, Japanese encephalitis (JE), and West Nile viruses. Zika virus is transmitted to humans primarily by the *Aedes* species mosquitoes, existing in an urban setting in a human-mosquito-human transmission cycle. In the forests of Africa where it is enzootic, it exists in a mosquito-monkey-mosquito cycle.

The virus was discovered in 1947 in the Zika Forest of Uganda. Over the course of the next 50 years, there were only approximately 12 to 14 reported cases in humans. In 2007, there was an outbreak reported on Yap Island in the Federated States of Micronesia. Subsequently, the virus began circulating from island to island. Humans are the primary host of the virus in urban settings. Given that humans travel by plane, the virus spreads effectively and rapidly. The next large outbreak occurred in 2013-2014, with more than 28,000 suspected cases reported from French Polynesia. At first there was little concern in both outbreaks since the Zika virus presents as a mild, dengue-like illness.

In urban settings, *Aedes aegypti* is the primary vector of the Zika virus. *Aedes albopictus*, or the Asian tiger mosquito, is thought to be a vector for Zika as well. It has never caused a large human outbreak, but it was associated with human Zika cases in Gabon some years ago. Both mosquitoes are difficult to control, particularly *Aedes aegypti*, which lives indoors and bites people indoors. Both mosquitoes breed in small amounts of water and are primarily daytime biters, but they also will bite at night. *Aedes aegypti* primarily bites humans. It is an efficient vector because of several properties:

- It likes to live near human habitation
- It bites humans indoors
- It tends to bite multiple people in a single bloodmeal, which increases its ability to acquire and transmit the virus

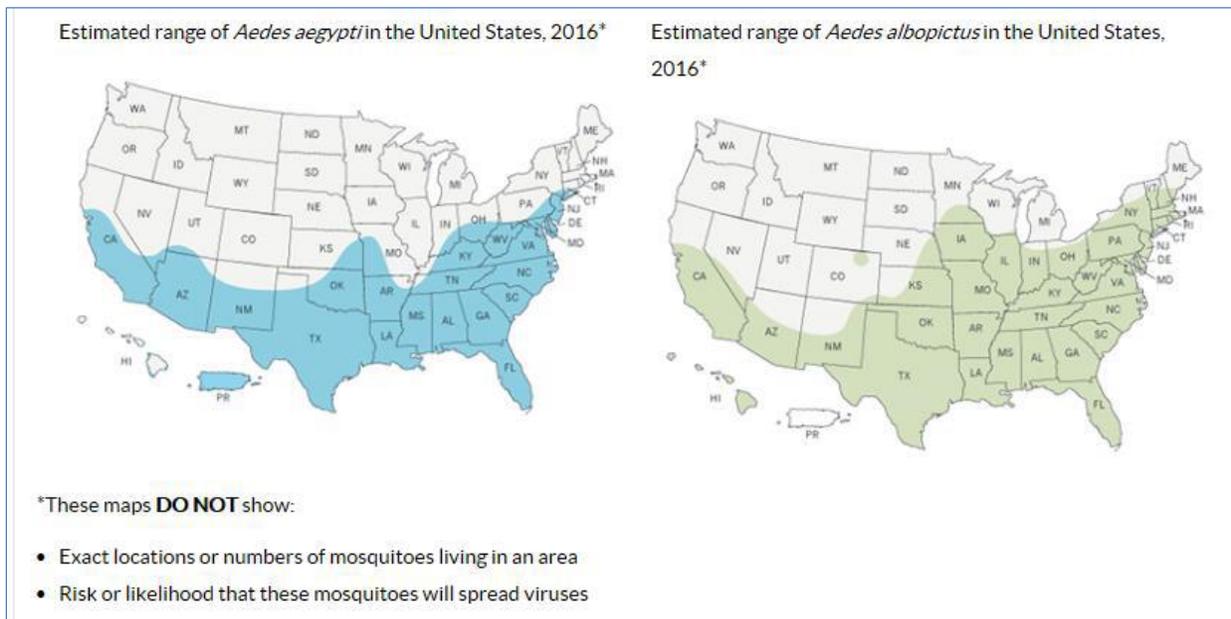
*Aedes albopictus* is somewhat less efficient, as it bites other animals in addition to humans.

Larvacide treatments and indoor/outdoor residual spraying seem to be helpful for vector control. The current strategy in PR incorporates indoor and outdoor residual spraying, particularly near pregnant women's houses; larviciding; and source reduction.

This strategy will not eliminate the vector and will not stop the wider, community-wide outbreak. It is extremely difficult to stop these outbreaks because there are so many breeding sites in an urban setting, making source reduction to lower mosquito populations difficult. In addition, since *Aedes aegypti* lives indoors, outdoor spraying may have little effect.

Insecticide resistance is a significant problem. The mosquitoes in PR are resistant to almost all of the available pesticides. The resistance of mosquitoes in the contiguous US is not well-understood, as data are incomplete. The data that are available suggest a high degree of insecticide resistance in the contiguous US. Because of the difficulty in controlling these vectors, a number of research and pilot projects underway to explore new methods of vector control. One of the projects focuses on genetically-modified sterile mosquitoes.

The distribution of *Aedes aegypti* and *Aedes albopictus* in the United States (US) is depicted in the following maps:



The mosquitoes may not be present in all areas shaded on the maps. Particularly in the northern distributions, the mosquitoes may be only transiently present. Data are incomplete regarding exactly where these mosquitoes are found. The maps are estimates based on approximately 20 years of collections. The data are incomplete because most vector surveillance in the US is geared toward West Nile Virus or *Culex* mosquitoes. The trapping that is done for *Culex* mosquitoes does not pick up either *Aedes aegypti* or *Aedes albopictus*.

One of the great surprises of the current Zika virus outbreaks has been the discovery of additional transmission modes. The maternal-fetal transmission, which causes birth defects in children, was unexpected. There have been cases of perinatal transmission in French Polynesia, so it was expected based on that transmission and other experiences with Flavivirus. The sexual transmission of Zika was another surprise. It is not known how often this transmission occurs, but semen has a very high level of virus in it, apparently for extended durations of time. Blood transfusion is another method of transmission, with some reports of transfusion-related Zika virus in Brazil. Given experiences with other Flaviviruses such as West Nile and dengue, it is expected that Zika will be transmitted via blood transfusion.

At first, there was no alarm about the spread of Zika virus, as most infections in humans are very mild or asymptomatic. A serosurvey on Yap Island indicated that approximately 80% of people with the infection remained asymptomatic. People who do become sick seem to have mild illness. The hallmark clinical manifestation of Zika is a maculopapular rash, which tends to be itchy and to appear over much of the body. The fever may not be high, and joint pain is also reported. A fairly common characteristic is conjunctivitis.

The diagnostic testing for Zika is extremely complicated, confusing, and unsatisfactory. A reverse transcription polymerase chain reaction (RT-PCR) assay has been developed and distributed throughout the US and the world. It is part of a triplex test that monitors for dengue, Chikungunya, and Zika viruses. Unlike dengue and Chikungunya, the viral levels for Zika can be very low. Zika is also transient and can only be detected in human serum for a few days. The serology is problematic. There is an Immunoglobulin M (IgM) test for Zika virus, but it cross-reacts with other Flaviviruses, which is a significant problem in areas where the prevalence of dengue is very high. For instance, more than 90% of the population of PR has been exposed previously to dengue, which leads to a great deal of cross-reaction of antibodies. Neutralization tests can help, but they cannot discern a secondary Flavivirus infection. Immunohistochemical staining can be conducted in fixed tissues as well.

As of April 13, 2016, there were 3587 travel-associated Zika cases in the contiguous states. There has been no local transmission yet. Thus far, 31 infected pregnant women have been recorded. There have been seven instances of sexual transmission and one case of Guillain-Barre Syndrome (GBS). All are due to travel-associated cases. In the US territories, there are four travel-associated cases and 471 locally-acquired cases, almost all from PR and of which 58 are among pregnant women.

The approach to Zika prevention focuses on protecting pregnant women. The Zika virus is spreading widely in PR, where more than 40 CDC staff have been deployed. The efforts incorporate the following strategies:

- Vector control
- Zika Prevention Kits (ZPKs), which include condoms and mosquito repellent
- Increasing access to effective contraception
- Risk communication and community engagement

Widespread transmission is not expected in the contiguous US, based on the experiences with dengue and Chikungunya; however, small outbreaks or one-off cases are likely to occur. Nevertheless, Zika is a new virus, and it is important to be prepared for possible outbreaks anywhere in the distributions of the *Aedes* mosquitoes.

Surveillance is being increased throughout the risk areas, and states are preparing with a phased, risk-based response plan. CDC has released a number of guidance and recommendation documents pertaining to Zika.

Dr. Boyle indicated that microcephaly and other birth abnormalities are primary concerns. The science is evolving quickly, and there is a growing body of evidence that affirms that Zika virus infection in pregnancy does cause severe microcephaly. There is a unique spatial and temporal association between the virus outbreak in Brazil and a subsequent increase in microcephaly. This association is paralleled in other countries. For instance, a similar pattern is now occurring in Colombia. The Zika virus infection carries a distinct and unique phenotype of brain destruction in the late first and early second trimesters of pregnancy. Well-done studies in Brazil and French Polynesia show the same effect of severe microcephaly in different populations at different times, with the same virus.

Prenatal Zika virus infection is characterized by the destruction of central nervous system (CNS) tissue with a subsequent loss of brain volume. The phenotype includes severe microcephaly with underlying brain loss. The skull is collapsed in very severe cases, with overlapping sutures. The scalp then continues to grow, resulting in a “buckling” of the scalp. This fetal brain destruction sequence has been seen with cytomegalovirus (CMV), but it is very rare. It also has been seen with alcohol exposure in pregnancy. Prenatal Zika virus infection also carries with it a bundle of neurologic dysfunction, including hearing and vision problems, cognitive and motor deficits and delays, epilepsy, and limb contractures.

A great deal has been learned about Zika virus in general as well as its consequences to the developing fetus. Little is known, however, regarding its absolute risk and relative risk. There is a sense that the greatest risk is late in the first trimester and early in the second trimester of pregnancy, paralleling rubella. Other co-factors that might influence whether a baby is infected are unknown. The work focuses on learning more fast and translating that knowledge into prevention opportunities.

Two pregnancy registries have been launched in the US: 1) the US Zika Pregnancy Registry, which collects information about Zika virus infection during pregnancy and congenital Zika virus infection in the continental US and territories other than PR; and 2) the Puerto Rico Zika Active Pregnancy Surveillance System. The registries are actively enrolling women, following them in pregnancy, and following their children. The US registry follows children for 12 months, and the PR registry will follow children for up to three years. Women who are enrolled have either suspected or confirmed Zika virus infections, and the women can be symptomatic or asymptomatic, as the majority of people with Zika virus infection are asymptomatic.

CDC is collaborating with Panama, Colombia, and Brazil to better understand the consequences of this exposure. CDC is working closely with the equivalent of Colombia’s National Institutes of Health (NIH) and Ministry of Health (MOH). Colombia has a robust system for surveillance of this condition, particularly in pregnant women. CDC is also working intensively in three areas with the highest incidence of Zika, conducting more in-depth prospective follow-up in pregnancy. A CDC team works collaboratively with the MOH of Brazil in a region in the northeast of the country, examining the clinical phenotype and searching for answers to the questions that have remained unanswered.

Dr. Peterson added that there have been associations with neurologic manifestations of acute Zika virus infection. Little is known about these manifestations. GBS has been anecdotally reported to be increasing in multiple countries, and one case-controlled study shows a link between a previous Zika-like illness and the presence of GBS. Several studies are ongoing to examine this link. Further, a number of neurological disorders appear to be linked to Zika, including meningitis, encephalitis, myelitis, and optic neuritis.

The future domestic and global directions regarding the Zika virus are to:

- Maintain a primary focus to protect pregnant women and their pregnancies
- Better understand the full clinical spectrum of this illness
- Strengthen surveillance and reporting of cases
- Follow up on cases through pregnancy registries
- Improve laboratory diagnostics and expand speed and access to testing
- Implement robust vector surveillance and control programs, particularly given poor historical control of *Aedes aegypti*
- Identify and promote personal protection measures
- Issue new and revised clinical and public health guidance
- Develop and deploy safe and effective vaccines and other medical countermeasures, which NIH is working toward

Dr. Martin noted that the previous day's Global Work Group (GWG) meeting included opportunities to discuss the interconnectivity and mobility of populations, as well as population growth and the effects of climate change, all of which bring risks that affect everyone around the world.

The GHSA was launched in February 2014. Since then, CDC has tracked over 260 outbreaks in 145 countries. Only one out of three countries is prepared to respond to outbreaks. There are significant impacts on economics as well, particularly trade and travel. The GHSA was established to address, enhance, and accelerate the core capacities of countries under the International Health Regulations (IHR). It is a multisectoral approach, engaging both animal and human health. The GHSA focuses on the importance of the detection, response, and prevention components of countries' capabilities. To date, over 70 countries are involved in the GHSA.

In 2016, the US government has committed to work in 17 Phase I countries, actively collaborating with governments and contributing funding to support GHSA activities. Additionally, there are 15 Phase II countries in which the US government is working with the governments to develop one-year work plans and five-year road maps toward strengthening their public health infrastructure.

The GHSA includes 11 Action Packages. CDC works with all of them, with priority areas of:

- Surveillance
- Workforce Capacity
- Laboratories
- Establishment of Emergency Operations Centers (EOCs)

Community involvement and engagement are critically important elements of this work. There are a number of examples of success stories of the US government working with partners under the GHSA. Cholera outbreak responses in Cameroon and Tanzania have led to the establishment of Incident Management Systems, coalescing programs together in a multisectoral approach to respond in emergent mode. Ethiopia has done work in animal and human health, for example in brucellosis, rabies, and anthrax. Much of this work has focused on laboratory capacity, including assessments for biosafety and operational procedures and training of staff. Burkina Faso's work highlights the importance of community involvement in surveillance and surveillance for pandemic influenza in hospitals. Ghana's immunization work incorporates a Second Year of Life platform to ensure that children can receive vaccines through age 24 months. This platform has the ability to add other public health interventions for nutrition, malaria, and others. In Nigeria, work is building on the National Stop Transmission of Polio Teams to expand malaria prevention and care in underserved areas, including surveillance, monitoring, and case management. Globally, more than 30 members of CDC's Field Epidemiology Training Program (FETP) participated in over 350 outbreak investigations in 2015.

CDC is working with other partners, including Finland and the World Health Organization (WHO), to make sure that every country receives an independent, external assessment of its preparedness. The process begins with a self-assessment, and then an independent team conducts an assessment over five to seven days. The assessment covers a number of categories and results in a color-coded scorecard. The scorecard provides a snapshot of current gaps, how they can be strengthened over time, and where countries should focus their efforts moving forward. The scorecard also allows countries to seek additional domestic or international resources to support their efforts.

The funding appropriation for GHS was for five years, with \$600 million for the Ebola response high-risk not affected countries and \$600 million for GHS and the National Public Health Institutes (NPHIs). It is important to allocate the funding rapidly and in a high-quality manner to accomplish goals early in the five-year period. It is not clear what will happen after the five-year period is over to strengthen and maintain funding.

Funding is needed for outbreaks and for strengthening public health infrastructure. For example, CDC has been involved in accelerated measles control for over 20 years. This work includes prevention and vaccination of children. Cases have declined significantly, but these prevention efforts must continue. CDC also is involved in supporting countries with outbreak responses. GHS is an example of how the global public health infrastructure can be used to respond to address these objectives and goals.

Another example is the ongoing yellow fever outbreak in Angola. CDC has sent colleagues to Angola to work on strengthening the quality of surveillance and planning and implementing immunization campaigns. There is a preparedness aspect to the response as well, as YF has been exported into China, Congo, Democratic Republic of Congo, and Kenya. The public health implications are very high if YF continues to spread into areas where it has not been before. A sufficient vaccine stockpile is needed to be able to respond, and people should be vaccinated prior to traveling.

The US government must engage and leverage partners and other countries to help close GHS gaps identified by the independent assessments. Quick action is important. Without funding and action to build on the results of the assessments, the work will not progress rapidly. Sustainability of GHS activities and progress should be assured at the country level and within CDC.

### Discussion Points

Dr. Fleming identified three important issues for CDC: the acute response, both globally and domestically; how CDC should plan to address Zika in the long term as the epidemiology evolves; and how should Zika be considered in the context of other emerging infections and GHS. Congress may move funds from Ebola and GHS to address Zika. It is important for CDC to have a coherent picture for advocacy purposes.

Dr. Richardson was impressed by CDC's GHS work. Regarding Zika, the threat seems to be limited almost entirely to pregnant women and the serious sequelae that occur through prenatal transmission. She asked whether enough is known about the characteristics of acute infection and the conferring of immunity after infection to consider preemptively infecting women of childbearing age with Zika and encouraging strong contraception while a vaccine is being developed.

Dr. Peterson said that Zika is likely to become endemic in the Americas. A vaccination strategy is the ultimate long-term response, as it is not possible to eliminate the vectors. Once a person is infected with the Flaviviruses, immunity is likely to be lifelong. If a woman is infected before she becomes pregnant or as a child, she will probably be fine. Alternatively, part of the strategy of protecting pregnant women now is the development of herd immunity, which will slow transmission in subsequent years. People are probably becoming infected before pregnancy naturally. Contraceptives are the priority in this high-risk time.

Dr. Frieden added that the focus in PR is on expanding access to voluntary, effective contraception. The CDC Foundation has been able to secure donations from companies to pursue this approach. The "chickenpox idea" of getting infected preemptively carries problems. For instance, the course of infection is unknown. It could be many years before it spreads through the island. Within a few years, it is hoped that a vaccine will be available. In the meantime, women should be protected. Further, the idea of letting a disease run its course does not sit well philosophically.

Dr. Richardson observed that women who want to start a family, but who are being told to wait several years until it is safe to do so might welcome the option of being infected with a mild or asymptomatic illness in order to be free to become pregnant. It is challenging for public health officials to contemplate this approach, but patients might have a different attitude. There are many positive consequences that accompany access to effective contraception.

Dr. Frieden said that the vector control strategies are unlikely to work. There is a large gap in the availability of voluntary, effective contraception in PR. The rate of unintended pregnancy is 60%, and there is virtually no use of long-acting, reversible contraception. PR is the part of the US where the most can be learned about vector control globally, not just for Zika, but for other infections.

Ms. Rosenbaum said she understood that this issue is more complicated than simply delaying childbearing. She recommended that CDC immediately collaborate with CMS and the tri-agencies that oversee all regulatory activities associated with health plan coverage. With universal coverage of the most effective contraceptives, there could be an advisory for Zika-based preconception counseling as part of preventive benefits that women are entitled to receive, as well as full and rapid access to the most effective forms of contraceptives. CMS should be in immediate contact with the Commonwealth of Puerto Rico about its contraceptive coverage policies. Virtually everyone in PR is covered under Medicaid.

Dr. Berns agreed that it is philosophically difficult not to let natural infection play a major role in the efforts. However, historically polio was only a real problem in advanced societies. In societies with a great deal of natural, enteric viral infection, polio was a minor issue. The question of not knowing how long the Zika virus persists in infected individuals is problematic. Populations where Zika has been endemic for some time can be studied to determine the fraction of people with continuing Zika virus presence.

Dr. Nesbitt noted the ongoing work in establishing registries and continuing surveillance programs for humans. She asked about centralized vector surveillance to gather more information regarding mosquito patterns in the US. The Flaviviruses are not new and are not going anywhere. She wondered whether states will be asked to share meaningful information on vectors. DC is publicly reporting results on a weekly basis. Other jurisdictions are planning to report as well for public accountability and to allay concerns and anxiety regarding mosquitoes. This information could be reported into a centralized infrastructure to yield more insight into this vector presence in the US.

Dr. Fielding stressed that a high percentage of pregnancies in PR are not planned. The availability of contraceptives will affect those rates, but is not sufficient to reduce them substantively. An approach similar to tobacco, in which showing people the problems associated with tobacco use made a larger impact than simply encouraging people to quit smoking, could have impact. He asked how close we are to having an adequate epidemiological profile of the outcomes of pregnancies affected by Zika. Demonstrations and images are not pleasant, but could increase the rate of contraception. Further, it appears that there are increased rates of GBS. He wondered how much is known about those rates and what their effects might be. Regarding the GHS, he asked about the degree of cooperation from WHO. WHO's response to Ebola was concerning and slow.

Dr. Boyle replied that the epidemiological profile of Zika is diverse. A study in French Polynesia estimated that 1% of women exposed to Zika in their first trimester of pregnancy had a fetus impacted by the most severe form of microcephaly. The study also identified at least twice as many babies or fetuses who had an obvious neurological impact. The study used a denominator of an estimate of all infections, symptomatic and asymptomatic. The results contrast the observations in Brazil, which is part of a clinical follow-up study with women who experienced overt Zika infection symptoms. That study showed impact on up to 30% of fetuses. With the pregnancy registry studies, as well as work in Colombia, more will be learned quickly.

Dr. Iton asked how CDC and the US government is coordinating with WHO so that the US is not the world's health policemen.

Dr. Goldman recalled how well the US Geological Survey (USGS) mapped the movement of the West Nile Virus and wondered whether they could do the same for Zika. Regarding pesticide resistance, she encouraged consulting the EPA. The EPA states that pyrethroids should not be used near women who are pregnant. Dealing with resistant bugs and the use of pesticides could be problematic, and it is important to get in front of the resistance problem. EPA and pesticide companies are important partners. Bugs become resistant in two ways: the bugs become able to metabolize many xenobiotics, or the voltage-sensitive sodium channel is protected. Many bugs have both kinds of resistant genes. It is important not to use pesticides unless they are effective.

Regarding WHO, Dr. Martin said that the collaboration is on the joint external evaluations and independent assessments. Under IHR, countries report annually to WHO on their progress toward the core competencies. Rather than asking countries to conduct two separate assessments, they have been combined into a joint survey. The Regional Director of the Eastern Mediterranean region has been a leader in achieving a joint process. The US government works with countries on the GHSA in a bilateral approach, working directly with countries on their efforts. There is a great deal of effort within WHO to examine how WHO surges and responds, and accountability at the country, region, and global levels. Performance and funding will be based on their capabilities.

Dr. Frieden said that it important to work with and strengthen WHO. The fundamental challenge at WHO is technical excellence and technical independence of the staff. WHO does not have staff at all levels who are technically excellent, and WHO does not operate as a technical organization at all levels. WHO has buy-in from member states, but there are significant problems. Unless the quality of the staff at WHO improve, organizational reforms will not matter, because WHO will not be able to meet need. CDC can offer training and support, but WHO improvement is crucially needed.

## Prescription Drug Overdose Guidelines Update and Discussion

Debra Houry, MD, MPH (Director, National Center for Injury Prevention and Control, CDC) reported that drug overdoses are one of the main drivers of changes in deaths in the US. Opioid overdoses are closely correlated with the overall drug overdose numbers. It is important to realize that the epidemic is changing and evolving quickly. For instance, New Hampshire was considered a low-burden state in 2005, but was ranked number three in opioid overdose deaths in 2013. Because all states are dealing with the epidemic, CDC plans to develop a national program on opioid abuse. The drugs also cross state borders, increasing the need for a unified approach. Since 1999, the rate of prescriptions of opioid drugs has quadrupled. In lockstep, deaths from overdoses of these drugs have also quadrupled. There is variation across states. States that prescribe more opioids tend to have more opioid deaths, with a correlation coefficient of approximately  $R = .91$ .

The National Center for Injury Prevention and Control (NCIPC) began a rigorous process of creating prescribing guidelines for opioids. The guideline was based on an Agency for Healthcare Research and Quality (AHRQ) review on chronic pain and opioids. The report found that there were no long-term studies showing the effectiveness of opioids for chronic pain. NCIPC updated the literature search and found 130 recent articles on this topic, conducted systematic reviews, and consulted experts. NCIPC then engaged stakeholder organizations for full reviews of the draft guidelines and also worked with CDC's federal partners. A constituent Webinar was held with over 700 participants. There were calls for additional opportunities for engagement, so the draft was posted in the *Federal Register*. Within 30 days, 4372 comments were received—a CDC record for a guideline. At

each step in the process, the draft was refined. After the public comment period, NCIPC's Board of Scientific Counselors (BSC) convened an additional workgroup to review the guideline and public comments and to provide input. At that point, the Opioid Guideline Workgroup of the BSC recommended, with a few considerations, that NCIPC move forward with the guideline.

The final CDC Opioid Prescribing Guidelines were published in March 2016. Dr. Houry expressed thanks to the many organizations that supported the process and provided input. She noted that the public comment period allowed for the sharing of many stories of individuals who have been impacted by prescription opioids. NCIPC also received letters from 160 medical organizations, the vast majority of which were positive and supportive.

The Guidelines are intended for primary care providers, as this group prescribes more than 50% of opioids in the US. The Guidelines focus on chronic pain in adults, with chronic pain defined as lasting for three months or longer. They are not intended for patients undergoing active cancer treatment, palliative care, or end-of-life care. Throughout the guideline, there are discussions of risks and benefits for individual patients. In cases of active cancer treatment or palliative care, the risk-benefit profile is different.

The Guidelines include 12 recommendations, which fall under three key principles:

*When to initiate or continue opioids for chronic pain:* Non-opioids should be the first-line treatment for chronic pain. If opioids are used, they should be used in conjunction with a non-opioid treatment. The long-term risks of opioids are significant, and their impacts worsen over time. Conversely, there is better effectiveness from non-opioid therapies.

*Opioid selection, dosage, duration, follow-up, and discontinuation:* "You start low, and you go slow." Patients, especially opioid naïve patients, should not begin opioid therapy on a high dose. The Guidelines also include caveats regarding specific dosages, suggesting that escalating doses should have precautions in place, such as referral to a pain specialist. With each increased morphine milligram equivalent (MME), the rates of overdose increase. While the Guidelines address chronic pain, the process included discussions and feedback regarding acute pain, especially how acute pain leads to chronic pain. One of the recommendations addresses acute pain out of trauma and surgical fields and provides a range of three to seven days, emphasizing the importance of using the lowest course possible.

*Assessing risk and addressing harms of opioid use:* When a provider prescribes any kind of addictive and potentially deadly drug, the patient should be reassessed. As part of the reassessment, providers should determine the potential need for a co-prescription of naloxone or for medication-assisted treatment (MAT) if the patient is at risk for addiction.

Now that the Guidelines have been published, NCIPC is working on implementation so that they are utilized and do not "sit on a shelf." The implementation plan has four key areas:

1. *Translation and Communication*

Develop key materials that providers will use. For instance, a checklist has been developed with key actions for providers to take. Patient materials are being developed on topics such as urine drug testing, and a mobile app is in development.

2. *Clinical Training*

The White House encouraged 60 medical schools to pledge to incorporate the Guidelines as part of their curriculum. Informing curricula is an important step, and there are other opportunities in this arena, such as adding questions on Board exams; incorporating these concepts into maintenance and certifications, and potentially into licensure; and holding Webinars for continuing medical education (CME) activities.

3. *Health System Implementation*

NCIPC is developing a Coordinated Care Plan and looking to pilot some of these initiatives in partnership with WellStar. Other health systems will partner with CDC on the implementation of the Guidelines and integration with electronic health records (EHRs) with prompts to assist in provider decision-making.

4. *Insurer/Pharmacy Benefit Manager Implementation*

Plans in this arena include developing quality metrics and medical utilization reviews. Coordination of plans with Medicaid and Medicare are also important considerations. Coverage of, and access to, non-opioid medications will be critical. Also, the proactive use of claims information and improvement in coverage and service delivery payment models will be important, including reimbursement for clinician counseling; coverage for nonpharmacological treatments; and drug utilization review or prior authorization.

NCIPC is working with the American Hospital Association (AHA) on patient materials and welcomes opportunities to work with any organization to get the Guidelines in the hands of clinicians, and implemented. Ideally, the conversation will incorporate patients taking ownership of their care, asking clinicians about the risks and benefits of opioid treatment and the risks and benefits of non-opioids. Materials can also answer questions about Prescription Drug Monitoring Programs (PDMPs), how to utilize urine drug tests, and other issues that may be new for clinicians who were trained before these tools were developed.

NCIPC received a funding increase for its work with state health departments and opioid programs. Currently, 29 states are funded to roll these efforts out nationally. There are four pillars to the state programs: 1) PDMP: A state must have a PDMP to qualify for the funding and apply to enhance and improve it. For instance, states could propose a notification system for providers to alert them about patients who might be at risk, or a program could be in real time; 2) Health Systems: This includes innovative insurer programs, state Medicaid programs, or enhanced prescriber programs; 3) Policy Evaluations: This is an optional component of the programs; and 4) Rapid Response Programs: This is also an optional component.

NCIPC hopes to expand these programs to all 50 states. A smaller program will focus on building capacity and readiness in states that are not prepared to utilize the programs. The capacity-building may include opportunities to develop interventions and surveillance systems. NCIPC also received a \$5.6 million increase for illicit opioid surveillance. In the past, data have not been timely enough to drive interventions. This surveillance will incorporate fatal and non-fatal incidents. Some of the systems include using the NVDRS, which has an opioid module to collect information about the circumstances of overdose, combining law enforcement and healthcare information. Newer technologies, such as syndromic surveillance, will provide more timely information about communities. The funding announcement requires the reporting of much of this data at quarterly intervals in order to be able to take action. Because this epidemic continues to evolve and change, the strategies to address it must be creative and adaptive.

## Discussion Points

Dr. Frieden asked that ACD focus on how to get the Guidelines put into practice widely. Changing medical care is difficult, especially when doctors are concerned because patients demand these drugs and are concerned about their ratings declining. Now there is no scientific doubt regarding the risk/benefit issues of opioids. In every area, from smoking cessation to immunizations to blood pressure control to infection control, the crux of the public health–healthcare interface is implementing public health ideas in clinical practice.

Dr. Farley recalled that when he was in New York, Staten Island was the “hotbed” for opioid prescribing. There were only two medical centers on Staten Island, and the public health department invited all doctors to emergency meetings about the opioid problem. The meetings were filled with hundreds of doctors. The public health officials talked about the opioid problem and the importance of prescribing opioids less. The meetings were followed up by public health detailing visits to every primary care physician in the borough. Within six months, there was a reduction in the amount of opioid prescribing. The drop was not sharp, but the rates had been rising, and they did fall. This approach was labor-intensive. Most physician reaction was due to a lack of awareness about the problem. Broader coverage with simple tools might be a better approach than a hard message with only a few physicians. He noted that publicity about the opioid problem has increased in Pennsylvania, where he now lives. He wondered how much physician behavior might have already changed and asked about national-level surveillance on opioid prescribing and where that graph currently stands. There is a legacy of people who are currently addicted to opioids, but it is worthwhile to understand the status of the “front end of the problem.”

Dr. Houry replied that such data will be available. CDC has purchased data from IMS Health to assess prescribing trends. There is a Prescription Behavior Surveillance System in eight states, which aggregates data. There have been decreases in prescribing in some areas such as emergency medicine, which has experienced a 10% to 13% reduction in prescribing behaviors. CDC has not examined the data specific to states and specialties yet, but as the impact of the guidelines is evaluated, the baseline will be important to understand.

Since alternatives to opioids are available over the counter (OTC), Ms. Rosenbaum suggested pursuing CMS to add reminders to state Medicaid directors that federal financial participation is available for OTC medications. This point is often forgotten, and a reminder might prompt substitution.

Dr. Iton commented that the only way to change physician behavior is to tie the behavior to quality measures, and/or to utilize public shaming, such as advertising who the big prescription mills are. He wondered about the phenomenon of buying opioids in bulk at these mills and then selling them on the streets in other places and the extent to which that, rather than local prescribing, is driving the epidemic.

Dr. Houry answered that 90% of the opioid prescriptions come from within a given state, and 5% to 7% come from neighboring states. The remaining 2% may come from across the country. Unfortunately, a supply of drugs is probably easy to access almost anywhere, so people do not have to cross states. Particularly in illicit drugs, the ready availability and relatively low cost are considerations. CDC is working closely with the Drug Enforcement Administration (DEA) and other law enforcement, recognizing the importance of enforcement and prevention working in concert.

Dr. Fleming noted that some of his friends who are in practice have raised a third way to change physician behavior, which is fear of lawsuits. The CDC guidelines are likely to become a standard of practice for lawsuits, which will influence physician decision-making.

Dr. Houry said that Massachusetts has passed legislation regarding registration for the PDMP. Physicians will be proactively notified regarding their place in a range of prescriptions. The information is not public, but the physicians will know where they stand in the quartile. A palliative care physician might be in the 90<sup>th</sup> percentile, which might be appropriate. Other physicians in high percentiles might be prompted to examine their practices.

Regarding implementation and training, Dr. Wooten noted that many states require physicians to receive a certain number of CME credits in pain control. The CDC guidelines should be included in those training areas. The National Association of County and City Health Officials (NACCHO) and Association of State and Territorial Health Officials (ASTHO) are potentially important partners in pushing the guidelines to the local and state levels. Opioid prescribing is a significant issue for the Big Cities Health Coalition (BCHC) as well, and they can help push the guidelines to the 28 cities in their membership. San Diego has a Prescription Drug Task Force. Many other local jurisdictions are likely to have similar groups. San Diego's task force focuses on emergency department (ED) physicians, not just primary care providers. This work incorporates public health emergency rooms, the hospital association, and the physician medical society in creating a campaign targeting ED physicians, providing a toolkit with guidance regarding how to prescribe. She asked about efforts to consider legislation to regulate Internet access to opioids. It is not difficult to get these medications over the Internet.

Dr. Houry noted that the American College of Emergency Physicians (ACEP) and the American Academy of Emergency Medicine (AAEM) endorsed the guidelines. She agreed that the availability of these drugs over the Internet is an important area to pursue.

Dr. Nesbitt encouraged CDC to have direct relationships with state medical boards, either with each board or through the Federation of State Medical Boards (FSMB). Many boards are independent of state health departments and pride themselves on that independence. The relationships between the boards and state health departments in some states may be tenuous, and CDC's funding opportunities may not encourage that relationship-building. When the boards create CME opportunities, there should be a pathway to using CDC's guidelines and materials for training, as opposed to materials that may be available through the marketplace and may not be the most up-to-date or scientifically informed. The medical boards invest a great deal in marketing directly to providers.

Dr. Richardson observed similarities with the blood pressure issue, particularly in initiating conversations with healthcare systems with populations at risk. In this area, the incentives for physicians and healthcare systems might be aligned to allow for rapid implementation of the guidelines. It is not clear whether the guidelines will save health plans or systems as much as blood pressure control in terms of downstream financial cost, but she has been struck by the speed at which systems have been able to implement and standardize various kinds of practice guidelines when financial interests are aligned.

Dr. Fielding commented on the different segments of physicians. Some are surgeons who have been prescribing opioids for 30 days. The Kaiser system in Southern California has reduced its opioid use by approximately 70% among its physicians, who are all fully employed and salaried by the system. Health plans should take a proactive role in integrating the guidelines among the physicians who are part of their plans. He supported the

suggestion to partner with medical boards, which should make the guidelines a priority. The boards are generally understaffed and hear a number of complaints. He suggested focusing not only on the prescriber level, but also on what can be done to prevent overdose deaths. The distribution of naloxone and the passage of Good Samaritan laws are examples of state-level approaches that are important for addicts, partners, and paramedics. Regarding CME credits, he noted that a company has been fined over \$500 million for giving the false impression that opioid drugs are not addictive. California required a certain number of hours in training regarding pain medication, but the training was indicating that the pain medication was being under-prescribed. This experience offers lessons to be learned. Further, the US Food and Drug Administration (FDA) has allowed doubling and quadrupling of doses, which has not helped the situation. The problem is extending into heroin and fentanyl. The efforts should also reach downstream.

Dr. Wooten added that California has a registry for physicians known as the Controlled Substance Utilization Review and Evaluation System (CURES). It is not necessarily an instrument of change, but it does bring transparency to physician prescription practices. The database is not available to the general public, but public health can potentially access it. Perhaps a nationwide registry of physician prescribing practices could be established.

Dr. Fielding noted that physicians should be required to access the registry before prescribing.

Dr. Frieden thanked ACD for the advice. CDC will return to the implementation plan and identify key levers. Broader public education, in addition to earned media, may be of value in order to address the demand as well as the supply side of this problem. He agreed that CMS is an essential partner, and determining how to monitor prescribing in real time with IMS Health and others will be important. The opioid epidemic can be viewed epidemiologically with two population models: 1) people who are currently addicted and dependent need services and care to prevent them from dying or contracting infectious diseases related to their drug use; and 2) everyone else who could become addicted or dependent, who need protection from these dangerous drugs.

## Ethical Considerations for Public Private Partnerships Workgroup Presentation of Recommendations to ACD

Sara Rosenbaum, JD (ACD Member, Ethical Considerations for Public Private Partnerships Workgroup Chair), presented the final recommendations of the Ethical Considerations for Public Private Partnerships Workgroup to ACD. She thanked the workgroup members and Ms. Becky Payne the workgroup's DFO. She reported that CDC Foundation representatives were extremely helpful to the workgroup, and they agreed that the more transparent and collaborative the process and the more aligned the review criteria, the better for all.

The workgroup was established in the spring of 2015 to advise CDC and develop recommendations for ACD to consider in response to the growth of CDC's partnerships and sources of potential gift funding. As these partnerships between CDC and the private sector increase, it is advisable to re-examine the current guidelines regarding the acceptance of gifts to ensure that they are appropriate. CDC has the legal, statutory authority to accept gifts. In a unique arrangement, federal law established the CDC Foundation, which has the singular mission to advance potential partnerships between CDC and the private sector. It exists under its own authority and receives support from CDC, but it operates independently.

When the workgroup's preliminary findings, principles, and recommendations were presented at the October 2015 ACD meeting, ACD provided important feedback, which has been incorporated into the final recommendations.

- There could be a separate gift policy in the case of certain kinds of foundations. For example, existing donors could be grandfathered in, or there could be different standards for different kinds of donors.
  - The workgroup concluded that while it might be possible to expedite the review of certain gifts in certain circumstances, all donors and all proposed gifts should be reviewed. There may be some foundations whose sources of financing do not come from prohibited sources, and nothing about the foundation's proposed gift suggests actual or potential undue influence or impact, but even when the donor appears to be above reproach, it is a wise policy to review any proposed gift and to re-examine existing gifts.
- Consider a list of "no go" donors and sectors.
  - The workgroup concluded that the tobacco industry should always be a prohibited donor source. The group debated the question of whether there should be other absolute prohibitions and is recommending a slightly less conclusive standard for other sources of funding, as there should be heightened scrutiny for certain kinds of funders, but there may be situations in which CDC, for humanitarian purposes, for example, needs additional flexibility.
- Consider case examples.
  - The workgroup considered nine case examples which were drawn from actual cases as well as hypothetical simulations that reflect the kinds of cases that come before CDC. The workgroup discussed situations in which a donor desires early access to data and results. It is noted in the final report that certain Formal Research Collaborative Agreements build early access into the design. The workgroup is concerned about implied access to early results in exchange for funds, a "quid pro quo," not when access is part of the design. The workgroup found that considering the case examples was useful in refining a common list of criteria.

The workgroup utilized basic criteria as well as "Enhanced Scrutiny Factors." The basic criteria are:

- Appropriateness of the gift
- Potential of the gift to damage public trust; the original CDC guidelines refer to "public perception" and the workgroup felt that it is more important to focus on public trust
- The weight of donor benefit against the potential benefit to public health and damage to public trust
- Management that is needed of the gift; every gift should be managed, even one from a known and trusted source
- Whether CDC will maintain autonomy over funds
- Whether any funds come from a forbidden source

The "Enhanced Scrutiny Factors" incorporate issues related to the following questions:

- Is this part of a campaign on the part of the donor?
- Is there a real or implied product or service endorsement by taking this funding?
- Is there a quid pro quo in the context of early access to draft standards?
- Is this funding a harm investigation for which the donor is implicated? The workgroup reviewed a real case example in this instance, in which funds were coming from an entity to investigate itself and its potential harm to individuals and the public.
- Is there early access to data or results, as opposed to a formal project with formal access built in?

- Is there a dominant funder?

The recommendations were driven by several guiding principles:

#### *Public Trust*

- Will acceptance of the gift affect public trust? Almost anything can affect public trust. This point is related to a deliberative, careful approach to the question.

#### *Transparency*

- Written funding priorities should be available for all to see. CDC has a number of public priorities, and certain ones can rise to the surface at any given time and could give way to sudden public health threats that require nimbleness on the part of the agency. CDC can indicate priorities pertaining to gifts and donations.
- A review process should have written criteria and clear stages, including a clear deliberative stage.
- There should be public access to information regarding materials relevant to a particular gift.
- The relationship between CDC and the CDC Foundation should be transparent.

#### *Core Mission (including a transparent agenda regarding donations and gifts)*

- Nimble responses
- Research and investigation
- Health promotion
- Interventions and evaluation
- Professional development
- Standard setting

#### *Accountability*

- Every person who works for CDC is covered by these standards, principles, and recommendations. No personnel are exempt from the process of vetting a potential gift for clearance, acceptance, and management.

The workgroup created recommendations in the following seven areas:

#### *Transparency*

- Management of financial relationships
- Funding priorities
- Project information
- Proactive on website: information is currently available on a website, and it is important to maintain this information over time

#### *Mission Alignment and Outcomes*

- Mission relevance: a gift should always align with CDC priorities
- Projected primary benefits to public health should outweigh potential risks to public trust
- The project should potentially yield substantial, clear, and measurable public benefit and should not primarily benefit the private funder or position the funder to exercise undue influence over any phase of the project

### *Clear Criteria*

- CDC can apply and share these criteria with the CDC Foundation when it comes to deciding whether to enter into a financial relationship and how to manage it
- There should be clear and measurable public benefit to be gained
- Potential for adverse impact on public trust or to create reputational risk
- Degree of private financial interests benefiting, either directly or indirectly
- Management of the relationship

### *Establish a Comprehensive Review Process*

- Clear policies should be communicated to all CDC staff and to the CDC Foundation
- CDC Foundation is an independent, autonomous entity, but it exists to advance CDC interests
- Maintain a Comprehensive Review Process
- The process should apply whether a gift is given to CDC directly or through the CDC Foundation in order to leave no doubt as to the adherence to the recommendations and principles that underlie them.
- Application phase
- Presentation phase
- Deliberation phase
- Written explanation, rationale, terms/conditions for final decision

### *CDC Autonomy in Carrying Out Projects*

- Project control lies with CDC, not the sponsor or donor

### *Excluded Funding Sources and Activities*

- Prohibited categories of funders, such as tobacco corporations or foundations related to tobacco corporations
- Other funders, such as one that is a private interest involved in the manufacture, sale, or distribution of products or services that in CDC's view directly conflict with the agency's mission and do unequivocal harm to the public's health
- A private entity that seeks to fund an investigation into its own conduct and practices
- A funder that seeks to exercise undue influence over the design, management, reporting of results, or the dissemination of findings, and will not agree to modifications that permit CDC to maintain control of all phases of the projects and avoid undue influence, either in fact or in appearance

When the workgroup began this process, it was assumed that they would learn from, build upon, and modify existing ethical standards developed by federal agencies. It is now obvious that CDC is the pioneer in this area. Should the ACD recommend these standards, either in their proposed or modified form, the standards will be a model for all other federal health agencies.

### **Discussion Points**

Judith Monroe, MD, FAAFP (President and Chief Executive Officer (CEO), CDC Foundation), thanked CDC for being a trailblazer in this area. She thanked Ms. Rosenbaum and the workgroup for creating thoughtful, thorough recommendations which the CDC Foundation strongly supports. She assumed her new role at the CDC Foundation on February 1, 2016 and she has a growing appreciation for the complexity of running a nonprofit that is authorized by Congress to support a federal agency. These recommendations are coming at an opportune time. The CDC Foundation operates in a unique space, connecting CDC with individual and

philanthropic organizations and private business. It is the foundation's honor and privilege to support CDC. The foundation is helping with the responses to Zika and Ebola, as well as with CDC's other priorities.

Dr. Iton commended the workgroup for the clear, cogent work and he anticipates that the recommendations will serve as a model for other organizations and agencies that encounter similar balances. His organization has experienced a similar issue. They were vetting an organization using a set of screens. The organization, a foodservice conglomerate, has multiple heads including private, for-profit prisons. His organization conducted research to determine all of the entity's activities and interests. Regarding the recommendations, he wondered about a moment in which CDC can engage in due diligence activities pertaining to the entity that is proposing a gift in order to discover relationships that may not be obvious, and that may be surprising.

Ms. Rosenbaum said that this question was a significant part of the workgroup's discussion. The starting point for accepting a gift is understanding the donor. Understanding who the donor is, is often very difficult. For instance, an entity could be a corporate "shield" or "umbrella" for many things that may have actual or perceived influence on the behavior of the corporate entity that is proposing the gift. It is important to unpack the legal status of donors. This point arose in the context of corporations and of foundations, which can be strong affiliates of corporate entities. The point weighed heavily in the workgroup's thinking regarding the need for absolute alignment between the CDC Foundation and CDC. Since the Foundation exists to develop these relationships, bring funding, and help CDC manage funds, the due diligence may be done by CDC or by the Foundation.

Rebecca L. Payne, MPH (Deputy Chief of Staff, CDC; DFO, Ethical Considerations for Public Private Partnerships Workgroup), added that CDC conducts research on potential donors but as public health professionals, they are not necessarily trained in the expertise needed to do this kind of research. They have begun to develop more capacity and identified resources to help CDC staff. Principal Investigators (PIs) are expected to have responsibility for understanding with whom they enter into relationships. CDC is also considering the space between the "handoff" from the CDC Foundation and their research, which is their strength, and what they are able to share. CDC is already positioning itself to consider how the reviews are conducted by the agency and to determine whether the agency has sufficient staff expertise, especially in the case of direct gifts which the Foundation cannot help research. Staff need the training, resources, and ability to find help to get the necessary information. CDC asks a number of questions during the review process with PIs that assess the secondary and tertiary relationships; that is, the funder that's funding the funder.

Ms. Rosenbaum added that this due diligence process is assumed to take place in the development of the proposal, whether the proposal is presented through the CDC Foundation or directly to CDC. The proposal vetting process includes not only what the funder wants to do and the techniques for managing the award, but also a deliberation of who the funder is and whether the funder is a nominally and unpacked one that meets CDC standards. She observed that 95% of the review process focuses on the funding source, where the greatest implications for reputational risk and threats to public trust emerge. Funders may try to exercise undue influence in ways that are important to understand. Understanding who the funder is, is part and parcel of the proposal.

Dr. Iton suggested that the due diligence process should be as explicit as possible.

Dr. Elias said that the new recommendations will significantly impact donors, such as the Bill and Melinda Gates Foundation for whom he works. He will look to CDC for guidance regarding how their support might be impacted. The policy is important and has been an important set of work. In the appendix to the report, he noted that the case reviews include as an example the Gates Foundation support of the rotavirus program. The report indicates concern regarding the use of donor funds to support research in which the CDC research staff and the agency have a proprietary interest, as well as the magnitude of the funds. He asked how magnitude of support figures into the review criteria. He also wondered about the issues of data access and autonomy. In its partnerships with CDC and other organizations, such as WHO and the United Nations Children's Fund (UNICEF), the Gates Foundation has negotiated specific data sharing agreements in work related to polio as well as Ebola. Because of its unique role, CDC is often the supplier of important data for more sophisticated modeling and analyses. The GWG meeting the previous day included a presentation from the Malaria Team that referred to work supported by the Gates Foundation to model malaria to help target interventions. The presentation noted that CDC is often the supplier of the data for the modeling, as well as the consumer of the outputs of the models. The Gates Foundation often enters into complex alliances and consortia for important public health roles such as polio eradication, Ebola response, and malaria elimination. CDC and other entities are often in a position, through laboratory networks and other relationships, in which they have critical data for input into complex analytics that need to drive the most effective global initiatives, of which CDC is usually a critical partner, but not an autonomous agent. The proposed recommendations give CDC the flexibility to proceed as it has in this capacity. He said he hoped that CDC and the workgroup considered the complexities of some of these relationships. CDC, the Gates Foundation, and other entities often are part of complex partnerships to achieve global public health goals. The partnerships may involve the transfer of resources among partners. He did not see any restrictions to these relationships in the proposed recommendations, but he hoped to assure that CDC's hands would not be tied in these complex research and programmatic collaborations.

Ms. Rosenbaum replied that heightened scrutiny is warranted when a funder becomes dominant. There is a "50% trigger." The point regarding data and resource sharing in complex partnerships is related to the difference between a behind the scenes quid pro quo expectation versus a research design in which it is understood that there is a data gathering phase, during which information may be available across a constellation of actors involved in a joint enterprise. There is then an analytic phase, which may also involve a collaboration among partners. It is important that when there are joint undertakings, which are assumed in the context of partnerships, that they should be clearly thought through and articulated in the project management so that all partners understand the partnering arrangement and that it is understood that even if a donor supports the bulk of a project, it is not the donor's project, but CDC's project in partnership with the donor. This clarity is as much to protect the partner as it is to protect CDC.

Regarding the magnitude of the gift, Ms. Payne said that no thresholds were established. Rather, the point relates to ensuring that there is explicit awareness. The idea applies to single gifts and also to the review of all gifts from a source, keeping a rolling total of gifts across multiple different projects and centers, institutes, and offices (CIOs) across CDC. The agency is grateful to have repeat customers, which speaks to CDC as a steward of funds. Donors enjoy partnering with CDC and see good impact and benefit, so they return. CDC should be ready to maintain the integrity of its projects.

Dr. Bal commented that the recommendations are an outstanding document and can serve as a model for local health departments and others, as well as federal entities. He recalled his experience with these issues when he was with the American Cancer Society (ACS). The proposed criteria mainly address situations in which donated resources will be used for scientific purposes, and perhaps for program purposes. Humanitarian enterprises, it is noted in the recommendations, may be considered with a different, charitable eye. He asked for further discussion of this concept. When partnerships seem explicit, depending on the donor, they can become implicit in some ways. This “slippery slope” should be considered. Further, it is not CDC’s intention to co-brand with donors and partners; however, some partners, particularly “bad actors,” may co-brand anyway with an “innocence by association strategy” that was utilized by the tobacco industry. The food industry and others, such as pesticide manufacturers, may utilize this strategy. Regarding public benefit versus the violation of public trust, he noted that these issues are ephemeral and difficult to quantify. Public benefit may be defined somewhat precisely, but the violation of public trust is determined by a slew of factors. Dr. Bal reminded them that CDC is “hallowed ground.” CDC and ACS have the highest brands in their sectors. People tend to have a poor view of government, but CDC’s brand is valued. It is important for CDC to have outside support and funders, but the brand should be guarded. There are overt issues as well as covert issues to consider. The more noble the project, the more carefully they have to watch it.

Ms. Rosenbaum said that the process of creating the recommendations was complicated not only because of the question of a hallowed institution such as CDC partnering with private interests, but also because of the official statutory expectation that CDC will have these partnerships. Congress established a legislative intermediary, the CDC Foundation, to develop these partnerships affirmatively. Lawmakers have therefore decided that these relationships are in the public interest, and the partnerships have produced incredible good. Laws have unintended consequences, however, and it is possible for a partnership not to do what it was intended to do, and not to do good. The workgroup was concerned not only about CDC receiving gifts, but also about ensuring that the gift is managed throughout the process and that there is complete understanding before the gift becomes realized. The management plan minimizes the potential for a breach of public trust and maximizes the beneficial elements that the law was designed to foster.

Dr. Bal noted that the Congress that created the CDC Foundation is the same Congress that does not give CDC more funds to support its priorities. This mechanism of the Foundation was created as part of the idea that the private sector will support this work. It would seem that Congress would derive enjoyment from “hoisting you on the petard they themselves set up.” They should always exercise caution: *caveat emptor*.

Dr. Richardson asked whether the guidelines only apply to monetary gifts. He observed that the document does not refer to gifts of services or personnel, and these issues should be explicitly defined.

Ms. Rosenbaum said that the recommendations refer to any consideration, whether it is cash, in-kind donations, or other examples. One of the case examples included in-kind donations as well as cash. It should be unequivocal that the recommendations refer to any consideration.

Dr. Wooten added that equipment is another important consideration. Ms. Rosenbaum added personnel and discounts, emphasizing that the recommendations should be very clear that they refer to the term “consideration” in its fullest meaning.

Dr. Goldman served on this workgroup and noted that it was an extremely complicated situation, particularly because of the statutory relationship between the CDC Foundation and CDC. It was worth the time and effort to elaborate recommendations and guidelines that could be used. If the reviews address all of the issues raised in the recommendations, it is unlikely that CDC will be in an embarrassing situation. The recommendations give CDC the ability to turn down gifts and offers when proposed work is not well-aligned with the agency's mission. Managing projects requires time and effort, and the capacity to turn down gifts that are not critical is important.

Dr. Fleming summarized the ACD's comments:

- It was suggested that language related to the process of reviewing the funders should be reviewed to ensure that it is appropriate. This due diligence is imbedded in the intent of the document, but the language should affirm it.
- The language pertaining to the definition of "magnitude" should be reviewed.
- ACD cautions that as good as this document is, there should be continued attention given to the risks involved with accepting gifts.

Dr. Fleming asked if any ACD member felt unprepared to vote on the current document, based on the proposed modest revision. Hearing no such sentiment, he called the question for a vote on report and recommendations from the Ethical Considerations for Public Private Partnerships Workgroup.

### Motion / Vote

It was moved and seconded to adopt the report and recommendations from the Ethical Considerations for Public Private Partnerships Workgroup. The motion carried unanimously, with Dr. Elias and Dr. Iton recusing themselves.

### Director's Observations

Dr. Frieden thanked Ms. Rosenbaum and the workgroup for their superb work. This issue is one of the most theoretically challenging issues that he has faced as CDC Director. When some offers are made to CDC, the agency must choose between doing something that will help people and not doing something because of concern about undermining public trust. There can be middle ground. The CDC Foundation will not likely be affected significantly by the recommendations. In the eagerness to fund worthwhile programs, he was becoming uneasy about some of the directions that were being pursued. The recommendations and report are enormously helpful. The application of the guidelines will not be simple, however. He offered the example of hypertension and programs to increase global treatments of it. Hypertension is the most neglected disease in the world and is second only to tobacco in causes of death, with nine million global deaths reported per year. The global control rate of hypertension is only 13% to 14%, even with medicines that cost very little. Even so, if drug companies were to fund hypertension control efforts, the situation would be uncomfortable. He thanked the CDC Foundation for helping CDC "do more, faster." The Foundation raised more than \$56 million during the Ebola response. Those dollars were crucial for CDC and allowed the agency to work with unparalleled speed and flexibility that were lifesaving. The Foundation has continued to respond to Ebola and is rising to support the Zika response. When Dr. Frieden became Commissioner in New York City, he established the Fund for Public Health in New York to allow an interface with the philanthropic and private sectors, providing more flexibility and a means for working legitimately to help the "creaky government bureaucracies function better." He has advocated for the creation of fiscal intermediary organizations for state and local health departments. Some states allow these organizations, and others do not. In New York City, the health department was audited by

the US Government Accountability Office (GAO) because they wanted to know how New York City was the only jurisdiction that had spent money well and quickly. Regarding Dr. Elias's comments on data, Dr. Frieden reflected on how the world is changing with respect to the funding of health programs, with public, private, for-profit, not-for-profit, individual, and patient-owned entities. The world is also changing with respect to data. Last year's Langmuir Lecture speaker was Jeff Dean, PhD. As a high school student, Dr. Dean wrote Epi Info, which became the language of public health for a generation. He then became a legend in the world of informatics, designing important elements of Google. His thoughtful talk incorporated the importance of liberating data and sharing it so that people can work on it and connect it. Anyone who has researched a rare medical condition has wondered why text-searchable data from all medical literature from the last century is not available. Modern public health seeks to identify and establish boundaries for collaboration, opening access to information.

## State, Tribal, Local, and Territorial Subcommittee Update and Discussion

John Auerbach, MBA (Associate Director for Policy; Acting Director, Office for State, Tribal, Local, and Territorial Support, CDC; DFO, State, Tribal, Local, and Territorial Subcommittee), and Wilma J. Wooten, MD, MPH (ACD Member; Member, State, Tribal, Local, and Territorial Subcommittee) shared updates from the STLT Subcommittee.

Mr. Auerbach reminded ACD that the work of the STLT Subcommittee assists CDC with many different issues that arise for CDC's partners. The Subcommittee structure allows for a great deal of work to take place through the following Think Tanks:

- Social Determinants of Health (SDOH)
- Public Health Finance
- Surveillance

He thanked Dr. Fleming, chair of the STLT Subcommittee, CDC staff who support the group's work, and the Subcommittee members from ACD. The two newest members of the STLT Subcommittee from ACD are Dr. LaQuandra Sherese Nesbitt and Dr. Wilma Wooten.

### ***SDOH Think Tank***

This Think Tank focuses on the major objective of enhancing the capacity of CDC and its public health partners to identify and address SDOH as a part of public health's ongoing work. The Think Tank has identified the long-term goal of making this work a natural part of the way that public health functions. The group has developed a set of questions that will assist public health departments in considering the work that they should be doing regarding SDOH. The trajectory of questions incorporates gaps in resources, an understanding of technical assistance (TA) needs, and the ability of CDC to collaborate. The questions begin with a determination of a public health department's commitment and readiness to engage SDOH through the necessary tools and resources.

The Think Tank has developed materials. In the fall of 2015, a website was launched in response to recommendations from ACD. The website provides a one-stop shop of materials on SDOH. It provides easy access to data sources that reflect SDOH, guidance for moving from data to action, programs at CDC that incorporate SDOH and their ongoing work, and resources to identify policies that affect SDOH and the likely resulting health outcomes. The website also includes case studies.

The group is now developing a resource to reinforce to partners the connection of the incorporation of a SDOH approach into core public health. The materials link the 10 essential public health services to necessary SDOH work. The goal is to emphasize that SDOH is not a separate activity, but is part of the “DNA” of public health. Other tools will be developed for partners, including highlighting policies with a SDOH orientation for which there is clear evidence of positive health and cost impact within a discrete amount of time.

### ***Public Health Finance Think Tank***

This Think Tank focuses on key issues associated with the financing of public health, particularly issues that represent significant challenges or opportunities. ACD approved two recommendations in this area in the past which are to: 1) improve the accountability and transparency of the Prevention Health and Health Services Block Grant, and 2) assess the factors and strategies to support the financing of “foundational capabilities.”

In the coming year, this Think Tank will focus on a range of issues, including the need for a permanent Emergency Fund to be drawn upon on an interim basis in emergencies. In addition, the group will consider issues related to flexibility and the use of categorical funding, linking funding to health equity, support for tribal health, and funding that can be useful in terms of partners seeking accreditation.

### ***Public Health Surveillance Think Tank***

In October 2015, ACD adopted the recommendation that by mid-2016, CDC should convene appropriate partners to develop recommendations for a national strategy for electronic case reporting (eCR). Dr. Wooten presented a progress report on this effort. Case reporting is a fundamental component of disease surveillance. While many jurisdictions have electronic reporting, many still utilize paper-based reporting, presenting substantial limitations regarding the timeliness and completeness of data. Paper-based reporting also represents a burden on both clinical reporters and health agencies. The development of EHRs is moving ahead rapidly and has been defined largely by healthcare delivery systems working with health information technology (IT) developers.

eCR is defined as the generation and electronic transmission of reports of potential cases of reportable conditions from the EHR to relevant state and local public health jurisdictions for review and action. There is widely-recognized need for what EHRs could do, including:

- Providing more complete and accurate real-time case data
- Earlier detection of cases
- Improved detection of outbreaks
- Enhanced infrastructure that can respond to newly recognized and emerging conditions

The subcommittee proposes a shared vision for the eCR framework, which is:

*A nationally interoperable system for eCR that allows for timely reporting to public health and sharing of information between jurisdictions.*

The framework is intended to:

- Foster interoperability
- Limit the burden of reporting for EHR developers and healthcare deliverers
- Address jurisdictional needs of STLT health departments
- Establish governance structure and processes that foster the evolution and improvement of eCR function over time

The framework requires openness to change in current public health approaches. There is a planned meeting in Chicago to discuss a vision for eCR, create shared governance, and determine initial steps for eCR implementation. The meeting, convened by the Robert Wood Johnson Foundation (RWJF), will be held June 13–15, 2016. Attendees will include leaders from health IT, healthcare organizations, and public health.

The subcommittee generated two proposals:

***Proposal 1a: Governance for eCRs***

CDC should support development of a governance entity for a nationally interoperable system for eCR. CDC should commit to working with partners in STLT public health, healthcare, and health IT developers under such a governance. The goals of this eCR governance entity are to provide for:

- Secure sharing of reports of potential cases between platforms and jurisdictions
- Ensure the regular, periodic evolution of standards, tools, and processes to enhance eCR performance and efficiency
- Meeting the case reporting and information needs of both healthcare providers and all governmental public health agencies, including CDC

***Proposal 1b: Public Health Adaptation to EHR Standards***

To successfully implement the eCR framework, CDC supports the notion that public health programs will need to adapt to standards that are widely adopted by healthcare in EHRs. Therefore:

- Changes in standards will need to be made by the governance entity rather than by individual programs, creating consistency
- Disease-specific programs should not work independently with vendors to develop their own IT programs for data collection, as such arrangements will be counterproductive to the overall effort and its intent
- State and CDC program standards for data collection from EHRs, including surveillance, should evolve to be consistent with this new way of doing business

## Discussion Points

Chesley Richards, MD, MPH, FACP (Deputy Director for Public Health Scientific Services; Director, Office of Public Health Scientific Services, CDC) thanked Dr. Wooten and looked forward to ACD's feedback regarding the two proposals. There has been a consistent refrain from state and local health departments, as well as from EHR vendors, that variability in this space is creating problems for making progress. There needs to be a means, from the clinical community and from the EHR vendor perspective, to create standards for sharing data. There has been a productive start to this effort, RWJF has been a strong partner, and it is important to take big steps quickly and in an organized fashion.

Dr. Fleming noted that some local public health departments take some pride in being independent of each other. This issue of data-sharing is important and is a game-changer because historically, local, state, and federal programs have not necessarily had similar or compatible information architecture, and it has been difficult to exchange information. As the healthcare system is developing its own way of exchanging information, the problem has become compounded. The STLT Subcommittee is proposing a strategy to create a single governance mechanism, with standards that all can live by, with a commitment from CDC to work within that governance.

Dr. Richards added that this work is a process. The proposals are asking ACD to validate the process. Further, Meaningful Use 2018 includes case reporting as a mandatory requirement for clinical providers. He emphasized that they do not want to be in a position in 2018 in which these providers seek waiver requests from CMS because the reporting cannot be implemented.

Dr. Iton commended the Subcommittee on this work. He related an experience in California, with mandatory reports being the responsibility of the provider, but not necessarily on the health system. The Health Insurance Portability and Accountability Act (HIPAA) does not govern at the state level. If a state has a more stringent standard for medical privacy, the state law governs. California state law had to be rewritten to access surveillance data from the health system, as opposed to from health providers. He asked whether the Subcommittee has discussed the legal architecture that may create impediments to these reporting systems being directly established between the health systems and public health agencies.

Dr. Richards said that the Subcommittee has discussed these issues, but there is more deliberative work to be done. These issues vary by jurisdiction. In talks with clinical systems and with EHR vendors, there are advantages to think about how systems will put reports forward.

Regarding legal vetting, Ms. Rosenbaum said that a state could have a more stringent standard that would bar reporting certain information without patient consent. Increasingly, however, states are moving toward modification of the legal standard to recognize the importance of public health reporting, assuming that security safeguards are in place. On this point, she recommended consultation with experts on the legal aspects of a uniform health information system. Further, she noted that recently, the Supreme Court overturned state-based reporting systems for quality and claims data as those systems related to insurers and health plans. The decision was stunning and has enormous significance, particularly for all-payer rate-setting issues. The US Department of Labor (DoL) must develop national standards for a uniform claims data reporting system. It is worthwhile to learn about DoL's progress, as they are setting standards for national claims data reporting, and CDC is setting standards for surveillance. To the extent possible, it would be helpful to bring the standards into alignment. All of these efforts will be affected by the same HIPAA and preemptive state law issues.

Dr. Wooten noted that from state-to-state, there are legislative mandates in place regarding what should be reported by clinicians to health departments. This effort focuses on a mechanism for how those reports are made. She was glad that CDC is entertaining this thought, because it could make the process for identifying outbreaks easier, more efficient, and timelier.

Dr. Fleming noted that in its current state, the process would not create a uniform, mandatory list of reportable conditions across states; rather, it would recognize that each state has such a list, and they differ. This process focuses on standardizing the electronic mechanisms by which the information is reported so that providers in multiple jurisdictions are not navigating different systems for reporting.

Dr. Richardson commended the Subcommittee for taking on this complex and important issue. In addition to the Meaningful Use framework that is rolling out and the issues with claims data, a spate of clinical registries are sprouting up in almost every specialty, including emergency medicine, which could be relevant to this kind of surveillance, to address the mandatory Physician Quality Reporting System (PQRS) requirements from CMS. There may be opportunities for synergy, as those clinical registries are being built to incorporate and capture all of the data elements needed in eCR. These registries could be a source for surveillance, or at least providers could use the same interface to report to public health departments for eCR. The more that these initiatives can be aligned so that they can leverage work being done in other sectors, the more likely there will be progress. The mandatory PQRS reporting has already begun and first-year penalties have been levied. Many practices are scrambling to report to CMS.

Dr. Fielding supported the proposals. There are many questions regarding how medical care interfaces with public health, and this effort clearly at that nexus. It is important for public health to be proactive, strong, and to assert leadership. As issues of disease reporting and EHRs are considered, it might be helpful to consider how medical records can provide information on SDOH and well-being.

Dr. Elias commented that this work is great and important. In the move toward implementation, he urged them to pay attention to data security and cybersecurity issues. This work will likely include entities with weak and under-funded health information systems. Early data or privacy breaches could set the entire enterprise back.

Dr. Goldman asked about the scope that is envisioned for this effort and whether the scope might extend beyond communicable diseases. For example, some states report on opioid overdoses and pesticide illness reporting systems. Could chronic diseases be reportable through a system like this, and conditions such as hypertension? It is important to think through the scope of the system, as the scope will affect the variables and data elements that are collected and reported.

Dr. Richards answered that they are taking “fast baby steps” toward larger issues. This baby step of eCR focuses on electronic, probably notifiable diseases, from local clinicians, health systems, and EHRs to a local health department, not to CDC. This work is in response to Meaningful Use. Clinical systems, EHR vendors, and states have a world of other data that will be useful to public health. Making quick progress with this eCR work will bring credibility to address other areas. Further, there is a movement with quality reporting, patient-centered outcomes research, and a variety of other areas that are yielding common data models in clinical care and EHR systems, and standardization of data elements. Public health must be able to take as much as possible from the standard data model and identify public health information gaps to focus primary data collection in those areas.

### Motion / Vote

Dr. Fleming entertained a motion for adoption of the two proposals from the STLT Subcommittee. The motion was made by Dr. Fielding and seconded by Dr. Iton. The motion carried unanimously, with no abstentions.

## Flint Update and Discussion

Patrick N. Breyse, PhD, CIH (Director, National Center for Environmental Health / Agency for Toxic Substance and Disease Registry) joined CDC in early 2015. He has been energized by the opportunity to help a large number of people at an unprecedented level across the entire City of Flint, Michigan as part of a broader governmental response.

There are many aspects to the lead problem in Flint, Michigan. The situation is a water quality problem, an infrastructure problem, and an environmental justice problem. There are political and criminal justice issues as well. The community is angry at many levels, and the lead issue is part of a broader environmental justice problem in places like Flint. Each of these dimensions affects work in Michigan. Environmental health professionals in Flint feel like they are under investigation creating barriers, in some cases to the free flow of information.

As a cost-saving measure, the city of Flint, Michigan switched from the Detroit drinking water system to a separate system coming from the Flint River in April 2014. In the summer of 2015, the lead problem came to light when investigators from a local hospital and Virginia Tech University discovered elevated lead levels in the water and in children in the city. In October 2015, the city returned to Detroit drinking water. The system is still recovering today. An emergency was declared by the state in December 2015, and the federal emergency response was initiated in January 2016. CDC stood up its EOC to support the Unified Command Group at the federal level in February 2016.

The four main US government objectives in Flint are:

- Federal Emergency Management Agency (FEMA): Immediate access to safe water. It was clear that people could not drink, cook with, or bathe in the water. The federal government has provided access to bottled water for this city of nearly 100,000 people for a long period of time.
- EPA: Ensure the long-term safety of the water supply.
- US Department of Health and Human Services (HHS) and Unified Command Group: Address immediate needs regarding health.
- HHS and Unified Command Group: Address community resilience and issues with long-term follow-up in the community.

CDC's response is a joint effort of the National Center for Environmental Health (NCEH), the National Center for Immunizations and Respiratory Diseases (NCIRD), and Agency for Toxic Substance and Disease Registry (ATSDR). The CDC response has included:

- Providing guidance and a plan for monitoring children with elevated blood lead levels
- Identifying community members and linking them to case management
- Coordinating health messaging among multiple federal agencies, state and local agencies, and local nonprofit groups for unified, clear messaging
- Assessing chemical exposure on the community, including persistent concerns about rashes, skin conditions, hair loss, and other health effects that might be associated with use of the water
- Addressing the risk of Legionnaire's Disease and increased *E. coli* in the water, and developing a water management toolkit to reduce *Legionella* growth and spread in buildings
- Identifying long-term community needs

CDC/ATSDR deployed the first staff to Flint in mid-January 2016, shortly after the federal emergency response was announced. Over 125 CDC/ATSDR staff have provided leadership and support in Flint since that time. Currently, three staff are in the field. Three task forces were established to address the problem:

- Assessment of chemical exposure (ACE), which includes visiting homes to report rashes and skin conditions, referring individuals to dermatologists
- Water quality, which includes assessment of water contamination beyond typical sampling
- Case management for children with elevated blood lead levels

Over 360 individuals reporting rashes have been visited, and over 200 have been referred to dermatologists. These data are being analyzed and a report will be published regarding the likelihood that rashes and skin conditions are due to the water. This point is important, as a nonprofit group came into the city of Flint and, with a limited amount of data, declared that the water was unsuitable for bathing. To date, there is no evidence to suggest that bathing is not appropriate for the people living in Flint.

CDC/ATSDR recommended that all children less than six years of age receive a blood lead test after the City of Flint returned to Detroit water. As of April 2016, 70% of children in Flint received that testing. Of families with elevated blood lead levels (BLLs) (defined as a child with levels of greater than 5 mcg/dcl), 88% have been contacted and offered case management. These families must be visited in a timely manner to begin case management.

ATSDR is in the process of planning a Community Assessment for Public Health Emergency Response (CASPER) to consider mental health issues in the City of Flint. There is a great deal of stress and worry in this community. It is not clear whether the water can even be used for recreational purposes, and a hot summer is approaching. ATSDR has attended multiple public meetings and provided support for 107 communication products. Additionally, 12 congressional briefings have been conducted about the situation in Flint and also about larger concerns regarding the crumbling water infrastructure. ATSDR responded to more than a dozen written requests for information and TA from congressional offices.

There are several challenges and opportunities associated with ongoing work in Flint, including the following:

- *Environmental Health Infrastructure and Surveillance:* The state of the water infrastructure is a challenge, lead service lines remain a source of potential lead exposure
- *Risk Communications:* Communication is a struggle, because the communities are angry and messages are complex.
- *Long-Term Monitoring:* A complete picture of the blood level profile across all affected children in the city is not available. ATSDR is in the process of evaluating available data to consider evidence about the water levels, the presence of lead service lines, and modeling blood levels to create categories of potential lead exposure. Little data are available from the year in which the water came from the Flint River, before the system returned to Detroit water. These issues will inform long-term monitoring.

Future considerations incorporate a national view. The Flint problem has shone a light on the problems with water infrastructure in the US. ATSDR is receiving calls from numerous communities across the country expressing concern about their lead levels. Water is being considered as a route of lead exposure in a new way. Currently, less is known about conditions under which water is a key contributor to children's elevated blood lead levels.

The lead surveillance system is being re-evaluated to ensure that it is more robust and provides more timely and sensitive data so that situations such as the one in Flint can be addressed proactively rather than reactively. CDC and ATSDR are working with EPA regarding their Lead and Copper Rule, which is used by local water environmental groups to assess compliance with EPA regulations for lead in water. The revised rule should include the expectation of work with environmental health groups. .

Dr. Breyse thanked Dr. Frieden and CDC for standing up the EOC, which supported the management of the beginning of the complex federal response. He further thanked staff at CDC and ATSDR, noting that the Flint response was truly a centralized, CDC-wide effort.

### Discussion Points

Dr. Farley asked how the problem in Flint compares to other jurisdictions, and about data on children with elevated BLLs. Different reports use different numerators and denominators.

Dr. Breyse indicated that the surveillance data that are collected by CDC cannot be used to compare cities. Currently, the denominator is "number of the kids tested." The data can show in a given city how many children have BLLs above 5 mcg/dcl. While universal blood lead testing is expected for children on Medicaid, for

example, that testing is not always comprehensive. It is known, however, that there was a roughly two-fold increase in children with elevated BLLs in Flint based on the surveillance. There is not a great deal of data available on children from the ages of 0 to 1 year, when the lead levels are the most hazardous.

Dr. Fleming asked about the level of confidence that there are not other Flints now that have not realized their situation.

Dr. Breyse replied that he is not confident that there are no other communities in similar situations; in fact, it is likely that there are cities like this. Small changes in water chemistry can have profound effects on the quality of the water. It is not clearly understood how widespread this problem is.

Dr. Fleming wondered about proactive steps that should be taken to encourage localities to assess whether they have the same problem.

Dr. Breyse said that CDC/ATSDR is considering changes to its lead surveillance case management guidelines to include assessing water when Lead and Copper Rule violations are identified and when lead service lines are identified. Targeted risk communication could also be provided so that people understand that flushing tap water after long periods of un-use can minimize lead contamination.

Dr. Goldman observed that there are problems with the way that the Lead and Copper Rule relies on a proportion of samples that are over the "action level." Some communities respond by collecting more samples to bring the proportion down. The rule should be reconsidered, but there is no science behind the strategy that is used to collect the samples at the taps. She applauded CDC and ATSDR's work and expressed concern that there could be more cities like Flint. She has heard many calls about schools and she wondered if NCEH and ATSDR are also fielding other lead and water-related issues.

Dr. Breyse answered that CDC/ATSDR is also receiving calls about schools. Traditionally, schools address lead problems by shutting down the water fountains and providing bottled water to children. This fix is not long-term, and many school districts are considering replacing plumbing to make the water more drinkable. EPA is in the process of reevaluating the Lead and Copper Rule, which has come under a great deal of scrutiny. It is a regulatory rule, and CDC plays an advisory role in these situations. EPA is aware of concerns regarding how the rule is being implemented.

Dr. Iton asked about a date after which lead service lines or lead solder was no longer used in plumbing, or whether these materials are still being used today.

Dr. Breyse said that lead services lines are not being used today. He did not believe that lead solder is used. They have a sense of the periods of time when water distribution systems are at risk for having lead service lines and/or lead solder. Lead solder applies to all aspects of a house's water plumbing situation, so it could be a factor as long as a house stands, presenting a long-term challenge.

## Global Workgroup Update and Discussion

Thomas Farley, MD, MPH (ACD Member; Chair, Global Workgroup), described the previous day's GWG meeting, which included presentations from CDC staff. GWG includes representation from ACD as well as experts from around the world. The discussion was rich and did not result in formal recommendations, but several important points were raised.

Dr. Martin provided an overview of activities at CGH, including GHSA and work in child mortality surveillance, malaria and filariasis, polio eradication, the National Action Plan for Multidrug-Resistant Tuberculosis (MDR-TB), and YF. Discussion was in-depth regarding the GHS Country Assessments, malaria research, and Zika.

Several issues were raised by GWG members that cut across these topic areas:

- CGH handles an impressive variety of important issues.
- Ebola funds are being rechanneled to address Zika, and there was concern regarding the potential loss of GHSA funding over time. It is important to communicate that support is needed for both as well as for global public health infrastructure for outbreak recognition and response and crisis response to problems of global significance. Money should not be removed from one area to support another.
- There was a common theme in the discussions of malaria, tuberculosis (TB), and Zika: biomedical and public health tools are available to fight these infectious diseases, but the tools are limited. There should be responses to these health problems, but at the same time, research should be conducted to develop better tools. That research should inform programs as the programs inform research questions. CDC does an excellent job in this area, but the work should be maintained and communicated.
- Control of these problems and the implementation of programs tend to be local. Local community involvement in health promotion is essential for long-term success. This aspect of the work should be considered as global health crises are addressed.
- GWG noted the increasing interplay between NCDs and infectious disease problems, such as diabetes increasing the risk of TB and influenza. Diabetes is a global epidemic in its own right, and these intersections will be seen more and more, presenting challenges as well as opportunities.
- The group discussed how CDC and CGH can be better prepared and funded in the future to address global crises such as Zika and Ebola. It was suggested that CDC communicate to the new administration and the US government a package of ideas to include both comprehensive infrastructure and response capabilities. With climate change disrupting ecosystems, more global events can be expected in the future than in the past. Packaging and branding these initiatives could present an exciting initiative for the new administration to take on, not unlike the “cancer moon shot.”

It is exciting that the GHS Assessments are moving forward. The quantitative and concrete nature of the assessments is important for advocacy. GWG noted that countries may be afraid of public reporting of their deficiencies in preparedness; however, public reporting is important or the system will not work. The balance of these needs will be difficult so that organizations can address priorities. When countries conduct these assessments, funding can be brought to bear to improve deficiencies. This step will help allay countries’ concerns and increase their enthusiasm for participating in the process. There was concern about the governance of this system, and GWG discussed concerns regarding housing the governance at WHO.

Regarding Zika, in the short-term, prevention will not succeed to the extent that no more babies with birth defects will be born. It would be unfortunate if CDC is blamed in the future for not preventing the problem. Prevention tools and knowledge are limited, so there will be short-term failures. Communicating these facts may help protect CDC from being unfairly criticized in the future. GWG suggested studying locations where Zika is endemic or that have experienced past epidemics, given that little is understood about the virus and its immunology. Does it “burn out” after one season? Do individuals develop lifelong immunity? Is there benefit to being infected in childhood to avoid new infections during pregnancy?

## Discussion Points

Dr. Frieden asked for ACD's help in thinking of pathways, criteria, or models that can be helpful in pursuing the GHS Assessments. CDC and the US government have to work with WHO and strengthen WHO so that this initiative will not fail. WHO has important strengths and many good people. Advice is welcome on all issues related to CDC's global portfolio. He offered an apology that he would need to leave the meeting in approximately 10 minutes due to an unavoidable commitment. He thanked ACD for their input throughout the day. There have been many examples of how ACD has strengthened CDC so that the agency can protect the country and the world better.

Dr. Elias said that WHO is in the midst of reform. The United Nations (UN) has commissioned three separate reports to understand what did not work in the response to the Ebola outbreak, including the late detection of the problem and the failures at the country, regional, systemic, and global levels. The leadership of WHO is trying to incorporate those recommendations, which have consistently called for broader oversight of the organization's response capabilities. There is counter-pressure from the World Health Assembly (WHA) not to make many changes to WHO. Currently, the governance is exclusively driven by member states. Recently, the Director General appointed an Oversight Committee for the new Office of Health Emergencies (OHE). That committee represents little broadening of the governance. It includes representation from five governments, including the US, which is represented by the head of the Office of Foreign Disaster Assistance (OFDA). It does not represent a strong change. The GWG discussed the tremendous effort that CDC devoted to developing the Joint External Evaluation (JEE) process, which is moving forward in 17 countries with roadmap planning under the first phase of GHSA. There is now a broad alliance among the US, Finland, South Africa, and other countries participating in the GHSA. The initial assumption is that the Secretariat will reside at WHO within the new OHE. An advisory committee will advise the program and will not report to the new oversight committee or the WHO Executive Board. The mechanism does not appear to be strong. In the case of polio, the Polio Oversight Board (POB) was created five years ago to fix the governance, which was not working. If an entity like the POB will be needed someday in regard to GHSA, it should be designed from the beginning of the process. The accountability for program strategies, finance, and other issues that was put into place over the past five years for the Polio Initiative has made a difference in the success and progress of polio programs. Such a mechanism should be created for GHSA now, rather than waiting until the current governance does not work and requires fixing later.

Dr. Frieden said that the POB incorporated a pre-existing coalition of five spearheading partners. It also created an Independent Monitoring Board (IMB) report that drew an intentionally uninterpretable table illustrating how obtuse the governance process had been. If those lessons will be built on for a GHSA infrastructure, an equivalent to the spearheading partners will be needed to serve as key stakeholders, including WHO and perhaps CDC, Finland, other countries, and foundations.

Dr. Elias replied that the membership that Dr. Frieden described is what many hoped would come out of the reform recommendations for WHO so that there will be broader, more robust oversight of health emergency response, if not the entire organization. The current approach clearly did not work in the case of Ebola and has not worked in a number of other places. Had the Director General appointed an oversight group for the health emergencies cluster that had a strong coalition of engaged partners in health emergencies, additional strategies would not be needed. So far, it appears to be business as usual. Discussions now focus on the need for an IMB or IMB-like structure, or some other structure, or whether a coalition of stakeholders at WHA should challenge the ways that reform efforts have been implemented to date.

Dr. Frieden said that the UN World Food Programme (WFP) functioned effectively as a logistics hub in the Ebola response. UNICEF does not respond to all emergencies, but WFP could be a second UN response agency. He asked how the IMB was established.

Dr. Elias said that the Director General of WHO has certain authorities. For instance, the constitution of the strategic advisory group of experts that advises the agency on immunization policy is an entity that the Director General can create. The current Director General has indicated that she will probably create some type of committee like that for the health emergency group. It is a valuable structure, but it is not a nimble structure, as its processes are complex. The IMB was commissioned directly by the Director General, but member states have been reluctant to endorse such structures.

## Health Disparities Subcommittee Update and Discussion

Lynne D. Richardson, MD, FACEP (ACD Member; Chair, Health Disparities Subcommittee), provided an update on the progress made by the Health Disparities Subcommittee (HDS). She acknowledged the members of HDS and welcomed ACD member Dr. Tony Iton to the group. The membership is a diverse group of individuals from different backgrounds, and they work together to think through how to move the health equity agenda forward at CDC.

HDS brought six recommendations to the ACD two years ago. The recommendations were approved by ACD. Progress in the six areas has moved at varying rates. Dr. Richardson reported on three of the recommendations:

### ***Recommendation One: Develop a CDC health equity framework:***

This recommendation represents a combination of important conceptual work and “nuts and bolts, front-line” planning and coordination across CDC. The work is led by Dr. Leandris Liburd, Director of the Office of Minority Health and Health Equity (OMHHE). A supplement to the journal *Public Health Management and Practice* was released in January 2016 focusing on health equity. The supplement provided an overview of the research and science associated with health equity, as well as important policy initiative and practice programs that can drive health equity. It addressed various models that inform this work, including SDOH and the importance of environmental influences. It touched on the role of CDC and of state and local public health officials, serving as a call to action for how to move the health equity agenda forward. Dr. Richardson wrote a commentary for the supplement describing the recommendations that came from HDS and progress on them to date.

Additionally, the Strengthening the Capacity of Public Health Departments to Advance Health Equity meeting was convened on April 11-12, 2016. More than 200 individuals from CDC and state and local health agencies attended, representing 41 states. The meeting targeted offices of minority health and/or those with operational responsibility for health equity within public health departments. It presented opportunities to share what works, needs and gaps, and to build understanding of the framework being adopted by CDC to ensure collaboration and synergy. The meeting was well-received, and there has been feedback from attendees asking for continued communication and collaboration. There has been significant progress in organizing the public health infrastructure regarding health equity.

### ***Recommendation Two: Establish and monitor health equity indicators:***

A problem must be measured in order to demonstrate that there is a problem to be fixed, and to fix it. CDC has appropriately chosen to partner with other efforts to identify health equity indicators:

- Pan American Health Organization (PAHO), developing international health equity indicators
- The National Collaborative for Health Equity, in partnership with RWJF, developing a set of health equity indicators
- Leveraging Healthy People (HP) 2020 work was an initial piece of this effort, and these partnerships move the effort to a new stage

A public health and healthcare workforce diversity indicator is an important component of this work, as is the SDOH website that was launched in the fall of 2015. Each of the six identified areas for collaborations between public health and healthcare systems is a condition that is affected by disparities and that disproportionately affects various racial and ethnic minorities. Creating the infrastructure for health equity and aligning it with these efforts, whether focused on blood pressure control, suicide prevention, or other conditions is critically important. The HDS recommendations should be remembered as this work moves forward.

***Recommendation Six: Support health equity training and professional development:***

CDC continues to make progress in the area of health equity training and workforce diversity. The fifth year of the CDC Undergraduate Public Health Scholars Program (CUPS) will launch in May 2016. The program accepted approximately 180 students for placement at four participating sites to gain public health experience. The program is highly competitive, and interest in it is high. This program, and the James A. Ferguson Emerging Infectious Diseases Fellowship Program, are beginning to address the diversity of the future public health workforce. The Millennial Health Leaders Summit took place March 31-April 1, 2016. Talented young people from diverse backgrounds should be engaged early for public health careers.

Regarding training of the existing public health workforce, collaboration is beginning with CDC University to develop health equity training materials for project officers and first-line supervisors. The existing public health workforce should be retrained in how to apply the health equity lens to their work.

### Discussion Points

Ms. Rosenbaum observed that the HDS recommendations might interface with CDC's work regarding community benefit spending. It would be interesting to know how many hospitals have incorporated health equity as a specific aim in their community benefit investment planning and strategies. RWJF is active in this area and has a large community benefit project, with a large Web-based tool that will soon be launched to help local communities see community benefit spending across hospitals. There will be a lag in the data, but it will be accessible in a way that it has not been before. She wondered whether there are similar groups to HDS working at other federal agencies, such as the US Department of Housing and Urban Development (HUD) and DoL, with work that bears on health equity. HUD is active in many of these areas, and it might be beneficial to connect across these large federal agencies.

Dr. Richardson appreciated the idea of assessing the extent to which health equity has been part of the community benefit initiatives undertaken by hospitals. The RWJF tool presents a means to monitor these elements and to determine missed opportunities. HDS has discussed working with other, similarly-focused groups across the federal government and has made modest progress in reaching out to those groups. Their goal is encouraging and fostering greater collaboration across agencies. Members of HDS serve on other agencies' FACA committees and have noted how siloed the health equity efforts are. If they can "cross-pollinate" at the advisory committee level, perhaps that connection can trickle to the agency level.

Dr. Farley commented on the recent publication of a paper on the health benefits of the \$15 per hour minimum wage. He noted that Dr. Fielding is conducting modeling on the health benefits of universal pre-Kindergarten. There may be a category of areas that public health may not think of because those social issues and health have not been connected before. These policies can have meaningful and substantial impact on health equity through changing social problems. HDS could think about processes by which those social processes could be identified to draw connections to long-term health benefits.

Dr. Richardson replied that HDS has discussed including these issues from other sectors, particularly in the rubric of the health equity indicators. HDS has a great deal of interest and expertise in these other sectors. They have discussed broadening the base of people who think about these issues, who partners might be, and how to operationalize the “health in all policies” approach.

Dr. Iton commented on the emerging equity issue among working-class white people in the US, particularly in the Northwest and Upper Midwest. These issues are manifesting in opiate addiction, suicide, and chronic liver disease. He wondered about developing equity indicators that include that population’s needs, particularly indicators that are policy-relevant and indicate a dearth of policy and investment that is correlated with some of the concentrated areas of disease. When addiction strikes working-class white populations, there is often broad, bipartisan and media attention. There is a moment of opportunity for health equity to gain broader traction and to be included in indicators and policy recommendations. African American and Latino populations have experienced these issues, which have manifested in different ways.

Dr. Wooten said that the Strengthening the Capacity of Public Health Departments to Advance Health Equity meeting was helpful, particularly for local, tribal, state, and territorial jurisdictions to provide input to CDC. The breakout sessions were helpful to that end, and she hoped that the recommendations made during those sessions are taken to heart and implemented where possible. Implementing those recommendations would help public health across the board. Health equity is also important related to public health accreditation. Health equity is included throughout several domains of the Public Health Accreditation Board (PHAB) version 1.5. It will be helpful for local jurisdictions to show that they are meeting PHAB standards and measures as they apply for public health accreditation.

Leandris Liburd, PhD, MPH, MA (Director, Office of Minority Health and Health Equity, CDC; DFO, HDS) thanked ACD for the input, which will be applied as HDS considers new priorities for the future. She hoped that CDC would be able to dedicate more staff time to the work of the HDS, including more follow-through in developing the recommendations and suggestions from ACD more fully. Regarding the framework, the feedback from state and local health departments is being summarized by ASTHO. Their overarching goal is to “lay a ground cover” that state and local health departments can tailor based on their unique resources and circumstances as they more fully integrate health equity into their work. These ideas are important as CDC is championing a 21<sup>st</sup> century model for addressing minority health and health equity.

## CDC Laboratory Safety Progress Update and Discussion

Steve Monroe, PhD (Associate Director for Laboratory Science and Safety, Centers for Disease Control and Prevention), thanked ACD and Dr. Berns and Dr. Kanabrocki for their leadership of ELSW. The group provided a framework and direction as CDC made improvements in laboratory safety.

A great deal of progress has been made in standing up the Office of the Associate Director for Laboratory Science and Safety (OADLSS) and in implementing programs and activities. An official package has been submitted to reorganize the office as it has grown. Initially, the office received nine new full-time employee (FTE) positions. With the realignment of existing staff from the Safety Office and the Infectious Disease Quality Office, OADLSS now has a total of 41 FTE positions. The office has been split into two offices to split its functions: 1) the Office of Laboratory Science, led by Dr. Conrad Quinn, and 2) the Office of Laboratory Safety, led by Dr. Mary Brandt. The reorganization process is not complete, so the subordinate offices are not yet official. The new leadership brings expertise in their respective areas and in leadership as well as credibility and respect with the laboratory science community both inside and outside CDC. They also bring enthusiasm to make an agency-wide difference and support laboratory science at CDC as they are making lateral reassignments to their positions.

Progress has been made on all of the ACD recommendations to CDC regarding laboratory safety. Some efforts are ongoing; for instance, CDC is working with IT vendors to establish the laboratory registration system. Their goal was to overcome the “culture of complacency” to reach a “culture of safety.” This work is not a “box to check off.” Rather, it is an ongoing effort.

In terms of ongoing efforts, the initial class of the LLS had seven participants. A special session will be held at the Epidemic Intelligence Service (EIS) Annual Conference in May 2016 to highlight the interaction between the EIS and LLS programs. The eight incoming LLS fellows will participate in the EIS conference and begin their program officially on July 1, 2016. The Laboratory Safety Review Board (LSRB) rigorously reviews all protocols related to bringing materials out of Biosafety Level (BSL)-3 and BSL-4 facilities. The board remains active and is involved in the process of reviewing the procedures on an annual basis. Regarding CDC’s role in promoting laboratory science and safety, laboratory Safety Champions are highlighted monthly on the CDC employee Intranet homepage, CDC Connect. This program has focused on people working on laboratory safety “at the bench level.” A risk assessment policy is in the final stages of approval.

While OADLSS has added staff, there are still not enough people to implement safety initiatives in all of CDC’s different programs. OADLSS provides agency-level guidelines and leadership while working collaboratively with the Quality Manager and Safety Manager in each of CDC’s centers with active laboratory activity. In some centers with small laboratories, one person fulfills all of the safety and quality functions. Other centers have multiple staff engaged in these activities.

### Discussion Points

Dr. Fleming congratulated Dr. Steve Monroe and OADLSS on what the office has accomplished in a short amount of time.

Dr. Wooten was aware that CDC has developed a Public Health Laboratory Assessment Tool. It is optional for jurisdictions to take themselves through the assessment. She recommended that the assessment should be required, and the results reported to CDC.

Dr. Steve Monroe said that the assessment tool is driven out of the Center for Surveillance, Epidemiology, and Laboratory Services (CSELS).

Dr. Michael Iademarco (Director, Center for Surveillance, Epidemiology, and Laboratory Services, CDC) said that the Clinical Laboratory Improvement Advisory Committee (CLIAC) raised that issue the previous week, commenting on biosafety issues not only for public health laboratories, but all clinical laboratories. This question is significant, and many partners are involved. CLIAC is a FACA committee and passed a recommendation to address these assessments. CDC, CMS, and FDA will work together to formulate next steps.

Dr. Berns commended Dr. Steve Monroe for all that he has achieved, and Dr. Frieden for giving him the opportunity to do so. The creation of OADLSS was one of ELSW’s central recommendations, and it is gratifying to see it in existence and functional.

Dr. Kanabrocki added his congratulations to OADLSS on its progress. He has been pleased and honored to see how the ELSW recommendations have been addressed and taken seriously. He asked about progress on the laboratory registration system, which is a problem that is not unique to CDC but has tremendous potential for providing a basis for moving safety forward.

Ms. Villar asked Dr. Steve Monroe about his testimony before Congress the previous day and whether other topics or issues arose that should be considered.

Dr. Steve Monroe replied that the hearing only addressed the GAO report slightly. The GAO report includes the issue of official channels for notification of incidents when they occur, both within the agency and more broadly to the Department level. The Secretary of HHS has chartered a new group, the Biosafety/Biosecurity Coordinating Council, which includes representation from CDC as well as other federal agencies. This Council will generate a consistent approach across HHS for notification of incidents, including the level of incidents that should be reported and a consistent mechanism for CDC, FDA, and NIH.

Dr. Kanabrocki said that the question of communicating incidents upstream arises frequently in laboratory settings. The Select Agent Program (SAP) has an appropriate approach, “If it results in a visit to Occupational Medicine, it is probably worth reporting.”

## Suggestions for Future ACD Agenda Items

Dr. Fleming asked for ACD’s ideas regarding high-priority items that should be included on the agenda for the next ACD meeting, which will be held in October 2016. This meeting will be the last ACD meeting before a change in administration. It will be important to hear thoughts regarding the most important and urgent issues to prioritize for this meeting, particularly in helping ACD and CDC transition into a new administration. There are mechanisms to provide continuity into new administrations; these mechanisms include ACD. ACD can discuss the role that it can play in educating and working with new leadership at CDC and HHS.

### Discussion Points

Dr. Berns thought that one of the day’s more interesting reports was on Zika. This situation will be ongoing in the fall and should be a major consideration at the fall 2016 ACD meeting.

Dr. Goldman commented on the succession to a probable new CDC Director. ACD may be able to provide broad and positive advice regarding the kinds of individuals who should be considered for the position. The effective leaders of CDC have been trained in public health and have brought a depth of experience to the position. It could be helpful for ACD to articulate this idea as a recommendation, not recommending specific individuals, but providing guidance about attributes that make a strong CDC Director.

Dr. Richardson agreed and noted that a great deal of information will be transmitted from within CDC to the transition team and beyond. As an advisory committee, ACD could develop a summary of ongoing initiatives and priorities of CDC, independent of information presented to the transition team and new administration. She wondered about a precedent for such a summary.

Ms. Villar was not aware whether such a summary had been developed in the past; however, as DFO to ACD, it would have been helpful to have a “playbook” of what went well, what did not go well, and what ongoing issues should receive focus. This guidance will allow ACD to continue its important work and to provide important advice, keeping watch to ensure that CDC is doing the right things. It is likely that there will be an interim CDC Director. If so, that person will need to keep the agency moving, and it would be helpful to have ACD’s thoughts regarding the most important initiatives that should keep moving.

Dr. Richardson suggested reserving a significant amount of time at the next ACD meeting to create such a list of priorities and recommendations. Health equity should be high on the list.

Dr. Fleming said that they could discuss whether that task is best accomplished by “white boarding” at the next ACD meeting, or whether work can be done in advance by a subgroup of ACD.

Dr. Elias agreed that the agenda should include a session on Zika, especially given the timing of the meeting and the likelihood that data will become available from the pregnancy registries at that time. He also suggested holding a separate session on GHSA. A great deal will happen in this space in the next six months. Decisions will be made at WHO regarding its structure and how the JEE exercises are incorporated into it. Further, there will be continuity issues, given changes in leadership in the next 18 months at both WHO and UNICEF. Given the transitions taking place at the global level, focused discussion about GHSA will be helpful.

Dr. Farley expressed interest in an update on domestic HIV. There are concerns in Philadelphia with rises in sexually transmitted diseases (STDs) and a lack of continued declines in HIV. He also is interested in global TB. Regarding the transition, he suggested that the transition committee would find it beneficial to have a document on “what makes CDC great” and how to maintain it, explaining the essence of CDC as a unique federal agency. A list of specific initiatives will be important, but a high-level document will help people understand that CDC is not just another agency and cannot be led by “somebody who happens to be a friend of a friend of the President.”

Dr. Iton commented that Dr. Frieden’s presentation on the Winnable Battles and their progress to date was coherent, succinct, and clear. If Dr. Frieden does not remain CDC Director, that information will be important to transmit. It would be helpful for ACD to examine the entire Winnable Battles effort and to learn what went well with the initiative, and which battles may not have been as winnable as had been hoped. He wondered about the next six battles that might be winnable and what it would take to make progress on them. This information would be helpful for a new CDC Director.

Dr. Wooten was also interested in an update on domestic HIV as well as a presentation on the rising rates of syphilis, gonorrhea, and Chlamydia. What efforts can get these rates under control? Given that there will be change at CDC, it would be helpful to have a compendium or report of the accomplishments of ACD. Additionally, jurisdictions could be encouraged to look locally at the progress on the Winnable Battles in their regions.

Dr. Nesbitt observed that organizational and structural changes at CDC over the last seven years have made the administration of programs more efficient and effective in their focus on prevention. That story may not always be told and how the work aligns with the Winnable Battles and the 6/18 Initiative. This information should be included in a transition document, as many leaders come to new organizations and establish themselves by making structural changes. It is important that any changes do not revert to an older infrastructure that is not as effective or efficient. The story of how streamlining and consolidating units, as well as creating new units, improved the organization is not highlighted well enough.

Dr. Bal agreed with Dr. Iton’s observation about the Winnable Battles. He noted that the Winnable Battles are tied to return on investment. The impact is explicit, and the investments needed to achieve that impact are explicit. It is also important to quantify the cumulative burden of disease and mortality associated with a public health concern. For instance, the largest global impact of disease burden and mortality comes not from tobacco, but from hypertension. The cumulative chronic disease burden is massive. In taking on chronic disease, there has been a reduction in infectious disease emphasis. This point returns to the idea of whether the agency is “an inch deep and a mile wide.” Dr. Frieden has accomplished something rare among CDC Directors in that he has identified a number of issues not traditionally regarded as public health issues and delved deeply to show how they should be CDC’s responsibility. He has viewed medical issues from a population health perspective, but the money hasn’t followed. It is not financially possible to be all things to all people. Dr. Bal did not have an answer to the question, but if CDC is the center of the public health world, then CDC should educate the general public and policymakers so that they understand why. If the funding is not in the cards to implement programs directed at these issues, then one does what one can. He hoped that Dr. Frieden would

provide a 90-minute, in-depth presentation on his perceived priorities. A return to disease mortality burden may be warranted, rather than a focus on short-range issues. He felt that some time ago, there was precedent for continuity between presidential changes. If the new president comes from the same party as the previous President, “if it ain’t broke, it would be stupid to fix it.” Dr. Frieden has been one of the best CDC Directors since David Sencer’s time in the 1960s. Dr. Frieden is really good—an “Energizer Bunny.” To change directors when he is doing the job so well would be a pity. The learning curve would be significant, especially for an outsider, and would be a waste. The ACD could take a position on this point. Dr. Frieden has given CDC a new direction of population health. For CDC to be called the “Centers for Disease Control” is a misnomer. It is a global center for population health, in every sense of the word “global.” Changing CDC Directors does not make sense under a new President. If ACD states this idea, then it will be a benefit to the process. For instance, the Federal Bureau of Investigation (FBI) Director has a 10-year term that extends between administrations. A similar approach to the CDC Director position would serve to depoliticize this public health mecca. If there is no business reason for a change, it would be a tremendous waste.

Ms. Villar said that Dr. Frieden has expressed that he is here at CDC now, and he will stay as long as “the people in charge will have him.” Each administration conducts business slightly differently. The CDC Director is a political appointee, but is not a Senate-confirmed position. Administration involvement in appointing this position has historically taken into account whether the agency is the way it should be. She noted that she cannot answer these questions or control the outcomes, but there is flexibility in how ACD looks at the situation and makes recommendations.

Dr. Fleming added that the CDC Director is the only position at the agency that is a political appointee. A new Director will have the prerogative to assess the leadership team. Decisions in that arena tend to be made based on competence and personal connections, not politics.

Dr. Goldman noted that other agencies in highly technical areas have leaders who are appointed with odd-year terms so that they serve as bridges for changes in administration, and they do not abruptly leave when there is an election. This structure is set by Congressional statute. She was not aware of statutory language indicating that the CDC Director is appointed politically; rather, over the years, the White House has been more engaged in the decision over time as opposed to the Secretary of HHS making the hire. ACD may not have any influence over the process or with the decision-making processes of the transition team. The transition team might be willing to meet with ACD, perhaps off cycle with the usual ACD meetings. ACD could convey to the team the pieces of the puzzle that work well at CDC and should be protected. New people always make changes, but they can hear about the core of the agency and aspects of it that should not be altered. Dr. Frieden has changed the agency a great deal, and the next Director will as well because the world is changing. There will inevitably continue to be change in CDC, but those changes should not be undertaken precipitously or in ways that are not well-informed or that cut at the core of the agency, as has happened before.

Dr. Fleming noted that this rich discussion illustrated the need to devote time at the next ACD meeting to discuss these issues in greater detail.

## Public Comments

At 2:49 p.m., Dr. Farley called for public comment. Hearing none, the meeting proceeded.

## Closing Comments / Meeting Adjourned

Ms. Villar clarified that the GWG meeting notes do not need to be approved by the ACD.

Meeting attendees offered final comments and thanks:

- Rima Khabbaz, MD (Deputy Director for Infectious Diseases; Director, Office of Infectious Diseases, CDC), thanked ACD for their tremendous comments and insights, which are appreciated, particularly regarding the upcoming transition.
- Dr. Farley expressed hope that these meetings would be as useful to CDC as possible. CDC works hard, often under difficult circumstances, and he encouraged them to communicate how these meetings can be most useful.
- Dr. Iton agreed and suggested making the presentations available to state and local health officials for their periodic meetings, perhaps through EIS, which could make summaries and takeaways available. This approach could help to disseminate the rich information about what CDC is doing.
- Dr. Richards thanked ACD for the day's wonderful discussion. He would find it helpful to discuss the topic of CDC's role in continuing to support states and localities regarding public health infrastructure, including workforce, data, and a variety of issues. There are funding challenges in various lines, especially when emergency funding comes in topical boluses, and maintaining public health infrastructure is critically important and needs more focus. Discussion from ACD on this point would be helpful.
- Dr. Wooten expressed her thanks for the opportunity to serve on ACD.
- Dr. Bal said that it has been a privilege to serve on ACD. He thanked everyone in the room. He has learned a great deal in areas other than his "silos" and has been forced to learn in areas that he should have known over his years in public health. He thanked Ms. Villar and everyone at CDC for organizing the ACD meetings.
- Dr. Berns agreed and expressed appreciation for the opportunity for back-and-forth discussions between CDC leadership and ACD. The approach shows that ACD's advice is valued, and that advice is taken and used by the agency.
- Dr. Goldman expressed her appreciation for how seriously the ACD comments are taken.
- Ursula Bauer, PhD, MPH (Director, National Center for Chronic Disease Prevention and Health Promotion, CDC), expressed hope that ACD could discuss Indian Country in the future. This area has great need and the agency has performed poorly in this area in the past. The agency would appreciate ACD's advice.
- Dr. Richardson values the opportunity to serve on ACD, especially as a healthcare professional in a room full of public health professionals. There is a great deal to be gained by pursuing that collaboration in an even more robust way to leverage the resources and talents of each sector to improve the health of the public.
- Dr. Kanabrocki agreed with the sentiments expressed. He has learned a great deal and added special thanks to the ACD chair and CDC staff for the organization of the meeting.
- Dr. Elias appreciated the meeting and as a new member was glad to see the quality of discussion, and looks forward to participating in the future.
- Dr. Steve Monroe said that having specific recommendations from the ACD ELSW workgroup was extremely helpful. The challenge for CDC is to pose specific questions that the committee can answer specifically with recommendations that CDC can act upon.
- Katherine Lyon Daniel, PhD (Associate Director for Communication, Office of the Director, CDC), thanked the ACD members who will help communicate the complex issues that have been raised. Everyone at CDC has been running at full speed for months or years. The external validation of ACD's voices is important.

Dr. Fleming commented on the robust and diverse meeting. He thanked the staff supporting the meeting and its organization, CDC staff attending the meeting, and those who helped ensure that the quality of the presentations and the meeting were high. He thanked ACD, referring to it as a fun and valuable committee on which to participate. The quality of conversation and discussion is high, as evidenced by the degree to which CDC is heeding the group's advice. Dr. Richardson congratulated Dr. Fleming on his performance as ACD chair.

Ms. Villar thanked Dr. Fleming and Ms. Aimee Schattner. Dr. Frieden took many notes during the meeting and looks forward to initial follow-ups in the next day or two. The meeting was highly productive. She thanked ACD for making the time to come to the meetings. ACD has evolved into a strong committee with great dialogue and access to people and information. She expected that they would discuss Zika again, perhaps with outcomes and future directions to consider. CDC staff would try to address the questions raised at the next meeting, which will be October 27, 2016. During the Ebola response, many ACD members offered their help as people connected to CDC and as third-party validators. CDC was not as good as it could have been in availing itself of that assistance, as the response took everyone's energy and time. CDC is heavily involved in the Zika response and is looking to a transition, but now is a good time to revisit these issues. Perhaps CDC can prepare talking points for ACD, sharing information in a better way so that ACD can communicate with, and for, CDC.

With that, Dr. Fleming officially adjourned the meeting at 3:02 p.m.

## Certification

I hereby certify that, to the best of my knowledge and ability, the foregoing minutes of the April 21, 2016 meeting of the Advisory Committee to the Director, CDC are accurate and complete.

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Date

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David Fleming, MD  
Chair, Advisory Committee to the  
Director, CDC

## Attachment #1: Meeting Attendance

### ACD Members Present

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

**Dileep G. Bal, MD, MS, MPH**, District Health Officer, Hawaii State Department of Health

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

**Christopher J. Elias, MD, MPH**, President, Global Development, Bill and Melinda Gates Foundation

**Thomas A. Farley, MD, MPH**, Health Commissioner, City of Philadelphia

**Jonathan E. Fielding, MD, MPH, MBA**, Distinguished Professor of Health Policy and Management and Pediatrics, Fielding School of Public Health and David Geffen School of Medicine, University of California, Los Angeles

**Lynn R. Goldman, MD, MS, MPH**, Dean, Milken Institute School of Public Health, The George Washington University

**Anthony B. Iton, MD, JD, MPH**, Senior Vice President, Healthy Communities, The California Endowment

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

**LaQuandra Sherese Nesbitt, MD, MPH**, Director, District of Columbia Department of 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 Law and Policy

**Wilma J. Wooten, MD, MPH**, Public Health Officer, County of San Diego, Health and Human Services Agency

### CDC Participants

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**Thomas R. Frieden, MD, MPH**, Director

**Noah Aleshire**, Office of the Associate Director for Laboratory Science and Safety

**Andrea Anason**, Public Health Advisor, OD/OCS/OD/PPPA

**John M. Auerbach, MBA**, Associate Director for Policy; Acting Director, Office of State, Tribal, Local, and Territorial Support; Designated Federal Officer, STLT Subcommittee

**Drue Barrett, PhD**, Public Health Ethics Coordinator, OD/OADS/OSI

**Ursula E. Bauer, PhD, MPH**, Director, National Center for Chronic Disease Prevention and Health Promotion

**Sherri A. Berger, MSPH**, Chief Operating Officer

**Alexandra Bhatti**, Office of the Associate Director for Policy

**Coleen A. Boyle, PhD, MSHyg**, Director, National Center for Birth Defects and Developmental Disabilities

**Chris Braden, MD**, Medical Epidemiologist, OID/NCEZID/OD

**Patrick Breyse, PhD, CIH**, Director, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry

**Yulia Carroll**, Center for Surveillance, Epidemiology, and Laboratory Services

**Kristine Day**, Public Health Advisor, ONDIEH/NCCDPHP/DCH/RSEB

**Leslie Dauphin, PhD**, Deputy Director, Office of the Associate Director for Laboratory Science and Safety

**Rita Helfand, MD**, Acting Deputy Director, Office of Public Health Preparedness and Response

**Debra Houry, MD, MPH**, Director, National Center for Injury Prevention and Control

**Michael F. Iademarco, MD, MPH (CAPT, USPHS)**, Director, Center for Surveillance, Epidemiology, and Laboratory Services, OPHSS

**Robin M. Ikeda, MD, MPH (RADM, USPHS)**, Deputy Director, Office of Noncommunicable Diseases, Injury, and Environmental Health; Director for Noncommunicable Diseases, Injury, and Environmental Health

**Harold W. Jaffe, MD, MA**, Associate Director for Science, Office of the Director

**Patrick Kachur**, Medical Officer, CGH

**Ramu Kaladi**, Health Policy Analyst, CGH/OD

**Rima Khabbaz, MD**, Deputy Director for Infectious Diseases; Director, Office of Infectious Diseases

**Leandris Liburd, PhD, MPH, MA**, Director, Office of Minority Health and Health Equity; Designated Federal Officer, Health Disparities Subcommittee

**Judy Lipshutz**, Office of State, Tribal, Local, and Territorial Support

**Katherine Lyon Daniel, PhD**, Associate Director for Communication, Office of the Director

**William MacKenzie**, Deputy Director, OPHSS/CSELS/OD

**Amy MacKenzie**, Public Health Advisor, OSTLTS/DPHPI/OD

**Mark Mandelbaum**, Microbiologist, OID/NCIRD/DVD/PPLB

**Rebecca Martin, MD**, Director, Center for Global Health; Acting Designated Federal Officer, Global Work Group

**Jay McAuliffe**, Center for Global Health

**Audrey McCulloch**, ASPPH Fellow, CGH/OD

**Jonathan Mermin, MD, MPH (CAPT, USPHS)**, Director, National Center for HIV, Viral Hepatitis, STD, and TB Prevention

**Nancy Messonnier, MD (CAPT, USPHS)**, Director, National Center for Immunization and Respiratory Diseases

**Steve Monroe, PhD**, Associate Director for Laboratory Science and Safety

**Dena S. Morris, MPP**, Director, CDC Washington Office

**Rebecca L. (Becky) Payne, MPH**, Deputy Chief of Staff; Designated Federal Officer, Ethical Considerations for Public Private Partnerships Workgroup

**Victoria Phifer**, Office of the Associate Director for Policy

**Amanda Raziano**, Policy Analyst, NCEZID

**Chesley Richards, MD, MPH, FACP**, CDC Deputy Director for Public Health Scientific Services; Director, Office of Public Health Scientific Services

**Laura Seeff, MD**, Director, Office of Health Systems Collaboration, Office of the Associate Director of Policy; Designated Federal Officer, Public Health – Health Care Collaboration Workgroup

**Michael Shaw**, Associate Director of Lab Science, Office of Infectious Diseases, OD

**Pattie Simone, MD**, Director, Division of Scientific Education and Professional Development

**Joel Stanojevich**, Strategy Lead, CGH

**Jordan W. Tappero, MD, MPH (RADM)**, Director, Division of Global Health Protection, Center for Global Health

**Carmen Villar, MSW**, Chief of Staff and Designated Federal Officer, Advisory Committee to the Director

**Marien Wiley**, Public Health Analyst, Public-Private Partnerships Team

**Sarah Wiley**, Public Health Analyst, Office of Infectious Diseases, OD

**Rayna Taback-Esra**, Senior Public Health Advisor, CDC, South Africa

**Diana Yassanye**, Public-Private Partnerships Team Lead

**CDC Foundation**

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**Judith Monroe, MD, FAAFP**, President and CEO

**Chloe Tonney**, Senior Vice President for External Affairs

**Betty Wolf**, Vice President for Advancement

**Verla Neslund**, Acting Vice President of Legal Affairs and General Counsel

**General Public**

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**Kendra Cox, BA, MA**, Writer/Editor, Cambridge Communications, Training, and Assessments (CCTA)

## Attachment #2: Acronyms Used in this Document

Acronym	Expansion
AAEM	American Academy of Emergency Medicine
ACD	Advisory Committee to the Director
ACE	Assessment of Chemical Exposure
ACEP	American College of Emergency Physicians
ACS	American Cancer Society
AHA	American Hospital Association
AHRQ	Agency for Healthcare Research and Quality
AMD	Advanced Molecular Detection
AR	Antibiotic Resistance
ASTHO	Association of State and Territorial Health Officials
ATSDR	Agency for Toxic Substance and Disease Registry
BCHC	Big Cities Health Coalition
BSC	Board of Scientific Counselors
BSL	Biosafety Level
CASPER	Community Assessment for Public Health Emergency Response
CSELS	Center for Surveillance, Epidemiology, and Laboratory Services
CDC	Centers for Disease Control and Prevention
CEO	Chief Executive Officer
CGH	Center for Global Health
CIOs	Centers, Institutes, and Offices
CLIAC	Clinical Laboratory Improvement Advisory Committee
CME	Continuing Medical Education
CMS	Centers for Medicare and Medicaid Services
CMV	Cytomegalovirus
CNS	Central Nervous System
CSELS	Center for Surveillance, Epidemiology, and Laboratory Services
CUPS	CDC Undergraduate Public Health Scholars (Program)
CURES	Controlled Substance Utilization Review and Evaluation System
DC	District of Columbia
DEA	Drug Enforcement Administration
DFO	Designated Federal Officer
DoL	(United States) Department of Labor
<i>E. coli</i>	<i>Escherichia coli</i>
eCR	Electronic Case Reporting
ED	Emergency Department
EHR	Electronic Health Record
EIS	Epidemic Intelligence Service
ELSW	External Laboratory Safety Workgroup
EOC	Emergency Operations Center
EPA	(United States) Environmental Protection Agency
FACA	Federal Advisory Committee Act
FBI	Federal Bureau of Investigation
FDA	(United States) Food and Drug Administration
FEMA	Federal Emergency Management Agency

<b>Acronym</b>	<b>Expansion</b>
FETP	Field Epidemiology Training Program
FSMB	Federation of State Medical Boards
FTE	Full-Time Employee
FY	Fiscal Year
GAO	(United States) Government Accountability Office
GBS	Guillain-Barre Syndrome
GHS	Global Health Security
GHSA	Global Health Security Agenda
GWG	Global Work Group
HAI	Healthcare-Associated Infection
HDS	Health Disparities Subcommittee
HHS	(United States Department of) Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act (of 1996)
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome
HP	Healthy People
HUD	(United States) Department of Housing and Urban Development
ICRC	Injury Control Research Center
IgM	Immunoglobulin M
IHR	International Health Regulations
IMB	Independent Monitoring Board
IT	Information Technology
JE	Japanese Encephalitis
JEE	Joint External Evaluation
LLS	Laboratory Leadership Service
LSRB	Laboratory Safety Review Board
MAT	Medication-Assisted Treatment
MDR-TB	Multidrug Resistant Tuberculosis
MERS	Middle East Respiratory Syndrome
MME	Morphine Milligram Equivalent
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
MOH	Ministry of Health
NACCHO	National Association of County and City Health Officials
NCBDDD	National Center for Birth Defects and Developmental Disabilities
NCCDPHP	National Center for Chronic Disease Prevention and Health Promotion
NCD	Noncommunicable Disease
NCEH	National Center for Environmental Health
NCIPC	National Center for Injury Prevention and Control
NCIRD	National Center for Immunization and Respiratory Diseases
NIH	National Institutes of Health
NPHI	National Public Health Institute
NVDRS	National Violent Death Reporting System
OADLSS	Office of the Associate Director for Laboratory Science and Safety
OFDA	Office of Foreign Disaster Assistance
OHE	Office of Health Emergencies
OMHHE	Office of Minority Health and Health Equity
OSTLTS	Office of State, Local, Territorial and Tribal Support
OTC	Over The Counter

<b>Acronym</b>	<b>Expansion</b>
PAHO	Pan American Health Organization
PDMP	Prescription Drug Monitoring Program
PDO	Prescription Drug Overdose
PEPFAR	President's Emergency Plan for AIDS Relief
PHAB	Public Health Accreditation Board
PHAP	Public Health Associate Program
PI	Principal Investigator
POB	Polio Oversight Board
PQRS	Physician Quality Reporting System
PR	Puerto Rico
RNA	Ribonucleic Acid
RT-PCR	Reverse Transcription Polymerase Chain Reaction
RWJF	Robert Wood Johnson Foundation
SDOH	Social Determinants of Health
STD	Sexually Transmitted Disease
STLT	State, Local, Tribal, and Territorial (Subcommittee)
TA	Technical Assistance
TB	Tuberculosis
UK	United Kingdom
UN	United Nations
UNICEF	United Nations Children's Fund
US	United States
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USGS	United States Geological Survey
WHA	World Health Assembly
WHO	World Health Organization
WPF	(United Nations) World Food Programme
YF	Yellow Fever
ZPK	Zika Prevention Kit