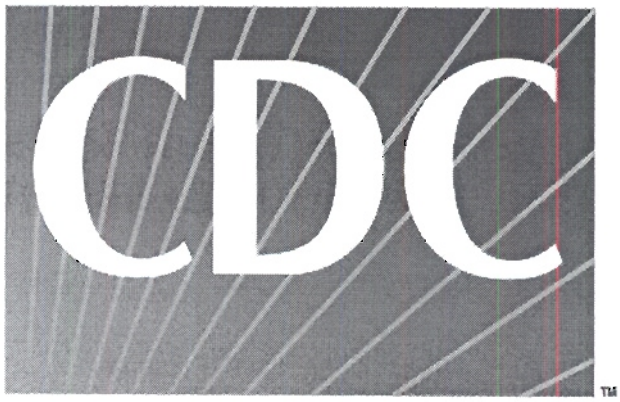
DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION



CENTERS FOR DISEASE CONTROL AND PREVENTION

Joint Meeting of the Ethics Subcommittee of the Advisory Committee to the Director, CDC and the CDC Public Health Ethics Committee

August 9-10, 2007

Atlanta, Georgia

Record of the Proceedings

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Acronyms Used in This Report

ACD	Advisory Committee to the Director
ACIP	Advisory Committee on Immunization Practices
AHRQ	Agency for Health Care Research and Quality
AIDS	Acquired Immune Deficiency Syndrome
AMA	American Medical Association
ASTHO	Association of State and Territorial Health Officials
CDC	Centers for Disease Control and Prevention
CRB	Central Review Board
DEET	N,N-diethyl-*m*-toluamide
DFO	Designated Federal Official
DHS	Department of Homeland Security
DNA	Deoxyribonucleic acid
EPA	Environmental Protection Agency
EPO	Epidemiological Program Office
FACA	Federal Advisory Committee Act
FDA	Food and Drug Administration
HAN	Health Alert Network
HHS	Department of Health and Human Services
HIV	Human Immunodeficiency Virus
HPV	Human Papilloma Virus
HRSA	Health Resources and Services Administration
IRB	Institutional Review Board
IRS	Internal Revenue Service
IT	Information Technology
MDR-TB	Multi-Drug Resistant Tuberculosis
MMWR	Morbidity and Mortality Weekly Report
NACCHO	National Association of City and County Health Officials
NGO	Non-Government Organization
NHANES	National Health and Nutrition Examination Survey
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Safety and Health
NSC	National Security Council
NVAC	National Vaccine Advisory Committee
OC	Office of Communication (CDC)
OD	Office of the Director (CDC)
OHRP	Office of Human Research Protections
OMB	Office of Management and Budget
OSHA	Occupational Safety and Health Administration
PHEC	Public Health Ethics Committee
PHEPR	Public Health Emergency Planning and Response
PHLS	Public Health Leadership Society
PHPPO	Public Health Practice Programs Office
SARS	Severe Acute Respiratory Syndrome
STD	Sexually-Transmitted Disease

DEPARTMENT OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION

JOINT MEETING OF THE ETHICS SUBCOMMITTEE OF THE ADVISORY COMMITTEE TO THE DIRECTOR, CDC AND THE CDC PUBLIC HEALTH ETHICS COMMITTEE

August 9-10, 2006
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Minutes of the Meeting

The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC) convened a joint meeting of the Ethics Subcommittee of the Advisory Committee to the Director (ACD), CDC and the CDC Public Health Ethics Committee (PHEC). The meeting was held on August 9-10, 2007 at CDC's 1825 Century Center Building, Conference Rooms 1 A/B. Meeting participants are listed in Attachment 1.

Introductory Remarks and Overview of Meeting Goals

Dr. Ruth Macklin, the Ethics Subcommittee Chair, called the joint meeting to order at 1:08 p.m. on August 9, 2007. She welcomed members of the Ethics Subcommittee and PHEC, as well as other meeting attendees.

Dr. Drue Barrett, Public Health Ethics Coordinator, Office of the Chief of Science at CDC, welcomed those present. She reviewed housekeeping issues regarding the building facilities, utilization of the microphones, muting communication devices, and evaluation forms. Prior to turning the meeting over to Dr. Macklin, she ensured that all Ethics Subcommittee members had submitted their conflict of interest forms. Following introductions, Dr. Barrett invited participants who were seated around the room to join the Subcommittee at the table, as there were available spaces. She requested that everyone sign in, and asked that those who wished to make public commentary sign up for time to do so. She then recognized the work and contributions of Roberto Garza, who was joining the staff in the Office of the Director (OD) of CDC. Dr. Barrett expressed her gratitude for his excellent work and said that he would be greatly missed.

Dr. Macklin reviewed the agenda and the goals of the meeting, which were to: 1) review progress on development of a guidance document on public health emergency preparedness and response; 2) continue discussion on additional actions relating to pandemic influenza; 3) begin discussion of ethical issues relating to CDC partnerships; 4) review progress on development of guidance document on genomics; 5) review progress on development of

guidance document on non-research data collections; and 6) follow-up on Ethics Subcommittee procedural issues from last meeting.

Ethical Aspects of Public Health Emergency Preparedness and Response

Review Draft of White Paper

Mr. Bruce Jennings thanked the members of the Emergency Preparedness and Response Workgroup, noting that the group had completed a considerable amount of work since the last Subcommittee meeting, building on the outline the Subcommittee had reviewed. They created a first draft of a White Paper and also commissioned a number of papers by outstanding experts in the field. These papers will make original contributions to the subject matter and, with the White Paper, serve as a strong resource for the field. He explained how the draft of the paper had been created, and how due to a fast turnaround deadline, Workgroup members were asked to read the draft of the paper only to identify significant problems, mistakes, or omissions. He hoped that following discussion at today's meeting, the Workgroup and the Subcommittee members would provide substantive comments, criticisms, and suggestions regarding the paper.

In creating the White Paper, Mr. Jennings and Dr. Arras intended to remain faithful to the outline that the Subcommittee had approved in their February 2007 meeting. They occasionally deviated from the outline when they discovered unnecessary redundancies and when they realized that another section was needed. The current Section Two of the White Paper addresses vulnerable populations. While the material is important to include in the document, Mr. Jennings pointed out that it might be more appropriately placed elsewhere. By including the information early in the document, they would address the problem of the document not delving into practical, "nitty-gritty" issues about emergency preparedness and response quickly in the narrative. The beginning of the paper is highly theoretical, so they hope to include greater detail early in the document. However, this goal could also be achieved in other ways, perhaps by inclusion of short case studies or scenarios.

Many aspects of the draft need improvement, but they hope to convey the general ethical position that the paper will present regarding the ethical goals and objectives of emergency planning. Mr. Jennings asked the Subcommittee to review the draft with an eye toward ensuring that the document was not focused in the wrong direction, and requested advice regarding ways to make the document more concrete and specific. They hope to strengthen the ethical framework of the document and to make it more rigorous. He and Dr. Arras did not address certain sections of the document which focus on CDC and its operations, given that those sections need to be developed with assistance from their CDC colleagues.

Dr. John Arras credited Mr. Jennings with much of the work in producing the first draft. He noted a few issues on which he hoped to hear comments and contributions from the Subcommittee:

- The draft might need more detail regarding the contrast between the ethics of emergency preparedness and the ethics in emergency preparedness:

  → The ethics of emergency preparedness include: What is the enterprise of emergency planning? How much priority should it get? What are its goals and aims? Is it a priority in establishing a good, general public health infrastructure in the United States?

  → The ethics in emergency preparedness account for all of the above concrete issues, but a contrast remains between the ethics of the work and the ethics within it.

- There is a connection between restrictions on personal liberty, particularly in issues of quarantine, and issues of justice and resources. If people will be quarantined for extensive periods of time during a pandemic, what are the practical concerns? How will they eat and pay their bills? Issues of efficacy should also be discussed.

- Questions of transparency and communication should be examined. Ethics professionals are often quick to assume congruence between "doing the right thing" and good results. Dr. Arras asked those with experience in these areas to elucidate examples of situations in which transparency may "backfire."

- The section on "professional obligations" ascribes a duty to "man one's position" during an emergency based on social contract reasoning and virtue ethics. Dr. Arras asked the practitioners in the room to reflect on whether these principles address professional obligations appropriately.

- Another issue concerns the obligations not of healthcare providers and typical public health workers, but of other people who work in hospitals, such as custodians, record-keepers, and other workers. A number of people who died of Severe Acute Respiratory Syndrome (SARS) in hospitals met this description. There is a standard literature on professional obligations within medicine, nursing, and public health, but little has been written on the question of obligations of citizens to help keep the public health system operational during emergencies. Are there resources for that discussion?

- Should the dialogue pertaining to professional obligations include a discussion of incentives? Concepts of virtue and duty are typically cited as rationales for physicians' obligation to remain on duty in the face of epidemic illness; however, in many situations incentives are offered. For example, during the Black Death in Europe, "Plague Doctors" received credentials and extra money.

Dr. Arras opened the floor for discussion, noting that they would welcome assistance on any of these issues either in this forum or via e-mail correspondence.

Discussion Points

- Dr. Levine commented that the draft represented a terrific start. He singled out the section on vulnerable populations, noting that the case study on persons with disabilities was quite rich. He raised the issue of voluntary restriction of activity, as opposed to mandatory activity restriction. He and Kathy Kinlaw experienced a similar problem as they created the guidance document for pandemic influenza. The restrictions might be voluntary, but if the public does not comply, then the restrictions become mandatory. He hoped that the message to the public would not be, "you will do these good things voluntarily, or else we will require it."

- Dr. Arras responded that the document does imply that voluntary interventions are preferable. In a public health context, coercion may have to be used as a last resort.

- Dr. Levine agreed with this implication and suggested that it become an explication. The draft provides the example of attempting to rescue an autistic boy during Hurricane Katrina who does not want to be rescued. In this case, workers will not debate his personal liberties; they will rescue him. In another example, a person who has been told not to travel may try to fly on an airplane, and the person will have to be stopped. The problem will be difficult to solve. They hope that people will behave properly and in the best interest of the public and themselves, but if not, they will have to be coerced.

- Dr. Arras said that voluntary measures tend to suffice for the vast majority of cases. In a recent case of multi-drug resistant tuberculosis (MDR-TB) in New York, few people were quarantined against their will. The same was true for SARS in Canada and China. The coercive "backdrop" does exist, however.

- Dr. Levine said that the document makes the coercive aspect of emergency planning and response clear, but the point is made separately from the discussion about reliance on voluntary behavior. He emphasized that while he raised the problem, he did not have a solution to it. He continued to address the section on professional obligations, which he felt was optimistic. It may not be possible to create obligations out of social contract or virtue ethics. For instance, the Black Plague doctors were credentialed and rewarded, but they were shunned by the rest of the medical profession. The American Medical Association (AMA) addressed the question of duty as far back as 1912, but during the early days of Acquired Immune Deficiency Syndrome (AIDS), members of the medical profession fought the obligation to care for AIDS patients. To resist this obligation, they drew on the AMA's revised ethical code, which states that providers must care for people "within the realm of their competence." Practitioners, particularly surgeons, therefore pled incompetence to avoid treating persons with AIDS. Dr. Levine recalled his experience on a hospital's ethics committee, when they considered whether surgeons should be required to operate on people with AIDS or Human Immunodeficiency Virus (HIV). That committee responded that the Department of Surgery is obligated to see that everyone who needs surgery, gets surgery; however, no particular surgeon has an obligation to perform that surgery. Physicians also went to state legislative bodies to argue that they did not have obligations to care for AIDS patients, since "they got what they deserved." Relying on virtues and social contract, therefore, is no guarantee that doctors will do things that they prefer not to do. Dr. Levine was concerned that there would be resistance in the face of an epidemic. He then commented on the section on research, which is yet to be written. The section begins with the statement that research should be distinguished from surveillance and other public health activities. This issue has been a struggle for some time. He did not believe it was

possible to define which activities fall under human subjects protections and which do not. He suggested that public health practices often use some of the same modalities that are employed in the conduct of research. When they are employed for the purpose of public health activities, they should be exempted from human subjects requirements. This is something that would call for a change in the Common Rule.

- Dr. Dixie Snider addressed the issue of transparency and when it could "backfire." He referred to the decision to include the smallpox vaccine as part of the preparedness plan for the country. He argued that the decision should be made by the Advisory Committee on Immunization Practices (ACIP), a public venue that would allow for transparency. The ACIP presented recommendations that influenced the ultimate decision regarding the vaccine. When making recommendations regarding preparedness, it is important to understand the risk of the event as well as the efficacy and safety of the chosen intervention. The Advisory Committee consulted with many experts regarding the use of smallpox vaccine and its safety; however, some details regarding the safety of the vaccine in the adult population were not recognized fully at the time. It was more difficult to understand the risk that smallpox would actually be released. Dr. Snider provided a briefing by the National Security Council (NSC) for the chair of the ACIP, but the chair was not able to share this background information with the rest of ACIP because he was obligated to keep it a secret. In bioterrorism preparedness, and perhaps in other situations, there may be reasons why some information regarding risks cannot be made transparent. The smallpox information that they had was not accurate, and even accurate information may not be able to be discussed because it has the potential to compromise national security. For instance, the information could relate to technological developments such as unusual agents that have been developed. There are situations in which transparency is not in the public's interest. Groups such as ACIP would likely appreciate guidance to help them when these situations arise. When should they insist on receiving all of the information in order to make recommendations, and when should they make recommendations and set up programs based on the information they have?

- Dr. Richard Besser concurred that issues of transparency and national security play into preparedness. In his experience, national security can be used as a "trump card" when situations may not, in fact, pose national security concerns, but the "trump card" is used to avoid public scrutiny. He noted few instances in which transparency in public health had backfired. Bad press can be a consequence, but he suggested that using transparency as a general principle is a sound approach, with the knowledge that there could be exceptions. The alternative, which he often sees, is that unless an overwhelming need for transparency is proven, then discussions regarding decisions and the process by which the decisions were made will not be made public.

- Dr. Arras said that these issues highlight the importance of the ethics of emergency preparedness and response. These questions not only affect public health, but also law enforcement, the military, national security, and others. He hoped that they could dwell on the combination of public health and police functions. There could be cases in which the different groups work together, but they could also work at cross-purposes.

- Dr. Macklin agreed with Dr. Levine regarding the strength and importance of the section on vulnerable populations. The placement of the section might not be ideal, though. It is included immediately after the introduction to the document, which gives the impression that special considerations for people with disabilities are the most important issue to deal with in preparedness and response, and these people should always be a priority. The placement

of the section leads to this assumption; it is not explicitly stated in the text. If they wish to make a case for priority for these populations, then it should be stated as an argument, rather than inferred.

- Dr. Arras agreed and repeated the need to have strong content early in the document. He felt that the section should remain in the document, but should be moved to the section on "justice." There is a strong tension between the individual needs of disabled people and issues of allocation. How much priority should they get?

- Mr. Jennings added the need for distinction between the phases of emergency planning and response. Ethical issues can differ in each context. The document generally aims to underscore the point that appropriate planning in the pre-event phase can avoid or mitigate many ethical dilemmas that arise in the response phase. They do not want to focus the document solely on the moral dilemmas of the response phase. These issues may come up, and they are dramatic, but they are not the root of planning, response, follow-up, and recovery.

- Dr. Steve Coughlin noted that they had discussed transparency in the context of national security and preparedness. These issues arise often in traditional public health and public health education. For example, the CDC Centers that do health education and health communication put information on the Internet, and many materials such as posters and slide sets are in the public domain. Local and state health departments and other entities are encouraged to download and use these materials with their own logos, if local populations are more likely to trust local organizations. Public health professionals also contribute scenarios to television shows, and this approach may not be completely up-front, but this type of intervention is still successful in promoting healthy behaviors. He found the draft of the paper to be insightful and informative. He pointed to page eight of the draft, which asserts that Americans in the last generation have become suspicious of authority. The purpose of public engagement and of creating documents such as this one is to help build public trust; therefore, Dr. Coughlin did not understand why the introduction to the paper makes statements about the public's belief that the government is not competent. He hoped that the federal government does good work and is a good steward of the public's money.

- Mr. Jennings thought the document emphasized the need for openness, for cultivating public trust, and for helping the public understand and agree with the priorities that are set. In order to lay the groundwork for this openness, he included observations regarding the current cultural context, which differs from more familiar public health stances. Benevolent paternalism and "doctors know best" approaches will not work today. The open and engaged stance is more likely to be successful, and it diverges from approaches in public health's history. He also felt that the statements were sociologically true. He hoped that the narrative did not seem like an "attack" on the government or on public service; rather, he hoped that it would state that the population would not be passive, and the population should have good reasons for doing what is asked of them.

- Dr. Tom Hooyman thanked Dr. Arras and Mr. Jennings for their work. He noted that the section on vulnerable populations uses the word "accommodating," which sounds paternalistic. He hoped that the relationship between public health response and people who are vulnerable could be expressed in a different, less-hierarchical way. "Service" may be a more appropriate word. He also wondered whether preparedness planning at the local, state, and county levels included ethics, as it has at the federal level. State, local, and

county levels may need an ethical infrastructure to address ethics response, consultation, and review in an emergency.

- Dr. James Thomas indicated that he has created a series of online modules on public health ethics, which have been accessed by a number of people across the country. He has also given telephonic lectures and conferences. Through his work, he senses that public health ethics is being discussed more now than it was 10 years ago. There is engagement at the local level; however, he did not have a sense for the number of local-level agencies that were bringing ethics into their institutional frameworks.

- Dr. Barrett reported that the National Association of City and County Health Officials (NACCHO) is involved in public health ethics and is trying to engage state and local health departments.

- Dr. Hooyman wondered whether the document should mention that ethics infrastructures for emergencies are being built at the national level and recommend that such efforts begin at the local level, proactively rather than reactively. He also addressed the issue of duties in emergencies. They may find some guidance in the literature for analogous situations, such as scenarios in which an earthquake has made a hospital structurally unsafe and whether medical staff are obligated to remain to care for patients. Is remaining and endangering one's own safety an act of charity, or an act of justice? These issues arose during Hurricane Katrina, for example, and they may find strengthening arguments in that experience and / or in the literature.

- Dr. Arras asked whether they should distinguish between a duty to remain in a natural disaster that poses risk or a situation that has been exacerbated by administrative or human neglect. He recalled discussions in the literature regarding physicians in China during the SARS event who refused to go to the hospital to treat patients. One of their primary reasons was anger at the hospital administration's management of the disease and its failure to provide prophylactic measures for its staff. In a case such as this one, people might view their duties differently.

- With respect to the issue of "bribery" or "tiered response," Dr. Hooyman pointed out that there is a great deal of wealth in the United States, and some people may be able to "buy their way out" in the event of a disaster. The document may need to address questions of affluence in a disaster situation. For instance, wealthy people who live in Florida may be able to evacuate easily when a storm is approaching. If a quarantine occurs, people will seek ways to "buy their way out of it," if they have the financial resources to do so. Another question concerns political expediency. He recalled a conversation with a former governor of Colorado who observed that public policy can only be created based on utilitarianism, not any other ethical methodology. Legislation relies, at its minimum, on cost-benefit analysis. With that in mind, will political expediency lead to a deterioration of virtue and community in favor of a "crass" cost-benefit analysis? He also raised the possibility of working with non-government organizations (NGOs) and service clubs as part of emergency preparedness and planning. He is a member of the Rotary and wondered whether they could serve a role in preparing for a public health disaster.

- Dr. Mary desVignes-Kendrick returned to the topic of transparency. Members of the community are concerned about these issues, and there should be an explicit presumption that any recommendations or decisions will be questioned by the community. Therefore, transparency is very important. Lack of transparency may backfire, especially in instances

when agencies work with partners to reach the best decisions. Individuals at these partner agencies may have information that they are not permitted to share with others, even with their planning and response partners at the local and state level. If it is not made clear to these individuals why it is not appropriate to share the information with partners on whom they rely, and who expect that information (especially if they disagree with the admonition that they not share specific information) will question the very process for decision-making and lose trust in the outcome. This layer of transparency within organizations and with planning and response partners is important, in addition to transparency with the community.

- Dr. Arras asked Dr. desVignes-Kendrick for examples of rationales that might be given for not sharing information.

- Dr. desVignes-Kendrick has noticed that in communities, local police chiefs are expected to share information with federal agencies, but the federal agencies do not, or cannot, share information with the local police. Reasons include national security or that the police chief does not have the proper clearance. At times, the chief may not have the appropriate clearance, but another staff member has it. In other instances, there are concerns regarding new technology being pirated, or not being "ready for prime time." In these cases, some, but not all, information can be shared. Local and state health directors make statements such as "What we can say is," or "What we know is," which sound like hedging. In working closely with partners and sharing information, there should be trust. Without it, another set of people will question decisions even as they ask the community to accept the decisions. She addressed the creation of ethical infrastructure in local and state communities. NACCHO has been working in this area, and some localities have created task forces to consider ethics in public health decision-making in emergencies. Regarding the duties and obligations of professionals in crises, community members do question whether professionals act in the community's best interests rather than in their personal best interests. For instance, the issue of whether pharmacists will provide certain medicines based on their beliefs is current.

- Dr. Mark White noted that, like Dr. Besser, he had never seen a situation in which transparency for a public health agency had backfired. The question of transparency emphasizes the importance of maintaining clear borders between public health and other sectors. For instance, public health works with politicians, but the ethics, tools, and culture are recognized as separate. If public health is associated with a particular agenda or administration, then it will not be able to do its job. Public health works with the military and with intelligence agencies, but it cannot become part of those groups. Thus, transparency is an essential defining characteristic of public health. Information that cannot be shared is useless.

- Dr. Barbara Koenig also endorsed the draft of the paper. She did not have questions regarding the word "accommodating" in the section on vulnerable populations, but she did wonder about how "disability" compares to other examples of vulnerability, such as poverty. Structural inequality results in a different kind of vulnerability, which the document should capture, perhaps with a different analysis. This section is probably too detailed to be included so early in the document, but she supported the idea of following the theoretically-based introduction with immediate and concrete examples. She suggested developing another case example, either hypothetical or real, to help readers connect theory with the "world." She favored discussing the distinction between the ethics of emergency preparedness and planning versus the ethics in an emergency situation more thoroughly.

This point parallels the distinction because the ethics of the planning phase differs from the ethics of the response phase. The "ethics of" is an appropriate time to discuss the balance of resource allocations to preparedness as opposed to more generic infrastructure development. Then, the "ethics in" addresses issues pertaining to virtue. She suggested pre-figuring some of the issues surrounding ethics of the professional by not drawing a stark contrast between utilitarianism and other views, but by including virtue ethics earlier in the document.

- Ms. Kinlaw returned to the issues of transparency and sharing information. The recent response to MDR-TB could serve as a case study. There was an attempt to share a great deal of information, and sharing should be a starting point. However, the concept of "sharing" may need to be refined. Beyond security issues and the release of information, there are questions regarding sharing information in a time of uncertainty and when the information itself is uncertain. How can they provide information responsibly? Another important element is timing, which was an issue in the MDR-TB experience.

- Dr. Arras agreed that they should give more attention to the issue of uncertainty. During the early waves of the SARS epidemic, Toronto public health officers were conflicted about which, and how much, information to share because of the concern about responsible sharing of information. There are downsides associated with sharing too much information before there is a thorough understanding of what the information might mean.

- Ms. Kinlaw added the question of procedural ethics regarding how the decision is made to share information.

- Mr. Jennings returned to the issue of communicating uncertainty. Another aspect of transparency concerns how to share uncertainty and the provisional nature of the information that is being provided. How can they tell the difference between responsible sharing of information versus withholding information for bureaucratic expediency or other political aspects? Some guidance is needed, particularly in an emergency event.

- Ms. Kinlaw agreed, noting that there is a risk of making a decision that information is not helpful, is anxiety-provoking, or difficult for the public to handle. A case study can provide an in-depth place to examine the principles and questions around this issue. She recalled Dr. Coughlin's comments regarding cultural context on pages 7 and 8 of the draft. She supported a clear description of the current culture and the importance of individualism and autonomy, particularly in light of historical abuses. The tone of the narrative, though, seemed presumptively paternalistic. She suggested changing assumptive comments such as "they will want to be together," or "they will want to leave their homes," to positive statements such as the one on page 8: "Americans value individual freedom of choice and reliance." This statement can ground the concerns expressed later.

- Referring to page 14, the beginning of the discussion of the document's values and structure, Dr. Thomas noted that the values listed seemed "disembodied," although they have an embodiment in public health. He encouraged Mr. Jennings and Dr. Arras to mention the Code of Ethics to root those values. Because the Code is prescriptive for institutions, it does not include "civic and personal responsibility." Additionally, the document addresses a number of considerations regarding communicat on with the public. He thought the document should address communication with the public through mass media more thoroughly. The document mentions the importance of not "trading off" preparation for an emergency with basic public health infrastructure. There is money to be

made in fear, which influences how the mass media communicates during an emergency. The public health infrastructure needs to develop relationships and establish trust with the journalism community, particularly to control "fear-mongering."

- Dr. Besser expressed his strong enthusiasm for the draft. He also agreed with the points raised in the group's discussion, which would strengthen the document. He was interested in many of the sections that are yet to be developed, especially countermeasure development and distribution. The concept of "crass utilitarianism" raises its head frequently in this area, and ethical guidance would be welcomed. There is a drive toward developing and getting more doses of products, when doses for certain groups may be more costly. Questions regarding definitions of vulnerable populations also apply to children and the framework that applies to response pertaining to them. The issue of information-sharing is valuable to address in the document. National security is frequently cited as a reason not to have transparency, but in emergencies that do not result from terrorism, the reason to withhold information is often a concern regarding public panic. He revisited comments regarding encouraging ethical consultation at the state and local level, which he felt was critical, since response and preparation is concentrated at those levels. Some aspects of preparedness and response pertain chiefly to CDC, and others will pertain more specifically to state and local public health agencies, which may have resource constraints. The document refers to the difficulty of conducting ethical consultation and debate during an emergency response, and he felt that ethical response is different and should be planned. He advocated for guidance regarding how to incorporate ethical considerations "around the table" in the midst of an event. The White Paper is exciting, and the final product will likely be a good resource. He also addressed the question of whether this document should go through a process of public engagement. A small CDC group discussed this idea and concluded that this document will provide recommendations for when public engagement should be sought. At this point, they hope that the Subcommittee will provide recommendations from their perspective as professional ethicists. The group felt that public engagement regarding this document, while it could make a contribution, is not as high on the priority list. Dr. Bernier, who could not be present during this meeting, provided a list of considerations for public engagement.

- Dr. Richard Dixon suggested expanding the scope of the document, wondering whether it has the appropriate balance between the interests of the individual and the interests of the community. He pointed out that CDC is a public health agency, and the ethical objectives listed on page 14 of the draft seem to tilt toward the needs and perspective of the individual. Most of the Subcommittee members have backgrounds in medical ethics, in which protection of individual is paramount. A public health agency should consider the balance of the community and individuals. One of the objectives on page 14 is "building sustainable, strong communities," but the document does not address building those communities, except through infrastructure. An example of this issue that emerges at CDC is the balance between science and non-science in emergencies. A public health agency that is trying to build future strength has an obligation to learn from its experiences. There is uncertainty, though, regarding whether it is proper to conduct research in an environment of destruction. If the agency is unable to learn from emergencies for any reason, be it discomfort, restriction, or lack of resources or ability, then the agency cannot build stronger communities. Public health ethics is a relatively new area, and it has two layers: public engagement and community good, and the effect of the individual community.

- Dr. Barbara Ellis felt that the document would be invaluable for CDC and the public health community. She spoke about the document's section on professional obligation. The

narrative alludes to responders' obligation to be competent, including sound best practices. The document should articulate the need to exercise or drill as part of the preparedness process as well as the importance of all providers and responders understanding each other's roles. The public health workforce needs education as well as a clear communication strategy for that education. She suggested that the document also address the obligation to protect first responders. Finally, she felt that the document should acknowledge the importance of global connectedness.

- With respect to the objectives listed on page 14, it was suggested that ethics be used to promote comprehensive planning and response efforts. This idea is implied, but not stated. The public's perception of justice will influence their willingness to undergo personal restrictions. If planning has been appropriate, and if "we are all in this together," then some of the more difficult ethical dilemmas may not arise. It is possible to obviate the public's concerns regarding whether measures are unfair or unjust.

- Dr. Georges Benjamin said that there is a consensus definition of "preparedness," created by the RAND Corporation. He felt that transparency was generally good. While secrets may be needed some of the time, there are times when people who are tasked with keeping secrets keep information secret even if it is not a "secret." This issue is a fundamental problem in preparedness. There is an emerging body of knowledge, based on a number of surveys from a number of entities, including CDC and the New York Academy of Medicine, regarding what the public will and will not do during emergencies. Some providers may resist providing services for the public good in favor of their interests, and they may have an individual right to do so. There is a "tipping point," however, between the good of the individual and the good of the community. The issue of socioeconomic status is significant and should be addressed before a disaster situation. The abilities of different communities to recover from emergencies and disasters are directly related to socioeconomic status as well as justice, racism, discrimination, and other issues that occurred before the event and will occur after the event. The document should be explicit about those issues and address them before an emergency takes place.

- Dr. Barrett asked members of the audience who were responders to provide comments via e-mail regarding how useful this document would be to them and whether it is practical enough.

- Dr. Macklin commented that the draft includes a preponderance of infectious disease examples. The introduction makes a good case for changing the paradigm and discusses the return of infectious disease, but the document needs illustrations to address whether different kinds of emergencies or emergency responses might call for different circumstances. Focusing on infectious diseases allows for rich discussion regarding the obligations of professionals; however, threats to the environment will affect everybody. The public will have variable abilities to respond, and the responders will be affected as quickly and significantly as everyone else. Hurricane Katrina is a good example of differences in socioeconomic status and response, but some circumstances might affect everyone equally, regardless of status. She hoped for additional non-infectious disease examples and their consequences for first responders, planning, the response itself, and the aftermath.

Pandemic Influenza Update

Update on HHS Vaccine Prioritization Guidance

Dr. Benjamin Schwartz, Senior Science Advisor and National Vaccine Program Office, Department of Health and Human Services, reminded the group that in the last presentation he made to them, he described the draft guidance on vaccine prioritization, including the process whereby the interagency group needed to consider the draft and give its approval to make the guidance public. After that approval and presentation, a series of activities to engage the public and stakeholders would begin, and the guidance would be modified as needed. He had hoped to share the guidance and the results of the public discussion; unfortunately, the interagency group had not cleared the guidance for public release. The delay was not due to reservations in other agencies or in the Homeland Security Council regarding the document's recommendations, but other preparedness issues that are not as far advanced have taken precedence, and so it is not yet cleared for release to the public. Plans for outreach have not changed, and include public engagement meetings, electronic engagement, stakeholders meetings, meetings with critical infrastructure sectors and their coordinating councils, and a Federal Register notice and collection of comments on the website. Therefore, Dr. Schwartz offered the group a presentation on antiviral drug draft guidance. This issue is important because it is the other major medical countermeasure, with vaccines. They are in the process of considering changes to the national antiviral drug strategy, which raises a number of important ethical issues. Further, Secretary Leavitt focuses on "shared responsibility," which is important in preparedness regarding antiviral drugs and other medical materiel and supplies. It is important to have ethical insights as the process moves into the public and stakeholders.

The antiviral drug situation presents a number of important ethical differences from vaccine prioritization. With vaccines, the goal is to vaccinate everybody, and the purpose of prioritization is simply to decide who should be vaccinated first. With antiviral drugs, the question may be who should receive these medications and who should not. Specific settings and strategies will be recommended. Some groups will be included, while others will not. Unlike vaccines, antiviral drugs can be stockpiled so that proposed strategies can be implemented from the start of a pandemic, assuming that stockpiling has taken place. The responsibility to stockpile poses another set of ethical issues that differ from issues that affect vaccines. Finally, the concept of shared responsibility is different for antivirals. In a pandemic, all of the vaccine in the initial stages will be purchased by the federal government and will be allocated to state and local governments to administer according to the guidance and strategies. In contrast, antiviral drugs for stockpiling are already being purchased by federal and state governments, and there will be an expansion of shared responsibility. The current antiviral drug strategy is to target them for containment of an initial pandemic outbreak and for early treatment of those who are ill, those who present for care, and those would benefit from therapy. These decisions would be made by individual clinicians. Overall, 81 million regimens will be stockpiled: 50 million will be purchased by the federal government, and the targeted state share is 31 million, with subsidization of 25% from the federal government. Most states plan to purchase their allocation of antiviral drugs, but not all of them intend to. Currently, federal allocation is about 80% complete, and the state allocation is about 40% complete.

Since the current strategy was formulated, the production capacity for antiviral drugs has expanded considerably. There is now a glut of antiviral drugs such that the manufacturer is unable to sell enough. There is enough Tamiflu for federal, state, and local governments as well as businesses to purchase the drugs they want to purchase. The expanded manufacturing presents an opportunity, and emerging information suggests potential benefits to a broader antiviral strategy. The Community Mitigation Guidance and strategy suggests that household post-exposure prophylaxis with antiviral drugs will reduce transmission of influenza infection not only within the household, but also in the community. The Guidance has suggested that if antiviral household post-exposure prophylaxis is feasible, then it should be implemented. In addition, published surveys of healthcare workers and state-level discussions with healthcare workers and emergency responders indicate that large portions of the workforce will not work unless they are protected with antiviral drugs. Prophylaxis may be important to reduce absenteeism and to maintain critical capabilities in healthcare and emergency services at a time when their burden is increased.

An interagency working group has convened to begin developing guidance. This group includes participation from state, local, and tribal public health representatives. Ethical principles have been an important part of their deliberations, including the following:

- Reciprocity: If healthcare workers and others will be asked to take additional risks and to be exposed to people with pandemic influenza, the principle of reciprocity would posit that these individuals should be protected. At the same time, if they are protected with antiviral drugs, then the same principle would posit that they should come to work. This principle is also relevant for household contacts of cases. Under the Community Mitigation Guidance, members of the household will be asked submit to a voluntary household quarantine and to stay at home with a case. These individuals will be asked to assume increased risks for the benefit of the community, so it may be appropriate to provide them the protection of post-exposure prophylaxis.

- Protection: Strategies should protect the health and well-being of communities broadly, and community services that will be essential in a pandemic should be prioritized.

- Fairness: There are caveats to the principle of fairness within targeted settings and groups.

- Flexibility: It is important to respond to new science and to the conditions of the pandemic itself.

Discussions are ongoing, but in addition to the two current strategies of containment and treatment, the expanded strategy will likely focus on household post-exposure prophylaxis and prophylaxis for the duration of a community outbreak for healthcare workers and emergency responders, who are frequently exposed to patients with infection.

Dr. Schwartz presented draft guidance to the Department of Health and Human Services (HHS) Executive Committee, chaired by the Scientific Counselor to Secretary Leavitt. Discussions in this meeting included ethical issues associated with developing the guidance and included mention of the Ethics Subcommittee's pandemic influenza document. Once the draft guidance is developed, stakeholders will be engaged to discuss its content and how the concept of shared responsibility can be implemented. Shared responsibility applies not only to stockpiling antivirals, but also to purchasing other medical materiel such as ventilators, respirators, respiratory protection, and antibiotics. He asked the Subcommittee to provide input regarding

how to disseminate the idea of shared responsibility to stakeholders as they struggle with some of the implications of shared responsibility, such as:

- ❑ The broader the responsibility is shared, the more likely it becomes that some groups will not take that responsibility and will not purchase their share. For example, if a healthcare organization decides not to purchase antiviral drugs to protect its workforce, it would seem to be contrary to the principles of reciprocity and fairness. The choice could also degrade the healthcare system's capabilities, putting the entire community at risk. How should this situation be addressed? Should the organization be forced to purchase antivirals, or does shared responsibility really mean voluntary sharing of that responsibility?

- ❑ Emergency service personnel are a consideration. If, for example, the police department cannot purchase antiviral drugs because they need to purchase bullet-proof vests, what response is merited?

- ❑ If a state or community has the responsibility to purchase drugs for household post-exposure prophylaxis or treatment, but chooses not to do so, would that choice violate the principle of reciprocity? Or, by not protecting the community, the entity would not be doing what they could do in order to dampen the pandemic in their community and therefore would hurt all members of the community by missing the opportunity to decrease the magnitude of the pandemic.

- ❑ A potential approach avoiding negative consequences is to inform entities and groups that they should buy the drugs, but if they do not, then the government will buy them. However, there are dangers inherent in this approach. For instance, if the government offers to fill gaps, it is less likely that others will accept their component of shared responsibility. The government's ability to fulfill other important missions might be reduced as well. If the government needs to buy all of the antiviral drugs, they may need to cut programs significantly, which would bring adverse consequences.

Discussion Points

- Dr. Benjamin began the conversation by addressing whether the concept of shared responsibility is an ethical concept or a policy decision. He agreed that the idea brings questions about how far it should go and trade-offs that will be required if entities choose not to abide by it, or cannot afford to participate. Legal issues such as federalism also play a role, and legal advice might be needed. The essence of the question is: Who is paying for it? Further, who will store and be responsible for it? Storage and maintenance carry costs as well, and these costs may not be considered in funding. They need to be specific about the concept and where responsibility starts and stops.

- Dr. Hooyman named frameworks for shared responsibility, such as a communitarian ethic approach, an ethics of care approach, and the Judeo-Christian perspective of "common good." Shared responsibility may have limits. The American Hospital Association's Patient's Bill of Rights is a bill of rights and responsibilities.

Dr. Arras suggested that the context in which these issues play out is important. For example, the question of the responsibility of healthcare organizations to provide post-exposure prophylaxis to their employees may have different implications within a for-profit context as opposed to a non-profit context. It could be to the advantage of a healthcare organization not to provide its people with prophylaxis. By spending less money on these measures, the organization can spend money in other areas and gain a competitive advantage. Perhaps these organizations could get tax benefits to provide these benefits.

- Dr. Koenig understood that the antiviral drugs are not "magic bullets," and some might be concerned about an over-emphasis on them. Providing these measures at the expense of other programs and obligations, such as the collection of health statistics, should be weighed with the importance of preserving infrastructure and shared responsibility that pertains to that. At the Mayo Clinic, they think about their obligations in state planning, as one of the largest practices in the United States with significant capacity. Even if they decide to provide services, what should they do about people who do not want to receive them? She felt that they should consider the obligations of healthcare professionals to be vaccinated.

- Dr. Schwartz commented on the effectiveness of antiviral drugs. For pre-exposure prophylaxis for the duration of a community outbreak, the drugs will be 70% to 90% effective in preventing infection. Post-exposure prophylaxis is similarly effective and will not only prevent symptomatic illness in the person who takes it, but also mathematical modeling suggests that it will decrease transmission within communities. Therefore, the overall attack rate of influenza will be lowered. If fewer people become sick, fewer people will need medical care and fewer people will die. The models indicate that the life savings could be significant. If they believe that the drugs are effective from a public health viewpoint, then they need to decide how willing they will be to allow states, localities, or organizations avoid using them.

- Mr. Jennings wondered whether a pandemic situation should alter the basic public health paradigms regarding what they do, what they procure, how they pay for it, and how they distribute it. In normal circumstances, drugs are viewed as economic commodities. People who have insurance or personal wealth pay for their drugs privately, and those who qualify for social insurance drugs may have public funding for their drugs, such as Medicaid. Others do not have any coverage at all. In a pandemic situation, because everyone in society benefits from the taking of the drug, then it is not appropriate to view drugs as commodities. The typical considerations, including whether someone qualifies for Medicaid, become irrelevant. A more apt model is the example of the fire department, which responds to fires regardless of whether the people who own the house can pay for the services. Similarly, residents of border states do not pay more for national security than people who live in the middle of the country, even though they are closer to risk. The services are general, and the need is general. With that paradigm in mind, he wondered whether considering the issues from a perspective of "shared responsibility" was a mistake. Shared responsibility should be parsed out based on the understanding that there is a genuine public interest and public good, not based on "who pays what share" and not to keep the federal government from having to pay for everything. Shared responsibility does not apply to dividing the bill, but to the common good and avoiding "free riders." The only way to avoid "free riders" is to make the service and purchase common.

- Dr. Levine noted that antivirals have a high degree of effectiveness in pre- and post-exposure prophylaxis. The impression that they are ineffective may be based on reports of their effectiveness in treating people who already have the disease.

- Dr. Schwartz replied that if treatment is started early in the course of the disease, then antivirals are fairly effective in shortening the duration of treatment, which is the basis of their licensure. Post-licensure, a variety of studies show that they reduce complications such as pneumonia and that they reduce complications and the rates of hospitalizations in the elderly and adults as well as in children. No data have been published on the mortality effects of antivirals, but if a person does not develop pneumonia and a need to stay in the hospital, then the person is probably less likely to die.

- Dr. Levine asked about the source of antivirals reputed lack of efficacy.

- Dr. Schwartz felt that the drugs were licensed based on their ability to shorten the duration of illness, so there is less general knowledge regarding their other effects. In fact, companies that manufacture the drugs are precluded from discussing other effects because the other effects are not part of the drugs' licensed indication.

- Dr. Hooyman asked about the scenario of a pandemic influenza outbreak. For instance, if Chicago suffers an outbreak, what is his practical course of action as a Hospital Administrator in Denver?

- Dr. Schwartz said that people in the community where the outbreak occurs should be protected. Outbreaks can occur in different parts of the country at different times. The only risk occurs in the specific outbreak community, though. The ideal situation includes strong surveillance so the beginning of the outbreak can be identified. When a person is identified with the flu, then the community would be informed and the hospitals would administer prophylaxis to those who have been identified as front-line workers who are likely to be exposed.

- Dr. Hooyman asked for clarification regarding the size of a community. Chicago, for instance, has a metropolitan area of eight million people and many health systems. Their "community" could include a 100-mile radius.

- Dr. Schwartz said that more work is needed regarding the "triggers" for action and the size of the geographic area that might be triggered by an event. The quality of the surveillance is important. For instance, if Chicago detects a case, should healthcare workers in Peoria take prophylaxis? Will they know when their community is affected, or should they assume that if Chicago is affected, then their community will be affected in time?

- Dr. Hooyman referred to hospitals' obligations to administer antivirals prophylactically to their workers. He did not think that any hospital CEO would not want to ensure that the workforce is capable of keeping the hospital running. A more pressing issue might be convincing the healthcare workers to take the drugs when they are available. The hospital's business model is to stay open.

- Dr. Schwartz replied that some hospitals may feel that since they are providing respirators and personal protective equipment, they are protecting their workforce sufficiently and do not need the expensive drugs. Facilities such as nursing homes have narrower margins and might not be able to afford the drugs. Another question concerns outpatient providers,

which may not belong to an organization and may have to purchase the drugs for themselves.

- Dr. Hooyman agreed, but noted that the culture and ethos of healthcare executives, even in a for-profit environment, is to be available to the community. Allocation could present problems for some entities, but the mindset is aimed toward caring for workers, even from a utilitarian perspective.

- Dr. Cetron commented on confusion about the efficacy of antivirals. Beyond a lack of labeling, the endpoints of different drugs are measured against different standards. Antibacterial agents have a different outcome pertaining to cure. Their standard, which is marked by a rapid "cure," does not apply to expectations of antivirals in the treatment of broad viral diseases. The outcome indicators are not "how rapidly can we cure," but have been scaled back in the trial and treatment setting to reflect "can we shorten the duration of illness" or minimize complications. They are not "magic bullets" in the same manner. In addition, the antivirals must be delivered in a narrow window of time in order to have impact. This "window" also applies to an extent to post-exposure prophylaxis. Regarding triggers, the Community Mitigation Guidance is an interim document, but it includes definitions of triggers. The definition on which the creators of the document settled is the first occurrence of laboratory-confirmed outbreak cases with transmission to others within a state or region. This definition recognizes that some metropolitan areas are epidemiologically linked across state boundaries. Pandemic influenza will likely move quickly, so if Chicago experiences an outbreak, the intervention should take place before the attack rate is one percent of its population. Within a week or ten days, the transmission will be wide. There is little time between successfully intervening and stemming the tide of the outbreak. For this reason, the entire state is likely to react as a political entity. There may be concordance across the entire nation, but the need to act early will compel large blocks of the country to act. Availability of drugs is one aspect of the plan, but logistical capacity is another crucial aspect that is key to whether the outcome will be successful.

- Dr. Coughlin commented on health economics questions that may illuminate their ethical questions. For example, the notion of "economies of scale," in which costs decrease and the process is more efficient if goods are purchased on a large scale, could be helpful. Through regulation and policy, the government can change the distribution of resources such as antivirals, making the process more efficient or equitable. Different approaches to distributing resources can have an impact on their accessibility or cost.

- Dr. White commented that the epidemiology of pandemic influenza is a problem of society, not of individual HMOs or individual people. They will be hampered if they get caught up in the details of a complicated funding system.

- Dr. Macklin returned to the concept of shared responsibility, noting that "obligation" is a stronger term than "responsibility" in ethics. If people do not fulfill their responsibilities, then they may be chastised; however, if people do not fulfill their moral obligations, then they are unethical. Rather than micromanaging the payment process, it might be more successful to consider prophylaxis as an obligation held by everyone (e.g., employers, hospitals, insurers, HMOs, and federal and state governments). The details are important and should be worked out, but in the context of responsibility or obligation. For instance, when a person or group fails an obligation, it is made public, and the reputation suffers.

- Dr. Schwartz thanked the group for their input and perspectives. He felt that the concept of obligation rather than responsibility was interesting. If administering these drugs were made an Occupational Safety and Health Administration (OSHA) requirement for employee safety, then the obligation could be forced. He wondered about the terms to use in discussions with stakeholders such as the states, Association of State and Territorial Health Officials (ASTHO), NACCHO, and healthcare organizations. He invited the group to contribute and additional thoughts and assistance.

- Dr. Barrett asked whether the Subcommittee should provide formal input and additional deliberations on the topic. She pointed out that if the Subcommittee wished to take the topic further, they could create a workgroup and a formal document, or they could use other means.

- Dr. Levine asked for an outline of Dr. Schwartz's comments to help with feedback.

- Dr. Macklin asked when stakeholders would be consulted. Dr. Schwartz hoped that they would reach out to stakeholders throughout the fall.

- Ms. Kinlaw asked what would be most helpful to Dr. Schwartz and his colleagues and whether Subcommittee members could address specific questions.

- Dr. Macklin asked Dr. Schwartz to provide Dr. Barrett with a series of questions or tasks for the Subcommittee to address, indicating that they would communicate via e-mail to collect responses.

Introduction to the Issue of Ethical Recommendations for Travelers with Infectious Diseases

Dr. Martin Cetron, Director of the Division of Global Migration and Quarantine, National Center for Preparedness, Detection, and Control of Infectious Diseases, thanked the group for the opportunity to speak. He shared some experiences with the group about dealing with travelers with infectious diseases and engaged the group more formally in case-specific or scenario-driven ways. The most recent circumstance of a traveler infected with drug-resistant tuberculosis was unusual for a number of reasons, and it raised numerous legal and ethical issues and dilemmas, for example:

- ❑ The federal government's use of restricted means to protect the public's health;
- ❑ The threshold for use of those means;
- ❑ Whether the current ethical constructs were appropriate in terms of fairness, least restrictive means, and due process;
- ❑ Issues of privacy;
- ❑ Communication and the use of the media for communication and for accomplishing public health objectives.
- ❑ Is there a difference between the medical paradigm that has been in place, which presumes a covenant of public trust that precedes the use of legal means to restrict

movement, and the paradigm in the law enforcement arena, which presumes that there is an intent to harm, and there is no covenant of public trust?

The use of this tool in the public arena is quite rare, but it is not the first or last time in which there is a need to consider the public's interest in the choice to use restrictive means on civil liberties. Many of the protocols and policies in place were decentralized and delegated to field staff at quarantine stations across the country. They have direct relationships with their state and local public health partners, as well as with other federal partners. They were able to use the current set of protocols to recommend the implementation of measures. Following this incident, most of the decision-making has been centralized, and the ways to access federal powers and toolkits for restricting movement have moved up from the field through headquarters, the CDC Emergency Operations Center to the Secretary's Operations Center to the National Operations Center of the Department of Homeland Security (DHS). They can move quickly through sets of protocols and exchange information. They are in the process of developing those information exchange requests and flows-down. As they go through this process, the protocols should be examined with an ethical eye to ensure that they reflect a balance, especially since they do cross lines with law enforcement and their colleagues in DHS. Since tools that restrict civil liberties will be used, they must make sure their decision-making process is clear and ethical.

In this construct, the Division must be able to deal with retrospective scenarios, which include reconstruction of the exposures, location individuals, and identification of people at risk to offer an intervention. Privacy and other issues are associated with these situations. Other scenarios will take place during an event or prior to an event. For instance, a United States citizen or lawful resident may want to leave the country, or could be in another country and want to return. It is not uncommon to find foreign nationals who are infectious and who pose a threat to the public good who wish to travel into the United States or who want to leave the country. Issues of privacy, balance, and the employment of legal means and tools must be considered with appropriate levels of fairness and least-restricted means. Are the processes proportional to reciprocity and compensation issues, and do they address due process? How should they use incentives, and when do they recognize that the balance between the public good and individual freedom has been disrupted?

Dr. Cetron then asked the Subcommittee whether they were willing to tackle these issues further, perhaps in a future venue.

Discussion Points

- Dr. Macklin asked for examples of how the information is discovered and communicated.

- Dr. Cetron replied that infectious travelers come to their attention in many different ways. The jurisdiction can shift between local, county, state, and federal levels. When the public health network is working well, and communication is accurate and timely, they may become aware of situations through requests made by state or local health departments for assistance in managing non-compliant, infectious individuals who have indicated an intent to move and to put others at risk. That method is the most common way of identifying cases, but occasionally the individuals themselves will post queries and ask for consultation or verification regarding whether they should travel. Sometimes, direct calls come from physicians. Most of the time, that information is honest and comes with corroborating evidence; however, all of the facts are not always available, and there have been cases

when calls have come from people with intent to deceive or to commit fraud by sharing false information to achieve a certain outcome.

- Dr. Hooyman commented that the issue was very interesting. The Subcommittee had discussed the restrictive liberties in the pandemic influenza document and in the emergency preparedness and response document. He felt that they should be careful to be consistent in each guidance document, and also through the history of the Subcommittee. The infectious traveler issue could have analogs to a scenario in which an elderly person in the early stages of dementia is still driving a car. If the driver's physician feels that the person is impaired, then the physician is obligated to report the driver to the state. This scenario does not play on a national level, but physicians grapple with issues of people who are potentially dangerous to the community. There could be parallels across responsibilities and jurisdictions.

- Dr. desVignes-Kendrick asked for more detail regarding shifting the decision-making mechanism from the local and state quarantine station to a centralized location at CDC and the potential implications of this shift, since restricted movement decisions are frequently made at the local level.

- Dr. Cetron replied that the shift will not interfere with the ability of state and local officials to make decisions for restricting movement within the state where they have authority and control. The shift changes the protocol when there is a request for federal assistance from a state or local jurisdiction, which may feel that there is an impending threat. Often, the timetable is short, so states and localities cannot mobilize their internal legal resources before the event may take place. Alternatively, they may feel constrained by their laws. For instance, community control laws are highly variable from state to state, and some require demonstrated non-compliance before they can take action. The action requires a court order. At the federal level, movement restriction can be carried out at the discretion of the Director of Quarantine Program or the Director at the Agency level. A temporary detention order can allow authorities to gather information and "sort things out" before a permanent order, which requires a hearing, is needed. The shift to the centralized model also affects the federal response to requests for assistance from the state and local level. In the past, the request might have been handled by the Quarantine Medical Officer in the Port of Atlanta or another Port and the local officials. By centralizing, the process is more formal and the action has to be reviewed and approved at the level of the Branch Chief and the Division Director in the Program before it goes to the CDC Emergency Operations Center for verification and review. Unlike the terrorism scenario, in which people are put on "watch lists" or "no-fly" lists, in situations with infectious travelers, their medical conditions bring a time limitation and restriction with them. They do not want to stigmatize people with diseases, but to protect self-interests and the public's interest.

- Dr. Koenig asked whether the United States borders would be closed in the event of a pandemic influenza strain in the world.

- Dr. Cetron answered that the United States' national policy decision regarding border strategy in a pandemic is based on a risk-based strategy for management. The plan includes how to contain flow, identify high-risk situations, isolate contagious and ill people, and offer interventions to exposed contacts. The work is operationally intensive, including a risk-based strategy to include triage and screening. The approach is time-limited. Once the pandemic is widespread, local transmission will account for more cases than importation from outside.

- Dr. Coughlin asked whether Dr. Cetron's interest in restriction movement was related specifically to pandemic influenza or to drug-resistant tuberculosis. He observed that tuberculosis tends to be prevalent among lower-income populations and other groups, such as recent émigrés to the United States. These groups' compliance with doctors' recommendations is often a matter of health literacy. The Institute of Medicine (IOM) convened an expert panel on health literacy which highlighted the extent to which health illiteracy impairs healthcare in the United States. This Subcommittee has discussed links between public health ethics and health literacy in the past.

- Dr. Cetron agreed, and his division's responsibility to prevent international importation and interstate spread of communicable diseases is not focused solely on pandemic influenza or tuberculosis. Federally-authorized restrictions on movement exist for a list of diseases. The Division's interest is broad, and with its regulatory responsibility, the Division has a public health mandate to deal with other diseases which could be spread by infected travelers that are not necessarily on that list, such as measles. The problem of health literacy represents one of the ethical challenges that they face as they operate with a disparity of understanding. They have an obligation to communicate risk so that it is clearly understood and there is an opportunity for less restrictive means to achieve the same goals. The division would provide scenarios to the Subcommittee that were somewhat disease-independent, but pose a threat to the public's health if movement is not restricted. An additional challenge comes from rapid movement with intense exposures in enclosed air spaces, such as airplanes. It is largely the responsibility of state and local health agencies to restrict movements within their states. The division is concerned with interstate and international movements and large-scale exposures.

- Dr. Levine said that the pandemic influenza guidelines emphasize the necessity for accomplishing planning without delay; it is best that guidelines be developed before a pandemic occurs. The planning phase allows for time to plan properly and to develop decision guidelines. He recalled that Dr. Schwartz asked for guidance in a few months, since the next opportunity for action to be taken is in the future; however, he sensed that Dr. Cetron urgently needs guidance in how to intervene in the movements of people with potentially threatening diseases. He wondered how ready they were now to respond to, for instance, an outbreak in Chicago.

- Lauren Broussard commented on challenges that emerge during a mandatory evacuation. She worked for the state of Louisiana during Hurricane Katrina, and she recalled cases of tuberculosis and sexually transmitted diseases in Baton Rouge and Houston. She wondered whether restricting movement in an emergency situation had been addressed in planning.

- Dr. Coughlin said that after Katrina, CDC epidemiologists ensured that people who were in shelters who had been receiving treatment for tuberculosis before the storm had continuity of care, despite their displacement. CDC staff worked on this important public health issue in partnership with local and state health officials.

- Dr. Barrett clarified on how the Subcommittee could help Dr. Cetron and his division, either by providing input on protocols or via commentary on case scenarios

- Dr. Cetron asked for "some of both." His division could provide protocols and collect general thoughts regarding whether the appropriate checkpoints were in place and whether balance

was achieved. In the "real world," however, in which decisions are implemented, case scenarios are helpful to crystallize and distill the ethical challenges. Preparedness is an ongoing and iterative process, and they are closer to being ready to deal with Dr. Levine's example of a pandemic influenza outbreak in Chicago. They are not completely ready, though, which makes the work more urgent as they face ongoing threats. The recent example of the infectious traveler highlights several aspects of the challenges that they face. What if there is no intent to deceive? As these issues and others emerge, they have a great deal of experience that can inform their planning.

- Dr. Macklin said that the Subcommittee has already addressed questions of restricted movement in general terms regarding pandemic influenza and emergency preparedness. As Dr. Hooyman mentioned, the Subcommittee must remain consistent. They have not yet examined their two White Papers for consistency. She recommended that they begin working on the specific case of infectious travelers by looking at what they already have in the area and determine whether they agree with what they have already created. Then, with case scenarios from Dr. Cetron, they can make general recommendations as well as case-by-case statements. She asked for volunteers from the Subcommittee to work on these questions.

- Dr. Magruder wondered about the extent to which centers themselves should examine these issues before they consult other committees. He asked whether these ethical issues and perspectives been presented and examined internally in the Division of Global Migration and Quarantine or at the Center level.

- Dr. Cetron replied that the division presented the idea of consulting this Subcommittee to the Center and the Coordinating Center, and both groups endorsed that course of action. There has not been a full and robust discussion regarding ethical questions at those levels. The Subcommittee presents a different skill set and perspective to the problem.

- Dr. Barrett said that this center does not have an established ethics team, and they are experiencing turnover in the area of their Public Health Ethics lead. This issue could help to create an Ethics Team within the center, and the subcommittee could work with them.

Public Comment Period

At 4:50 PM, Dr. Macklin called for the public comment period to begin, stating that they would return to the published agenda after the allotted public comment time.

Daniel Stockin, Lillie Center

Mr. Stockin introduced himself and explained his background in public health, which includes toxics assessment and hazardous materials management. His career has also included an interest in minority health issues. He complimented the Subcommittee on their work and noted that their discussions regarding transparency and information-sharing would have a bearing on his presentation. He noted the Public Health Ethics Code, which public health agencies across the country are urged to uptake. He also cited the notions of moral obligation and shared responsibility as he and his colleague, Jim Fessenden, distributed literature regarding the

fluoridation of drinking water in order to help prevent cavities. He assured the group that he has no financial stake in the issue, but became interested in it after a co-worker's illness.

Mr. Stockin pointed to statements released by the Oral Health Division of CDC, which they feel to be severe ethical lapses and that are contrary to other reputable government agencies, which have released information regarding fluoridation that is not being shared widely. Hundreds of doctors, scientists, and dentists across the United States and the world have publicly called for the end of water fluoridation in the United States. He said that he and his group were filing a formal complaint regarding unethical actions at the Oral Health Department at CDC, which do not adhere to the Public Health Code of Ethics. Eleven unions representing 7000 scientists within the Environmental Protection Agency (EPA) have called for an immediate halt to water fluoridation in the United States.

Despite these actions, CDC's Oral Health Department is not sharing information about fluoridation with the general public. Before fluoridation was implemented, the American Dental Association editorialized against it due to concerns regarding thyroid and bone disorders. Those concerns are surfacing now. A number of unexplained chronic illnesses exist in this country, and some of these issues, as well as dental fluorosis, are caused by overexposure. Mr. Stockin expressed concern about the lack of information that is shared with affected parties. In particular, African Americans are known by CDC to be disproportionately harmed by dental fluorosis, but that information is not shared. He cited a report from the National Research Council regarding fluoridation, which acknowledged susceptible sub-population groups such as people kidney disease, diabetes, senior, and immunodeficiency disorders.

CDC's Oral Health Division changed its policy on its website earlier this year to suggest that parents not use fluoridated water to mix with powder milk or formula for infants. CDC has stated in the past, however, that fluoridation is safe for all. Mr. Stockin felt that the lack of publicity around this change in policy was highly unethical. The National Research Council calls for fundamental research into the safety of fluoridation.

In closing, Mr. Stockin stated that this information, plus information included in the packet, is self-evident. He reiterated that they were filing a formal complaint regarding this matter and asked the Subcommittee to act within its power and scope on the issue. He expected that when the information went to the media, there would be a great deal of public interest.

Discusslon Points

- Dr. Barrett asked whether the complaint had been filed with another group within CDC, or whether Mr. Stockin viewed this venue as his formal complaint.

- Mr. Stockin replied that they were using the Subcommittee as a conduit to provide this information and complaint to CDC, since the issue is ethical by definition. He hoped that they could highlight and investigate the issue further, within their scope.

- Dr. Barrett offered to speak with Mr. Stockin regarding other ways to raise the issue within CDC. There could be other approaches for dealing with his concerns.

- Dr. Coughlin thanked Mr. Stockin for sharing his perspective with the Subcommittee. He asked whether the Division of Oral Health had been contacted. That Division's Associate Director for Science is a dentist by training and has been a committed public health professional for decades.

- Mr. Stockin replied that they opted to come to the Subcommittee because the nature of the information and complaint were professionally embarrassing to the Division of Oral Health. They have requested information from the Director of Oral Health and received evasive answers. Senators and state legislators have also sent specific questions, which have not received specific answers. He understood that the Subcommittee has a limited scope, but its outside input and influence might be beneficial.

- Dr. Hooyman asked for more details regarding the Lillie Center that Mr. Stockin represents. He added that the Subcommittee should consider procedures regarding public comments made to the Subcommittee. His understanding was that the public commentary was intended to focus on the agenda. Dr. Barrett specified that public comment could be about anything, regardless of whether it is on the agenda.

- Mr. Stockin replied that the Lillie Center is a public health and environmental health training firm.

- Ms. Kinlaw noted that Mr. Stockin's comment represented the first time a complaint had come to the Subcommittee, so they should determine their role, today or in the future.

- Dr. Magruder commented that the issue of fluoridation has been debated rigorously in many communities across the nation as they decided whether to fluoridate their water supplies. In most circumstances, the issue of the quality of studies that show that routinely-used fluoride levels do cause harm has been called into question. He asked for specific studies that have been recently published in journals that would refute the conclusions that communities have reached over the years.

- Mr. Stockin answered that United States agencies and other groups have gathered data that is not being shared and that is logically inconsistent with the stance held by the Oral Health Division of CDC. This debate has lasted for some time, but the National Research Council has now concluded that certain subpopulation groups are susceptible. These studies are not questioned for their veracity. Some of the systematic reviews that CDC cites to support fluoride's safety are cited incorrectly. The current situation has changed from a question of the credibility of those who are against fluoride, as more evidence is built against fluoride.

- Dr. Barrett said that there are mechanisms for filing data quality complaints, which Mr. Stockin might consider. The Ethics Subcommittee can discuss any potential role that they might play to address the concerns. She said that she would work with Dr. Macklin and the Office of the Chief Science Officer, as well as the Office of General Counsel.

- Mr. Stockin said that this issue is an ethical one and represents a "case study" of applying the Public Health Ethics Code to practice.

- Dr. Macklin and Dr. Barrett thanked Mr. Stockin for attending.

- Dr. Coughlin noted that the National Center for Chronic Disease Prevention and Health Promotion has a staff person who works with a number of outside organizations, including groups that represent the Hispanic community. She works in the Office of the Director and is an outstanding public health advocate and an advocate on behalf on the Hispanic community. He suggested her, Blanca Torres, as a potential liaison for Mr. Stockin.

Discussion of Next Steps: Development of Case Study

Dr. Macklin returned to the published agenda to complete the discussion on pandemic influenza. Dr. Macklin directed the group's attention to the case study created by Roberto Garza and others, indicating that Mr. Garza explained that he worked with other members of the Public Health Ethics Committee to offer an approach to provide practical insight into how to implement or interpret the guidelines on pandemic influenza. A case study seemed to be a good vehicle to generate discussion and to further "unpack" the ideas in the ethical guidelines. With that in mind, they created a case study, which would benefit from the insights and opinions of the Subcommittee. Members of the Public Health Ethics Committee Steering Group have already provided their feedback on this early draft of the case study.

Dr. Schwartz said that some technical issues regarding the case study need to be discussed. Further, CDC is drafting a document for HHS and the federal government to guide employers who wish to stockpile antiviral drugs. Now that the production capacity has increased, it is appropriate for employers to make decisions about whether they want to stockpile, so they will receive guidance. Choosing this topic for a case study is good, but it must be consistent with the technical information and with the guidance that is being created. He offered to share the guidance.

Dr. Macklin noted that one of the questions they had been asked to consider related to the relative strengths and weaknesses of using case studies to add value to the ethics guidelines. She replied that case studies are extremely valuable in educational settings because they prompt discussion and lend concreteness as they encourage people to think through problems. Case studies are so specific, however, that it is often not possible to generalize from a case study to other items that are in the guidance document. The issues that arise in this case study come from the specific situation of stockpiling by a private entity, which may limit its generalizability to the rest of the guidance document. The issues that face private entities may not apply to a public entity at any level.

Discussion Points

- Dr. Levine agreed that using case studies to teach ethics is constructive and useful. He felt that this particular case study used concepts that are familiar in ethical discussions in ways that are not familiar. For example, the subtitle of "self-determination" includes a discussion of the authority of the corporation to be self-determining. In ethics, however, self-determination usually refers to rights of individuals. He further felt that the discussion of beneficence, a limited ethical principle, to be problematic. As envisioned by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, it applies to research conducted or supported by the federal government. It would also apply in most cases of research carried out with funding from private sources. However, it is not at all clear that it applies to private corporations in the course of their customary business. The National Commission embedded in its discussion of beneficence the concept of non-maleficence, the ethical requirement to refrain from doing harm.

- Dr. Hooyman recalled that case studies are being developed to provide an opportunity to speak to the pandemic influenza guidance document so that when it is rolled out internally or to other agencies, people will have cases for referral.

- Dr. Arras applauded the work that had been done on the case study so far. He shared Dr. Levine's reservations regarding the use of certain terms such as beneficence, which is problematic in the context of a private, for-profit company. The use of beneficence in this case focuses attention on the need for the study to have a wider view to encompass business ethics. Corporations may have obligations of beneficence and justice like people do, but the majority view is likely to be that a company's only ethical obligation is to increase the wealth of its shareholders. In this scenario, beneficence comes at the company's, and shareholders' expense. If a private company is the focus of the analysis, then more work will be needed to fit it into the larger ambit of business ethics.

- Dr. Semaan commented that the meeting's agenda included discussions of case studies, ethical consideration for non-research data collection, and preparedness for emergency situations and public health ethics emergencies. Investigations of case contacts do not have guidance for emergency situations, in which the protocol does not fall under IRB or non-research activities such as surveillance. Dr. Cetron's situation could serve as a "case study" for their discussions of non-research data collection and how to respond to them in emergency situations.

- Mr. Jennings felt that the case study was well-done, but he was not clear regarding the context in which it would be used. As written and structured now, it would be helpful in a classroom-type setting in which a facilitator or instructor would ensure that the subsequent discussion was robust. In another setting, such as inviting commentary on it via a website, there might be too much material, and it might not be appropriately structured. For example, the points under "Assumptions" would be better stated as open questions to stimulate discussion. An alternative approach would be to post the scenario, but remove the labels about the ethical principles. A list of questions could be provided for commentary. If the case study is meant to serve as a base of comparison, then it needs to have a "voice," specifying the source of the answers. Each scenario could include a few short commentaries regarding the point being illustrated.

- Dr. Barrett specified the CDC Public Health Ethics Committee would work with Dr. Levine, Ms. Kinlaw, and Mr. Jennings to obtain additional guidance on the development of the case studies.

- Dr. Macklin returned to the question of whether the development of cases should be tied more directly to the guidance document. In this approach, the guidance document would be general, where the case studies would specifically illustrate the tension or dilemma. Dr. Barrett replied that this case study was intended to serve that purpose.

- Mr. Garza thanked the Subcommittee for their insights.

Discussion of Next Steps: Review of Public Input on Ethics Guidance

Dr. Barrett asked the Subcommittee to consider the public comments on the Ethics Guidance, asking whether the document needs to address any of the comments. Dr. Macklin noted that in the early stages of the guidance development, a CDC staff member raised the question of whether the document would address ventilators. They decided not to include ventilators,

because boundaries needed to be drawn in this document and ventilators could be addressed in another form. Many of the public comments dealt with ventilators, which suggest that they are an important topic. Other topics included questions of family members, which should be addressed in another paper.

Discussion Points

- Ms. Kinlaw viewed the request for a mention of ventilators as similar to the question of whether the paper should be extended in practical ways through the mechanism of case studies. She sensed that some issues needed to be "fleshed out." She asked the Subcommittee whether they should extend their thinking into ventilators. As there is overlap between this guidance and the work that Mr. Jennings and Dr. Arras are doing, they should be thoughtful about how to work in concert.

- Dr. Levine observed that the comments were largely positive about the guidelines. The comments also bring several issues to the fore, from dealing with institutionalized persons, responding to the needs and expectations of healthcare workers and first responders, and others. He thought that it was a good idea to address the issue of ventilators; however, he did not believe that the pandemic influenza guidelines should be revised to include ventilators. Rather, a separate annex or addendum could serve as a follow-up to the guidance. If the Subcommittee and Ms. Kinlaw were willing, he indicated that he would work on this annex.

- Dr. Hooyman asked whether, since the Subcommittee, as part of the Advisory Committee, had solicited public comment, they needed to respond to each of the comments. While they might not be legally bound to respond, those who offered comments might appreciate knowing that they had been heard. The question was procedural because they are setting patterns and expectations of behavior for future guidance documents.

- Dr. Macklin said that they should discuss not only whether they are bound to respond to public comments, but also whether they are even bound to seek public comments for each document that the Subcommittee produces.

- Dr. Magruder reminded them to consider CDC's boundaries as a federal organization. Many people might suggest that ventilators are a clinical consideration, which would fall under the purview of the Health Resources and Services Administration (HRSA) rather than CDC.

- Dr. Barrett added the issue of ventilators has been raised internally within CDC, so there is interest within the agency to hear guidance on ventilators.

- Dr. Ellis noted that ventilators are not part of the "push package" from the Division of the Strategic National Stockpile, but they are in the stockpile, so it is appropriate for CDC to address ventilators.

- Dr. Koenig noted that in her experience with other committees, public comments are solicited earlier in the process and integrated into a draft version of the document, not after it has been completed and approved. Regarding ventilators, she noted that the Minnesota State Department of Health has commissioned a report on allocation of a range of items and materiel, including ventilators. In other ongoing efforts, ventilators are considered to be scarce resources. Further, she asked whether the names of the commentators were removed from the responses. Dr. Barrett replied that she removed names to respect

privacy. Dr. Koenig replied that the comments were made publicly and urged that the names of the commentators be included.

- Dr. Hooyman noted that the question of whether to include names is another procedural issue that the Subcommittee has not dealt with before, so they should decide how to proceed.

- Dr. Levine observed that the New York State Commission on Life Sciences filed a document on ventilators, which Mr. Jennings and Dr. Arras cited in their draft paper.

Ethics Subcommittee Procedural Issues

During this session, the following issues were addressed:

- ❑ Revision of Ethics Subcommittee Policies and Procedures Document
- ❑ Selection of New Members for the Ethics Subcommittee
- ❑ Update on the Advisory Committee to the Director
- ❑ Evaluation of Public Health Ethics Activities
- ❑ Password-Protected Internet Site for Ethics Subcommittee Members

Dr. Macklin began by addressing the revision of the ethics subcommittee policies and procedures document. Comments had been collected, none of which were significant. The additions and deletions are reflected in the new draft.

Discussion Points

- Dr. Hooyman asked about an item regarding Subcommittee voting on page three of the document. He understood that as a Subcommittee of the Advisory Committee, in order to take a vote or to take formal action, a member of the ACD needed to be present in addition to a quorum of the Subcommittee.

- Dr. Barrett replied that in order for the Subcommittee to meet, a member of the ACD needed to be present. That point can be clarified in the document.

- Dr. Macklin shifted the discussion to potential new Subcommittee members.

- Dr. Barrett shared a list of names that had either been submitted to her, or names of people who contacted her directly because they were interested in serving on the Subcommittee. Four current Subcommittee members are scheduled to rotate off of the Subcommittee after the next meeting.

- Dr. Macklin wondered whether it was acceptable to be "lobbied" by an interested person. She said she only knew two people on the list, both of whom were well-suited to serve on the Subcommittee.

- Kimberly Geissman commented that one person on the list was involved in writing the first CDC Ethics Curriculum that was put online in 1996.

- Dr. Hooyman asked whether it would be helpful for the Subcommittee to think of its membership as including a range of persons with expertise in different areas such as ethical theory, public health ethics, research ethics, bioethics, and related fields. A multi-disciplinary and multi-experienced committee membership will be beneficial. He wondered about the policies and procedures regarding how people are nominated to the Subcommittee.

- Dr. Barrett clarified that she makes the recommendation to the Executive Secretary of the ACD, who then approves the appointments. There is no formal approval from HHS.

- Ms. Kinlaw returned to the question of the degree to which they wanted to think about the Subcommittee's composition to ensure that some diversity of disciplines is represented. It will be hard to determine the selection criteria by which the four new members will be identified, unless they wanted to ensure different types of representation.

- Dr. Hooyman added that gender and ethnicity diversity adds richness and robustness to their conversations.

- Dr. Ellis suggested that the disciplines be extended to include someone experienced in crisis risk communication.

- Dr. Macklin noted that there were more names on the list than there are vacancies on the Subcommittee, and she wondered about the next step.

- Dr. Koenig expressed confusion about the process. It seemed unusual to her to make recommendations for Subcommittee membership or for the Subcommittee to choose its successors. If they plan to continue to work in public health genomics, then she suggested including Subcommittee members who have experience in that area.

- Dr. Barrett said that as the Designated Federal Official, she is responsible for selecting Subcommittee members. She can solicit input from the sitting Subcommittee.

- Dr. Levine noted that several names had been submitted to Dr. Barrett, and she had not made judgments regarding those people. He further noted that Dr. Macklin had only "heard" of two people on the list. This is a cause for concern. People who are significant contributors to the filed of ethics as it relates to the development of policy are generally well-recognized by others in the field. However, he said that in his service on this Subcommittee, he has met new people who were excellent selections.

- Dr. Barrett said that her intention had been to begin the discussions and to hear input and thoughts from the Subcommittee regarding good potential members. She will make her selection taking into account the Subcommittee's input, as well as consideration of diversity and categories of expertise. She will also consider input from the CDC Public Health Ethics Committee. The Executive Secretary of the ACD will then approve or disapprove the selections.

- Dr. Dixon asked whether there had been a formal or informal call for nominees.

- Dr. Barrett replied that there had not. Putting out a call in the Federal Register was an option that could be considered. People must be identified so that they can come onto the Subcommittee before the February 2008 meeting.

- Dr. Dixon was not sure how broad the call was required to be, but a formal request might be helpful. It might also be helpful to think about the special skills such as genomics or international health that would benefit the Subcommittee. These thoughts should not interfere with CDC's ability to make a decision, but to help make a wise decision.

- Dr. Barrett said that a Subcommittee does not have to follow the same nomination rules as the parent committee. There is flexibility in how they identify people.

- Mr. Jennings felt that the Subcommittee had come a long way in the last few years. They are a functioning body that yields solid products. Their productivity may have been due to their chemistry, their ability to work together, and their shared commitment to the Subcommittee rather than to their specific areas of expertise. Subcommittees such as this one can become more institutionalized, and the selection process more formal and perhaps more equitable as time goes on. He did not feel that this Subcommittee was at that point yet and suggested that they remain sensitive to the personalities and working relationships that make the Subcommittee work. The group dynamic is more important than having specific categories of expertise. These thoughts make the selection more difficult at this point. He offered to provide additional names of potential candidates. He also observed that the working relationships on the Subcommittee have arisen because they are a group of generalists in public health ethics. They are quick studies, not experts—they are surrounded by their CDC colleagues who are public health experts. He advocated for maintaining this model rather than attempting to identify ethicists who are also experts in certain areas such as genomics. He hoped that the Subcommittee would not become too specialized, as the Subcommittee works at its best when they all talk about everything.

- Dr. Barrett felt that the Subcommittee would benefit from a member who could bring the perspective of state and local health departments.

- Dr. Dixon asked who was slated to rotate off of the Subcommittee. Dr. Barrett replied that Dr. Koenig, Dr. Levine, Dr. Macklin, and Dr. Thomas were at the end of their terms. She also noted that the Subcommittee's two ACD members would also be leaving. Their terms with the ACD have expired, but their terms were extended by six months so that they can work with the Subcommittee through the end of the year. The ACD nomination package has been prepared and is being reviewed. Twenty-one members will be nominated, and all but two of them will be new. There will be a new chair of that committee, and it is anticipated that the ACD will meet on November 1st.

- Dr. Magruder concurred with Mr. Jennings's comments regarding taking a "generalist" approach. Part of the Subcommittee's role is to help CDC personnel reach a point of comfort with ethics. This process will function more effectively if the Subcommittee is geared toward expertise in ethics rather than in public health. There is no shortage of public health expertise at CDC; the Subcommittee needs to help those public health experts gain knowledge in ethics. He also mentioned if there is a distinction between academic ethics and practical ethics, it might be beneficial to move from academic perspectives to practical perspectives, which would help them complete documents that will be of immediate utility to the field.

- Dr. Koenig asked about the process that was used for the first selections for the Subcommittee. Dr. Barrett said that she would speak with Dr. Snider, who was involved in that process.

- Ms. Kinlaw noted that the Subcommittee had "gelled," but that process took time. Each of the Subcommittee's significant projects had taken a great deal of time. For instance, she and Dr. Levine worked at length on the pandemic influenza document, and there appeared to be an opportunity to extend it. She wondered whether they could consider extending some of the members' terms.

- Dr. Barrett said that members can serve for up to four years. Some members will have three-year terms, and some will have four. If there was agreement, they could ask some of those who were about to rotate off of the Subcommittee to serve four-year terms. However, they do not want to create a situation in which everyone rotates off at once, after four years.

- Ms. Kinlaw noted that some of the Subcommittee's activities have benefited from continuity. She felt that they had just gotten to "the meat" of what the Subcommittee was. It would be a great loss to lose four members, and it would take time to bring new members up to speed. While this situation will always arise when members come and go, she wondered whether shifting the rotation for a year ought to be considered.

- Dr. Barrett clarified that members could not go beyond four years, but they could extend from three to four. She noted that they are also losing two ACD members at the same time, so they will have new ACD representatives at their February meeting. She asked the four who were rotating off to indicate to her if they were willing to remain for another year, but she would have to ensure that the entire Subcommittee will not be lost the following year.

- Dr. Barrett proceeded to follow up on the development of an evaluation mechanism of public health ethics activities. Two documents were developed: 1) an assessment of baseline knowledge among CDC staff, and 2) an evaluation of issues that the Ethics Subcommittee or the CDC Public Health Ethics Committee takes up and whether the program is satisfied with the outcome.

- Dr. Macklin suggested that they revisit that question at the next day's meeting, time permitting.

- Dr. Hooyman suggested that the Policies and Procedures include a "sunset clause" so that if the original concept for the Subcommittee was to build internal capacity at CDC around ethics competency, there is a point at which the Subcommittee disappears, or consists of internal CDC staff with an external consultant.

- Dr. Barrett thought that there would always be a role for outside input. They do want to build internal capacity, but considering how the Subcommittee's agendas have grown, there is a clear need for their work. They are working to create a process for which issues can be addressed at CDC and determinations made about which issues should be brought to the Subcommittee so as not to overwhelm it.

With no further business posed during the first day, Dr. Macklin officially adjourned the meeting at 6:10 PM.

Call to Order

Dr. Macklin called the meeting to order at 8:33 AM on August 10, 2007. She then introduced Dr. Bernhardt.

Ethical Issues Relating to CDC Partnerships

Overview of the National Center for Health Marketing

Dr. Jay Bernhardt Director, National Center for Health Marketing (NCHM), CDC, greeted the group and said that it was an honor to be able to address them. NCHM is a new center within CDC, and health marketing is a new principle at CDC and in public health. The definition of health marketing is based on the American Marketing Association's definition of commercial marketing:

"An organizational function and set of scientific processes for creating, communicating, delivering value to customers, and for managing customer relationships in ways that protect and promote the health of diverse populations."

The greatest difference between health marketing and commercial marketing lies in commercial marketing's goal to benefit the company and its stakeholders, where health marketing seeks to protect and promote the health of the people in a manner that is consistent with CDC's mission. Health marketing also uses "scientific processes," where commercial marketing does not. All of CDC's work is informed by science and by evidence-based practice. The use of the word "customer" is in line with CDC's perspective as it moves toward being a customer-centric organization. "Customer" appears in CDC's strategic imperatives, and NCHM is responsible for communicating with CDC's customers. The public is one of CDC's customers, including the communities, families, and populations that CDC serves. Other customers of CDC are health professionals at all levels and in all sectors and its partners. Further, marketing is not just advertising. It is about creating relationships and creating value for the customer. Health marketing is a multidisciplinary area of practice that should not replace other disciplinary practices that inform health marketing.

This center's work is science-driven and informed by many kinds of science beyond traditional health and public health sciences, such as: communication science, including health communication, risk communication, visual communication, and others; science of marketing; and behavioral and social sciences. The center includes staff members with expertise and training in all of these areas, and the center's vision is "a world where all people actively use accessible, accurate, relevant, and timely health information and interventions to protect and promote their health, their family's health, and the community's health." This vision is an "activist vision" and represents a departure from traditional health communication and traditional CDC communication, in which the agency's obligation ends where information is made available. In the past, for instance, a new discovery might be shared in a journal, on a website, or at a professional conference. This center argues that the ethical and moral obligations of CDC requires another step in which people actively use the information. This goal reaches not

only the type of information, its accuracy and accessibility, but also motivations of individuals to use it. The information should be relevant and easy to use so that more people will use it.

The center's mission is "to protect and promote health through collaborative and innovative programs, products, and services that are customer-centered and high-impact." Almost everything that the center does is a collaborative endeavor. The collaborations are primarily with other parts of the agency as they work with each center's subject matter experts, communicators, and others. The emphasis on innovation includes a charge to move CDC forward in its communication and marketing approach. In FY08, NCHM has an innovation set-aside to create, seed, and evaluate innovative approaches to marketing, communication, and problem-solving.

The center's values apply to center staff as co-workers and employees that work together as well as to their external work. Their communication should be clear, accessible, and candid. The center's vision, mission, and values were developed with an inclusive and collaborative process. The center is relatively new, and from the beginning, employees have been embraced inclusively. The center includes about 650 staff, about 450 of whom are full-time employees. They maintain a number of operational offices in the Office of the Director. They have a Business Office as well as a Preparedness Team, which also works with coordination regarding pandemic influenza. The MMWR is operated out of their Office of the Director, and the center also has a Global Communication Marketing Team. Further, the center operates "CDC Information," a toll-free hotline that is available in English and Spanish at any time to answer any questions. The Health Communication Science Offices are a major part of the organization. The Senior Communications staff in every other national center are matrixed to the NCHM as they remain imbedded in their individual center, but the matrix allows for high-level communication and collaboration. Matrix management is a new phenomenon at CDC, and they are committed to improving it. NCHM has four Divisions:

- The Division of Creative Services, which provides services such as television, audio/video, and multimedia production and broadcast. All of CDC's graphic designers and writer/editors have been consolidated and centralized in this Division, but they remain imbedded in other centers to continue to serve their needs.

- The "E-Health," or Electronic Health Marketing Division, is responsible for the CDC.gov website in collaboration with the informatics center and other parts of the agency. The site has been updated and improved recently to make the interface better for both public and professional users. They are moving into using new media and innovative social media, including Internet-mediated communication using mobile phones, the Web, and other tools.

- The Division of Health Communication and Marketing conducts a number of important activities, including the Community Guide for Preventive Services, CDC's research synthesis around various community-based preventive efforts. The Guide's recommendations and findings are "gold standard" for public health prevention. The Risk and Emergency Communication Branch leads all of CDC's emergency risk communication during outbreaks and other disasters. This division includes a Marketing and Research Campaign Branch, which includes audience analysis, campaign management and coordination, and marketing planning.

- The Partnership and Strategic Alliance Division is a critical piece of CDC's work and would be discussed further.

Dr. Bernhardt turned to the question of: Why Marketing? The word "marketing" makes many in public health uncomfortable. In the private sector, commercial marketing focuses on selling products and brands to maximize value to shareholders. These efforts can be direct, or they can occur through layers of intermediaries. Companies use a great deal of information and data to inform their marketing efforts, which is the key to successful marketing in the commercial sector. This endeavor is highly data-driven, and data influence product development, packaging, placement, and promotion.

CDC set the goal of creating a health marketing model similar to the commercial marketing model. CDC has products: science, research, evidence-based recommendations and interventions, and others. CDC's customers exist at two levels: intermediaries are the traditional CDC customers of state and local public health agencies and providers and other health professionals across the country and the world. The general public is also an important customer of CDC. Dr. Bernhardt emphasized that there is no one "public," but many sectors and segments that need to be reached. NCHM is charged with building systems and tools to advance audience research and formative research, and engaging the public and partners. When marketing to professionals, they consider their work a translation of research into practice or knowledge into action. "Disseminating best practices" is the public health parlance for these concepts. In CDC's case, direct-to-consumer marketing takes place through communication and social marketing interventions.

The center uses tools such as its websites, EPI-X, television and video products, Pod casts, and other activities that map to the model of health marketing. They are still formulating how to ensure that all of their efforts operate in unison, since many of the efforts existed before the center did. The center, therefore, has to create a strategy to see that the different pieces communicate and interact. A great deal of strategic planning is ongoing across CDC. Health protection goals are an important focus. These goals include healthy people, healthy places; preparedness; and global health. The center is actively involved in these efforts and is also working with an internal management tool called the Organizational Excellence Assessment (OEA,) which is being used to set metrics and measures for how CDC will operate effectively and efficiently as an organization to achieve excellence. The Coordinating Center for Health Information and Service is pursuing priority planning in the areas of partnerships; E-CDC, or electronic communication; Integrated disease surveillance and monitoring, and scientific communication.

NCHM developed a strategic map, and its divisions and offices are creating measurable objectives and actions to achieve the strategic priorities with two- and five-year targets. A tracking and monitoring system will determine performance-based management and progress toward these targets. The Center has four strategic goals and 20 strategic priorities under those goals. Their work cascades from CDC-wide priorities and the center's values. NCHM has four areas of focus: increase the impact of health marketing sciences; achieve consistent, high-quality service; expand the strategic and innovative application of the center's work; and improve and sustain their systems.

The center is responsible for, or collaborative on, most of CDC's campaigns, some of which bring ethical and conceptual issues. These campaigns include: Chronic Fatigue Syndrome, influenza awareness, violence prevention, fruit and vegetable consumption, HIV awareness, and more. Some of the campaigns are broad, where others are more narrowly targeted. They use a variety of communication media. The center also manages many of CDC's scientific communication channels, including the *Morbidity and Mortality Weekly Report* (*MMWR*), EPI-X,

the Health Alert Network (HAN), and the Public Health Information Rapid Exchange, a new tool that connects the CDC to a number of sectors for early warnings. The center does extramural work as well and has three Centers of Excellence in Health Communication and Marketing. The center is participating with the National Institutes of Health (NIH) in a program announcement for health literacy. They will host the first National Conference on Health Communication Marketing and Media at the end of August.

NCHM collaborates on a number of products and also produces its own tools. For instance, the pandemic influenza sector checklist is a tool to aid in pandemic planning and awareness. The website is a scientific enterprise both in the analysis and improvements that have been made and in its use as a health promotion tool to improve people's health. The center coordinates the Leaders to Leaders Conference, an annual meeting that convenes several hundred of CDC's partners to address significant issues that affect health and health systems. The center is expanding its direct-to-consumer products in audio and video. They are creating a weekly or bi-weekly streaming media product , and their radio product will be disseminated across the country. The center operates one of the only HHS blogs, an innovative move. CDC has an avatar in "Second Life," an online virtual universe. As a collaborative center, they have built a number of collaborative bodies across the agency, including the Excellence in Marketing Committee, comprised of agency leaders in marketing and communication. The Excellence in Partnership Committee and a number of councils and governance bodies will help build internal bridges and networks. One of the center's priorities is to build similar networks and bridges externally. The center is accountable for, but does not always lead, all of CDC's public communication and engagement, all of CDC's professional communication and engagement, and partner communication and engagement. Another communication activity at CDC is the Office of Enterprise Communication, which operates out of the Office of the Director. This group is responsible for internal communication to CDC employees, news media relations, and public relations issues management.

NCHM faces specific ethical issues. As leaders of campaigns, it is logical for them to question whether campaigns are an appropriate strategy for public health. Many would argue that media or marketing campaigns may be too paternalistic and may affect self-determination. In this case, beneficence may be challenged, depending on how the campaigns are constructed and conducted. Are they participatory, or top-down? To what extent are communities involved in the work? Many of CDC's campaigns have been done "by the book" in a participatory and engaging way, while other CDC campaigns have operated using a top-down model. Can information change behavior? Communication and marketing campaigns have a purpose, but complex behavior change in this modern social milieu, such as smoking cessation or dietary and physical activity improvements, many do not think that just putting commercials on the air will affect change. The ethical issue is: When should campaigns be used? Do these techniques follow best practices? A very important ethical question concerns unintended consequences. For instance, if a campaign regarding the dangers of drinking alcohol and driving includes a poster of a person in a wheelchair, implying that "this could happen to you if you drink and drive," the message could be powerful. What resonance does it have with people who are already in wheelchairs? Does it create stigma? Could those "fear messages" or consequence-driven messages blame victims in certain circumstances?

Another concern is co-branding. Marketers know that co-branding messages, if done correctly, results in more effective and powerful messages. However, this approach brings ethical as well as regulatory issues. Co-branding involves a collaboration with another entity in which, for instance, two logos appear on materials.

Access to information raises ethical questions. Access applies to the targets of their efforts as well as to the extent to which people have access to the information. For example, should campaigns target the highest-risk groups that bear the highest burden of disease or disparities, or should they take the approach of population-level interventions to move the entire curve. Equity of access to information relates to the phenomenon of the "knowledge gap." There is a difference between access to health information, media, and communication information between the "haves" and "have-nots" in the United States and around the world. This gap is pronounced in health. A significant portion of this country cannot access health information as it is currently presented. Health literacy applies not only to whether a person can read a pill bottle or an informed consent form, but also to whether a person can understand health information and messages that are on the Internet or in the media. The "digital divide" affects populations without Internet access. Broadband access has plateaued in this country, as its price point has not changed. There is no prospect that current levels of household connections to the Internet, which stands at a little over half, will change soon. If electronic media is an important communication tool, then what are the implications for communities and people who do not have access?

Discussion Points

- Dr. Macklin asked for examples of "top-down," "non-participatory" campaigns versus campaigns that are more participatory. She also asked to hear the arguments that campaigns are paternalistic.

- Dr. Bernhardt could not name a specific campaign that could be labeled "top-down." He provided the example of a good campaign, the VERB campaign. It had unusually high funding levels, but involved "tweens" in its planning. It used paid media, earned media, and community-based participatory work in schools and community organizations. It engaged partners, collaborators, professionals, and the target audience, including youth and parents, throughout the campaign's duration.

- Dr. Snider supported Dr. Bernhardt's observations. He offered the example of the Swine Flu campaign, which was expert-driven. The Advisory Committee for Immunization Practices makes recommendations, which could be called campaigns, and derivatives of those recommendations drive campaigns (such as the Human Papilloma Virus (HPV) vaccine), but the Advisory Committee operates differently. Members of the public often attend their meetings, along with subject matter experts and committee members. A great deal of marketing research was done before and after the vaccine was released. Campaigns regarding folic acid included research into what would motivate young women who could become pregnant to take 400 mg of folic acid per day. This partnership fell apart because the marketing research indicated that messages that would motivate this audience were not true to the science. CDC and its partners could not agree on a compromise. CDC is moving in the direction of participation. Examples of paternalistic campaigns are older, but they probably have not disappeared.

- Dr. Arras said that language is extremely important, and he focused on using the word "customer," which implies a commodification of health. If they hope to help citizens become more involved in their own health, then casting them as "customers" may not be the best choice.

- Dr. Bernhardt replied that they had heard similar comments in the past, both internally and externally. In the center's work and strategic mapping, they have explored various terms.

CDC is using "customer" more frequently across the agency. The commodification that may be implied by using this term is important. The word "consumer" has been suggested to describe the people that they are reaching with their efforts, and he feels that "consumer" is a more commodified term even than "customer," which is a standard term in marketing and communications parlance. "Audience" is also used, but it is a passive term, where customers tend to be more engaged. More dialogue around the issue would be helpful, and they are open to hearing other suggestions. They have also thought about the term "citizens," but the term can be exclusive, so if a government agency uses that term, it could give the impression that some people are being excluded.

- Dr. Dixon said that public health uses "top-down" messaging consciously and effectively. For instance, the Agency for Health Care Research and Quality (AHRQ) sponsors the United States Preventive Services Task Force. This group is an assemblage of experts that looks at evidence to make definitive decisions about effective practices. Their recommendations become standards of practice. That top-down, expert intervention has a significant effect on health and is generally beneficial. He hoped that they would not conflate paternalism and top-down messaging, which has a role in public health.

- Regarding the terminology used, Mr. Jennings said that there is no "perfect term." It is important then to be explicit and thoughtful about the assumptions that are built into the terms that they use. Terms such as "consumer" imply individual motivation and activity that is self-interested and self-referential. Consumers strive to satisfy their preferences and wants as they make the most of their money. "Citizen" has formal and legal implications, but it also carries the traditional meaning of an individual agent that is motivated not by self-interest and the desire to consume, but by a sense of common good, interdependency, and membership in a larger "whole." Whatever terms are used, they should determine whether their health marketing activities are designed to deliver information and services which are consumed, or to assist and serve individuals' interests as they educate and broaden their moral and civic imaginations. He turned to the question of health literacy, which has been discussed a great deal in the literature. "Literacy" can be defined broadly so that it reaches beyond the question of an ability to read and understand information to incorporate the capacity to act effectively upon that information. In that sense, developing the population's health literacy is an educational endeavor that should broaden the civic and moral imagination as it provides empowerment and institutional change. The capacity to act on information is not solely a function of an individual's knowledge and understanding, but also a function of the structures in which the individual lives and what the individual is allowed to do. Health marketing, therefore, can be seen not under the commercial marketing model, but as a civic, ethical, and social change enterprise.

- Dr. Semaan offered examples of ethical questions in social marketing. Posters for HIV prevention and awareness must not seem to blame the victim or to hide a person's infection. In the area of smoking, some people who quit smoking start again because even though they know that smoking is not good, they have not been presented with beneficial social alternatives, such as for people who smoke with their employers or colleagues. Further, vaginal douching is associated with a number of negative health effects, but sharing that message is difficult when douching has cultural meaning for certain populations.

- Dr. Koenig noted that NCHM is relatively new within CDC, but many of its activities and products existed before. She asked about the past history of the center staff.

- Dr. Bernhardt explained that parts of the Office of Communication (OC), parts of the Public Health Practice Program Office (PHPPO), and parts of the Epidemiological Program Office (EPO) were combined to create the center.

- Dr. Snider added that this center is a combination of older offices with some new additions. The Informatics Center is a new effort as well, even though CDC was involved in informatics previously through a small program in the EPO. Some activities at the Central Information Technology Office focused on informatics as well, but informatics was not used as a tool to help improve public health.

- Dr. Koenig asked whether the new center was related to what used to be called "health education."

- Dr. Bernhardt replied that health educators, health promoters, health communicators, and behavioral scientists work throughout CDC, and all health educators and communicators have not been consolidated into the Marketing Center, but remain at various levels in the agency.

- Dr. Koenig endorsed tailoring messages to particular populations. She expressed concern about the language of "consumer" and "customer" as well as with the concept of marketing. She felt that they may run the risk of sending the message that health is one of a range of consumer products that can be purchased in the marketplace. The message might imply that individuals can keep themselves healthy simply by making the right set of consumer choices, and the government's responsibility is merely to lay out the range of choices. This notion is at odds with public health goals. Improving the nature of communication is an excellent goal, but she hoped to avoid giving the impression that people have sole responsibility for their own health. This approach puts health too much in the private system and is an issue in clinical medicine as well.

- Dr. Bernhardt said that these concerns are inherent in marketing. Words have certain attachments and meanings, and they try to represent health communication, marketing, and partnerships that are consistent with public health principles and ethics. They use the term "engagement" when referring to the public and to their partners. This term captures principles of connecting, engaging with, and empowering the people that they serve. They hope that their priorities, collaborations, and actions address and alleviate any concerns that the terminology may raise.

- Dr. Snider was on the Executive Leadership Board that voted to move CDC in this direction. There was fear that CDC would follow a model in which their responsibility stopped at conducting the science and presenting it, not having an interest in the next steps. Often in this model, nothing happens as a result of the science. Their intent was to improve public health not only by targeting individuals, but also by including groups such as local governments that can make systems changes, institutions, health professionals, workplaces, and other entities. CDC aims to work with these different audiences regarding ways to improve health, either through individual behavior change, structural change, or societal changes. Their "audience" is vast, and they hope to institute a variety of changes. They should use appropriate language to characterize their efforts and intentions, which is difficult to do in a few words.

- Dr. Levine pointed out that as many as 30% of the residents of United States cities are functionally illiterate, regardless of subject matter. The statistics are higher for numerical illiteracy and for scientific illiteracy. He was not sure how to consider numbers for health literacy and asked for clarification regarding what "health literacy" means.

- Dr. Hooyman said that this direction is exciting for CDC. He understood that CDC has no regulatory power, so he wondered how CDC could bring about behavior change. Perhaps the only way CDC can change behavior is by leveraging its strong brand and scientific background. Because of the strength of CDC's brand, guidelines that it provides to state health departments are usually used. Acute care and clinical care settings have also undergone changes in their language and direction. Rather than a "physician-patient" relationship, the model has shifted to a "customer" relationship. The influence of business models on the healthcare setting has contributed to this change. Hospitals operate according to business models. These shifts apply to ethical questions in partnerships and marketing. The business model can co-opt the scientific model, but they operate on different paradigms. In the business model, marketing can create markets, which can be a double-edged sword. As partnerships are considered with outside vendors and contractors, they must keep in mind that potential partners have the primary purpose of increasing shareholder value. This approach is not consistent with CDC's mission, so working with these different structures will be challenging. He asked whether NCHM has an ethics infrastructure.

- Dr. Barrett replied that Dr. Dixon was the ethics representative for this center. Dr. Dixon added that the Division of Partnerships and Strategic Alliances includes four staff members who are active in ethics.

- Dr. Hooyman wondered whether health marketing was entering public health schools and whether the profession was changing at the degree level.

- Dr. Thomas commented that NCHM will have to balance a true marketing approach and a retreat into the idea of CDC as an isolated scientific organization that does not work with the private sector. He hoped that they would not return to an older model. He then turned to the idea of "agency" in terms of moral responsibility. The NCHM intends to share information with individuals so that individuals will change their behavior. This approach implies that the agency for change lies at the individual level. The individual will understand what needs to change and will then make that change. Agency also rests at the institutional and societal levels, such as how cities are structured and the rules that affect entire populations, such as the use of passive restraints, which do not require individual, voluntary decisions. They should be based on sound science. Sometimes information changes behavior, sometimes it does not. Targeting structural changes will change "the whole curve," as opposed to a target to structural changes. The communication in this case is targeted to such groups as industry and legislators.

- Dr. Snider pointed out that in the area of tobacco, CDC informs states and communities that if they implement a set of restrictions on smoking, then they will see certain effects. CDC does not force states and communities to enact these measures, but indirectly encourages them to do so.

- Dr. Thomas said that at times, in order to affect the whole public without requiring each individual to make a decision and to have the health literacy and basic literacy to make these decisions, then structural interventions are key. Audiences for messages can include legislators and industry.

- Dr. Coughlin noted that at times, unintended consequences can be positive. For example, a health marketing campaign to reduce HIV risk could also reduce risk of other sexually-transmitted diseases (STDs) and could have beneficial impacts on unintended pregnancies. He further commented that "stigmatization" is a complicated and nuanced ethical and practical question. For many years, health education materials for cervical cancer prevention rarely mention that cervical cancer is predominantly caused by HPV. This choice probably grew out of a desire not to stigmatize women with cancer. More recently, people argued that CDC should empower women and men to reduce their risk of HPV-related cancer by providing scientifically accurate information. On the issue of paternalism, it may be inappropriate for the government to lead health and social marketing efforts in certain areas. He offered the example of CDC potentially funding projects to encourage abstinence among women in their late 20s. This decision raised concern, since people in their late 20s likely have opinions on this topic and are not likely to listen to messages from the government about it. The notion that the government should not play a role in advocating for lifestyle changes has been discussed in bioethics and public health ethics literature.

- Dr. Benjamin supported NCHM's efforts and noted that CDC has a strong brand. According to most surveys, CDC is the most-recognized and most trusted federal agency. A new aspect of their work is its scientific base. Public health uses a great deal of brochures, for instance, with little idea of their effectiveness. Brochures look good but are generally not targeted. Public health entities often produce reports without including policy recommendations and without helping to translate the information so that it is useable. The communication of information is changing rapidly. Communication occurs faster than ever before, and more information is available as well. Someone must interpret that information and put it into perspective. This approach allows for transparency and full debate on the issues. Without the Internet, the SARS situation would have been very different. It also affects their capacity to effectively communicate facts, control panic, and get people the information that they need.

- Dr. Bernhardt responded to some of the group's comments, thanking them for their thoughtful ideas. Regarding the definition of health literacy, it is more than accessing information. Much of the research in this area has been medical-model-oriented and focused on clinical communication. NCHM defines "health literacy" as not only being able to read information, but as the ability to access and use information. The center has expertise in this area and hopes to move toward making information more accessible and useable as well as toward affecting systemic change and empowering populations to use information as it is presented. They hope to avoid moving toward an individualistic approach, but rather adhering to a social and ecological perspective of change, including predicting as well as changing behavior. All audiences and all types of changes are needed. CDC has a tremendous brand, which is one of its strengths. They try to guard the brand, but also need to be willing to use it, especially when they consider different audiences such as policymakers, stakeholders, and opinion leaders in order to bring about social normative change. Marketing has power in the area of normative change, as exemplified in smoking cessation efforts. Tobacco control represents policy change, societal change, environmental change at all levels, and the power of using information to bring about

individual change and changing societal norms. These efforts did not happen quickly, but they offer a number of lessons for the future. Further, they are aware that as a government agency, there are limits regarding where they can and should be a leading voice. This role leads to opportunities to collaborate with others who are, for regulatory or impact reasons, more credible sources for certain messages. Regarding evidence, the center has created an evaluation set-aside. An increasing percentage of their work will be devoted to evaluating their activities. Because health communication marketing is under-funded, people are faced with the difficult choice between doing an intervention and setting money aside to evaluate it. The center is mandating guidelines around evaluating its work in order to build the evidence base and to create data to drive their efforts.

Overview of CDC's Partnership Activities and Policies

Mr. Dan Rutz, Acting Director, Division of Partnerships and Strategic Alliances (DPSA), NCHM, introduced DPSA to the Subcommittee. DPSA came into being in order to integrate the agency's work in outside partnerships, to improve inter-agency, cross-cutting partnerships, and to bring outside experts into the process. He thanked the Subcommittee for their service and for bringing their essential areas of expertise to the agency. CDC has an outstanding national and international reputation that is grounded in scientific excellence. This reputation should be enhanced and protected, not abused. CDC's idealism leads it to want to achieve its goals, and partnerships can be important in making the agency even more effective, powerful, and influential. With this in mind, upper management at CDC have moved in the direction of expanding the agency's influence to address issues that remain unresolved. CDC has a sense of urgency regarding public health and for preventing preventable diseases and conditions, and their partnerships should build upon their assets. Partnerships are vital to CDC as well as to its partners. CDC has worldwide respect for its scientific excellence and is the most trusted federal agency. CDC respects the autonomy of states and responds to their needs. Those partnerships are vital. The agency's mission is ethically and morally grounded, and CDC cares about its mission as well as its reputation. A number of benefits are associated with CDC's entering into partnerships.

The agency has very little regulatory power, so its effects on public health depend on influencing people through other channels. CDC can persuade individuals to adopt more healthy behaviors and encourage organizations to implement policies to improve health. Businesses also have an interest in maintaining a healthy populace. They want less turnover and more efficient employees, for example. There is common ground in the two groups' goals. Nearly all of CDC's activities are done in partnership with others; however, as a government agency, CDC can tend toward isolation. Partnerships with the "outside world" help the agency ensure that its work is relevant, practical, attainable, doable, and resonates with the populace. As stated by Dr. Bernhardt, CDC uses its collaborations and partnerships to ensure that stakeholder interests and concerns are identified and addressed through robust public health programs and research. In short, CDC does not produce data and information without first ensuring that the work is on the right track. The agency helps to set public health agendas, so it must listen to its stakeholders. Information is received and interpreted differently by different groups based on a number of factors, such as culture, so the agency must collect feedback. Partnerships help gather valuable feedback and also contribute to the agency's overall diversity.

Mr. Rutz offered the example of the influenza vaccine, which is updated annually and heavily promoted for certain groups. The process for sharing information about the vaccine is complicated. Since the virus changes and vaccines must be updated, there is increased scientific demand. National and international partnerships gather information to help determine which strains of the virus are circulating. CDC relies on the private sector to produce the vaccine. Until recently, most vaccines have been manufactured outside the United States, which could be a problem in the event of a pandemic. Changes are being made at many levels to encourage the growth of vaccine production in the United States. Interaction and partnerships with businesses make this happen. Further, issues around vaccine delivery and public support require businesses, other government agencies, and the media to help public health.

DPSA borrowed from other areas of CDC and consolidated some activities. The DPSA is learning about the CDC center partnerships that are successful to help other centers problem-solve. DPSA is, thus, building bridges within the agency as it strives to move outside the agency to develop opportunities for novel partnerships. A deliberate and thoughtful approach is required for these endeavors. DPSA is also charged with "bundling" programs, products, and services that CDC has to offer to target audiences. Until the agency was reorganized, the current National Center for HIV/AIDS, Viral Hepatitis, STD, and Prevention did not include hepatitis, which resided in another center. Communication materials developed for HIV detection can be parallel to hepatitis B diagnosis and screening, so efficiency was increased by bringing hepatitis into that center.

DPSA includes a staff of 50 to 55 individuals. Mr. Rutz is Acting Director, and he noted that he has found the staff to be committed to address the public health need. DPSA can consider health communication and outreach challenges in new ways. Without following the commercial marketing model letter-for-letter, aspects of traditional marketing planning and strategizing can make sense in public health. The center will not create messages with the intent to deceive, as is associated with advertising and often with the media. He shared that he left the media world due to increasing pressure to "make more of stories than we should," losing integrity in favor of other priorities. At its best, media takes scientific information and shares it in responsible and user-friendly ways. DPSA hopes to take the best that CDC has to offer, such as the *MMWR*, and make it attainable and reachable.

DPSA has a number of deliverables. Pandemic influenza preparedness is a national priority in which CDC has been engaged. These efforts have collateral benefits, as they represent an "all-hazards" opportunity to make improvements and to draw attention to fragile structures such as vaccine production. A series of checklists is a way to package technical information in a format that partners can use. The checklists are tailored to different entities such as faith-based groups, educational groups, governments, and business. CDC's brand is a communications tool that demands attention.

DPSA shares responsibility for representing CDC to its partners. The agency has created successful partnerships out of necessity for some time. DPSA intends to seek new opportunities for partnerships as well as to share best practices across the agency and to address problems that may emerge. DPSA provides resources such as directories and provides consultative services, evaluating health communications and creating measurable ways to ensure that CDC's work and its partnerships are making the American public healthier. They will monitor and attend to the agency partners' satisfaction and to see that the partnerships are mutually beneficial.

DPSA looks for common interests among public interests, CDC interests, and partner interests. There is a continuum of interest in public health. Some may not care about public health because of a lack of understanding about what it means. Their marketing challenge is to acquaint members of the public with why public health matters to them. People may want to live longer and healthier lives, for instance, but they also want pleasurable lives. DPSA's work can help individuals understand trade-offs and to reconcile immediate gratification and long-term benefit. Different issues are important to different groups, and partners help CDC recognize other perspectives and reach different audiences to share the universal ideal of healthy lives. The Division operates with the belief that CDC shares common interest with businesses and the private sector. There are opportunities to work with the private sector without "tainting" CDC's ideals and interests. Efforts must be thoughtful. Potential benefits of partnerships include improved reach for the agency and minimizing duplication. Drawbacks exist as well, and they include conflicts of interest, the threat of compromising autonomy, resource commitments, implementation challenges, and the possibility of CDC being exploited. On the whole, the greater public good may over-ride these concerns, and risks may be called for.

Mr. Rutz offered a potential partnership scenario. To investigate nosocomial infections, determining their causes as well as discovering intervention and control techniques, CDC could work with for-profit and not-for-profit hospitals. The groups that choose to work with CDC may gain "bragging rights," but if the investigations reveal problems that were preventable, then the partnership can have a "downside" for the hospital. Is it proper for CDC ever to work with private sector organizations such as for-profit hospitals? Are there ethical differences in working with for-profit versus not-for-profit hospitals? What constraints are acceptable; that is, what is the public's right to know that, for example, a particular hospital has a high rate of hospital-acquired infections? How can that information be shared fairly and in context? Another scenario concerned a Fortune 500 company which seeks to employ techniques used by CDC's "disease detectives" to identify and correct business problems. The company suggests that CDC conduct research about worker safety, which might discover ways to improve product quality. Is it a proper "trade-off" to partner with such an enterprise to discover important ways to make workplaces safer, if the collateral benefit results in a more efficient business? What guidelines can help make these decisions? Does stated or implied motive matter? How hard should they look for ulterior motives and hidden agendas? In another scenario, CDC has been invited to speak on pandemic influenza at a meeting organized by a trade association that has a political agenda. Should CDC avoid appearing at events sponsored by political organizations with policy positions? This issue arises in the area of HIV/AIDS. Should it make a difference if the political organization is nonpartisan and centrist? What about the fundamental public health issue being addressed? Is it worth taking the risk for the chance that the risk of harm might be reduced, or if a life could be saved?

Other questions which arise include: Should "perfect be the enemy of good?" Which philosophical, practice, and policy differences matter, and which do not? CDC takes pride in its high scientific standards and traditions, which is why the agency is a valued source of information. With that in mind, the agency must be responsive without destroying or injuring its reputation. Should motive matter? What is a deal-maker or deal-breaker? Are answers to these questions case-dependent or absolute? The "bottom line" and making definitive statements is important in public health; however, public health needs to realize that it can be better than it is. Therefore, what degree of flexibility or "wiggle room" is acceptable in order to achieve a public health objective without destroying the tools needed to get there?

Mr. Rutz concluded by assuring the group that DPSA and CDC would not be reckless in making their decisions. They are charting new territory, however, which carries an element of risk.

Discussion Points

- Dr. Macklin asked that the group reflect on the list of partners, which was depicted on a slide. She suggested that a large part of their worries regarding CDC's partnering with private entities stems from troubles that the Federal Drug Administration (FDA) has recently experienced. The FDA's troubles are not exclusively due to its relationships with business, but its collusion and collaboration with the pharmaceutical industry have contributed to its loss of reputation.

- Dr. Snider pointed out that the business community is not homogeneous. Different companies operate differently, and many businesses choose to be "living asset stewards." These companies focus on the well-being of their employees, their customers, and the environment. Research has shown that profits flow from this approach. Many of these companies are more than 100 years old, so this phenomenon is not new, although new ideas regarding management theory and practice are influencing more companies today. Some companies see themselves as having a role in, and concerns for, the health of society. Without a healthy world, business cannot function. He urged them to take a broad view and recognize that not all businesses have the same focus.

- Mr. Rutz agreed with Dr. Snider and added that in the past, the barrier between public health and the private sector has been rigid, which has contributed to feelings of suspicion. Even well-meaning businesses have to make money to stay in business, which the government does not have to do. Companies which realize that it makes good business sense to be a good world citizen will probably make good partners for CDC.

- Dr. Arras asked about potentially conflicting criteria when assessing partnering with different groups. Certain organizations, institutions, or businesses may be impossible choices due to the consequences. He offered an example from his experience. His home institution forged a relationship with Phillip Morris to fund anti-smoking research and research on communicating anti-smoking messages. The press called him for his comments. His crucial question concerned whether Philip Morris would place restrictions on the university or massage the data. The answer was "no." He felt that significant public health work could be done with this funding, so he did not feel that the relationship was inappropriate. Many of his colleagues across the nation disagreed with him. He asked whether Mr. Rutz and DPSA had faced a situation in which there was a conflict between the consequences of forging relationships and the motivation of the prospective partner. In his example, many people felt that Philip Morris was entering into the partnership not to be a good public citizen, but to improve the company's reputation.

- Mr. Rutz likened Dr. Arras's example to how the government receives and spends revenues from cigarette taxes and lottery proceeds. Both sources have societal implications. Further, a percentage of the settlements from tobacco-related litigation go toward public health initiatives. While public health hopes that all tobacco users will cease their use as a matter of choice, the money that flows in because a quarter of the United States population chooses to use tobacco products is beneficial. To address these potential conflicts, all discussions should be frank and transparent on both sides, and public health should be aware of companies' motives. For instance, the tobacco companies claim that their marketing efforts are geared toward encouraging current users to switch brands, not to

recruit new users. However, these companies are working in areas such as Nigeria and the Ukraine, offering to invest in their infrastructure and bring in new jobs while introducing tobacco use to new populations.

- Dr. Magruder observed that CDC appears to be in the process of developing products. The products involve interventions. These interventions need to be effective, and people must have the desire to purchase them or to want to use them if they are able. One of the key aspects of marketing is determining whether people will want to use the products. CDC may be viewed as inadequate in expanding and sharing effective interventions, given its focus on extramural research. The second issue, encouraging people to want to use the products, requires a new way of thinking. Dr. Aguinabi is leaving his post as Assistant Secretary for Health to join the private sector; he could be a strategic collaborator, and his experience could be invaluable.

- Mr. Rutz said that one aspect of marketing is to create demand and to stimulate demand not by forcing people to make choices, but by creating sufficient interest in a product or choice so that it becomes attractive enough to override any opposition. He hoped that they would remain "on the high road" in the choices that they develop so that their products are for the health interests of the individual rather than for commercial benefit. For example, when West Nile virus was a significant problem in the United States, CDC heavily promoted the use of DEET-based insect repellent. The government did not endorse a specific brand, even though there were opportunities to partner with a manufacturer. CDC opted not to pursue a partnership so the agency could promote generic use rather than an exclusive brand. With this approach, all companies that produced DEET-based repellent sold more product, and fewer people were infected with West Nile virus.

- Dr. Bernhardt clarified that CDC is increasing its extramural research, but its most recent large-scale call for proposals focused not on creating new products, but on increasing the agency's ability to translate knowledge into practice. This call for translation and for closing the gap between what is known, and what is done, resulted in a large response.

- As CDC considers potential partnerships and sources, Dr. Hooyman suggested that they look for the principle of cooperation. He reflected on the framing document for discussions regarding CDC and partnerships. The document refers to "the CDC's power to improve health outcomes," and he said that CDC has moral authority and an ability to leverage its brand, but he suggested that the word "responsibility" was more appropriate than "power."

- Mr. Rutz believed that the word "power" was selected to imply that CDC has the capacity to influence behaviors and has not fully exploited this capacity. The agency has a great deal of public respect and expertise, and the agency itself is based on scientists who work faithfully to improve the common good.

- Dr. Snider said that they must understand that CDC has power to affect change. The agency's philosophy includes a responsibility to use taxpayer money, and accountability to do good work. Dr. Hooyman pointed out that power can also be abused, and Mr. Rutz added that CDC does not have power on the scale of other government agencies such as the Internal Revenue Service (IRS).

- Dr. Hooyman commented that the list of potential partners does not include NGOs. Rotary, for example, has contributed toward polio eradication and is considering a move toward working in malaria. A number of major players such as the Gates Foundation can be excellent partners. The framing document also includes a definition of "partnership" without providing a source for the definition. There are different definitions of partnership. Further, the document describes partnering with "agnostics" and even, on occasion, opponents of CDC initiatives. He wondered about scenarios in which these partnerships are possible.

- Mr. Rutz replied that they had agonized over the definition of "partnership," perhaps to the point of diminishing returns. Regarding partnering with potential opponents, he offered the example of an acute national emergency which might require working with a number of partners. Unlikely partners have worked together in the area of mental health.

- Ms. Kinlaw referred to the first scenario that Mr. Rutz posed, which concerned equity in partnering with particular hospitals. She wondered whether intermediary organizations could also be considered partners, such as the American Hospital Association or state-level hospital associations. This approach would not be a "competitor model," but work as a higher-level partnership to provide a different way to invite individual hospitals to work together. The fundamental, philosophical question of what it means to be a "partner" should be answered, and the Ethics Subcommittee can help wrestle with that question, which will help to answer other questions. For instance, what criteria are used to choose partnerships? She was curious about how the list of private organizations was populated. How should motive be assessed? It seems that a common commitment to the common good is the first opportunity for connection with partners, but how should this commitment be assessed? If partnering is meant to lead to an ability to influence key opinion leaders in industry to take on public health messages, then CDC must be thoughtful about whether CDC, or other industries, should be opinion leaders. CDC should be appropriately protected as it explores these opportunities. The scope of NCHM is enormous and new, and it touches everything that CDC and even other agencies are doing. She expressed interest in thinking about "entry points" and specific ways that the Ethics Subcommittee can be useful in the center's efforts.

- Mr. Rutz replied that the center is ready to consider whom to partner with, and under what circumstances. They should decide an "absolute deal-breaker." For instance, the tobacco industry is not a good partner for CDC because of its negative associations as well as because its business focuses on a negative public health outcome. Other federal interests may be involved, so they should be conscious of other influences as they think about partnerships. He appreciated the idea of working with groups such as hospital organizations. Further, there are possibilities for creating "middle players." He cited the example of the CDC Foundation, which began when a group of private businesses came together to help CDC. This collaboration has been successful, and the relationships have not been exploited.

- Dr. Snider replied that CDC uses "middle ground" entities such as hospital associations in specific program areas. For example, the "Hospital Infections Program" works with the Joint Commission on the Accreditation of Hospitals (JCAHO) as well as with the American Hospital Association (AHA) and other organizations to make hospitals safer. Many programs also work with health insurance programs. It has been successful at the program level, and this success could lead to equally successful collaborations in NCHM.

- Dr. Bernhardt said that the Ethics Subcommittee could help NCHM a great deal by providing advice and guidance. In the near future, NCHM will collaborate with the rest of CDC to develop guidelines and policies to govern its activities. Their goal is not to create a top-down model of control, but to develop evidence-based best practices to guide how they conduct their campaigns. There is no agency-wide set of guidelines for campaigns, but data are available. Similarly, the Subcommittee can help NCHM formulate guidelines for partnerships and circumstances. The CDC Foundation has written guidelines. CDC has some guidelines, but some of them are outdated, and there are limited guidelines regarding marketing, communication, and partnerships. Members of the Subcommittee could provide helpful input as they create their guidance.

- Ms. Geissman noted that CDC partners with a number of entities through its grants and cooperative agreements, and these relationships have an indirect marketing effect. She suggested that they consider the processes that govern the grants and cooperative agreements procedures to apply some rules about engaging in financial relationships to hold partners responsible.

- Dr. Bernhardt replied that they are evaluating those processes. NCHM has a number of cooperative agreements across the agency. Some are managed centrally; others are managed program by program. Every time a cooperative agreement partner is renewed, there are new opportunities to look at the process.

- Ms. Geissman clarified that all centers make cooperative agreements, and marketing opportunities could be written into guidelines to increase their benefits.

- Mr. Rutz agreed, nothing that one of the indirect marketing benefits of cooperative agreements is demonstrating that CDC is a good steward of public money.

- Mr. Jennings felt that the example of not endorsing a specific product, but a generic product that has a good health effect, is a good "rule of thumb" for their work. He suggested that they focus as much as possible on the project rather than on the partners. For instance, it should be clear that CDC is working with a partner for a certain purpose and to achieve specific outcomes, not with the whole of the partner. If a good project combines CDC's public interest with a private entity's interest, then they should enter into it. The enterprise is still subject to the "halo effect" of any public relationship. He noted that many of the questions posed to the Subcommittee concern how to vet a potential partner. He wondered how broad their net should be; that is, many organizations are large and complex, with different activities and subsidiaries. For instance, if CDC worked with the Nestle Corporation on an initiative regarding nutrition for children in the United States, CDC could then be associated with other activities of Nestle, such as the controversial issue of infant formula in developing countries. He wondered about the extent to which these possibilities should be considered. Partners may have "firewalls" and boundaries to allow CDC to distance itself from all of the company's activities. In addition, one partner could own a tobacco company, but its other ventures are good for public health. Is that relationship the same as working with the tobacco company? If CDC only looks for partners who have done good public health work and nothing else, then the pool of potential partners will be limited. On the other hand, CDC must protect itself, its brand, and its public trust by insulating itself from partners.

- Dr. Snider offered a historical background for the discussion. For years, CDC has been wary of working with the private sector. The agency's historical approach has been to avoid any entanglements to avoid being "tainted." In creating NCHM, the notion that CDC is not necessarily being a good and responsible steward by taking this restrictive approach came to the fore. Previously, for instance, CDC would not work with Kraft because of its relationship with Philip Morris. Their work in vaccines is difficult as they set ground rules about working with manufacturers. This job often falls to the FDA, which has had trouble regarding its relationships. NCHM is trying to "push the envelope" to engage the private sector to help CDC improve the health of the public, but they cannot begin these partnerships until they have general guidance documents and/or specific instances to address. The theory behind the new NCHM and behind CDC's reorganization is that the historical avoidance of the private sector was a conservative way to keep the agency "out of trouble," it might not be the most effective way to exercise the agency's responsibility to help the public. The for-profit part of society can play a role in the public's health, and CDC can help them do it.

- Mr. Rutz added that they need to find answers to their questions deliberately and persistently. Public health is one of many national priorities, and in many areas, the public's health is staying level or even losing ground. Resources are shrinking, and the United States operates on the idea that capitalism is good and wealth is generated in the private sector. Business is not an automatic adversary, and CDC can capitalize on its positive points without compromising the agency.

- Dr. Koenig expressed concern regarding using the word "brand" and other marketing terms in relationship to CDC. Her reaction came from the notion that in clinical medicine and public health, there is a fiduciary relationship between person being served and the clinician or public health provider. In this relationship, the provider acts in the best interests of the person being served, not in his or her own interests. This relationship is fundamentally different from the relationship between a business and a person to whom they sell. Preserving the fiduciary relationship may include an obligation not to have a brand or not "speak the brand." The integrity should be so high that a brand is not necessary. On the question of private sector relationships, she is not as concerned about relationships with businesses, as the private sector must be included in efforts such as pandemic influenza planning. Her area of concern was that the relationships would convey a commercialized image. With respect to the FDA and its troubles, there are different perspectives on how FDA got to this point. A set of structured decisions led to a requirement for financing from industry and relationships with industry. This move was a social choice on which some employees seem to have capitalized later.

- Dr. Levine commented that his background is in pharmacology as well as in internal medicine. Pharmacology is characterized by a nearly-seamless connection with the pharmaceutical industry. However, academic pharmacologists deal with the pharmaceutical industry with caution and with concern regarding protecting their options to speak on topics according to their findings.

- Dr. Benjamin felt that the public health community had for some time been unwilling to work in partnership with groups and companies in communities. Public health has traditionally held the fundamental belief that companies are "bad" and that their motives are not as "clean and wholesome" as public health's motives. He urged them to remember that all partners have motives; therefore, they should understand the motives on all sides, talk

about the motives, and decide which boundaries they are not prepared to cross. There are collaborative opportunities in "gray areas," which could require working alone, compounding funding, sharing logos, or coordinating messages to the public. He further noted that there were some groups with which he would never want to partner, but that list is small. He hoped that they would take care as they move into these new areas. Government may be uncomfortable partnering with the private sector because there is a risk that someone could take advantage of the relationship and gain as a result of it. They can create safeguards to ensure that the partners will act and benefit appropriately. If they want to improve the public's health, they need to use all of the tools and resources that are available to satisfy the public's need.

- Dr. Snider noted that the Technology Transfer Act requires that CDC and other agencies work with the private sector. Under this Act, government agencies are obligated to market and share intellectual property and discoveries made using federal dollars that have potential utility. Often, they will create non-exclusive arrangements to welcome a variety of partners. Because of the agency's history of not collaborating with the private sector, some initiatives such as vaccine safety have suffered. They had the opportunity to study long-term effects of a vaccine, but as the study required collaboration with a private company. There was concern that the study would not be credible, even though the company was to have no role in the study. The agency has to move forward and utilize private sector resources in a way that allows the agency to grow and gather information to provide appropriate risk assessment to the public without being questioned. The agency's previous attitude may have been too conservative and resulted in sacrifices to the public's health.

- Ms. Geissman suggested that CDC has experience in using criteria to select partners at the center level and at the program level. It might be useful to evaluate past partnerships, both successful and less successful. She offered the example of working with community-based organizations and advocacy groups in the realm of HIV, and there is information available about how those relationships worked. CDC has also worked with national Planned Parenthood groups in the area of STD reduction. Further, criteria for selecting partners could come from examples of state health departments. States with limited resources for public health partner regularly with local groups and businesses.

- Mr. Rutz addressed concerns regarding the notion of "brand" and whether using that term crosses a line. He suggested that they consider that brands have positive aspects. For instance, every person is branded by his or her name and by impressions that other people have. Branding is not necessarily used to deceive. Marketing is not inherently a deceitful practice that intends to trick people, but a way to focus attention positively. For instance, the "Good Housekeeping Seal of Approval" is a brand and standard that applies to products and entities that merit it. If CDC puts out recommendations with its logo, then professional as well as lay people pay attention to it. The brand must be used appropriately and wisely. The potential exists to use the brand unethically or recklessly, but NCHM must take care to protect the brand. The situation at the FDA illustrates the perils associated with working too closely with businesses. Other federal agencies work with businesses in various ways, based on their missions, and the potential for trouble exists there. NCHM needs to define parameters and cautions to consider when beginning partnerships. What are the potential downsides? He asked the Subcommittee to help them recognize the potential downsides to partnerships, to take a skeptical view, and help to point out "red flags." What can they do legitimately, ethically, and effectively to improve public health, especially in areas where technology is not an issue, but there must be will to affect change.

- Dr. Snider asked for clarification regarding how the Ethics Subcommittee can help NCHM. He wondered whether the Subcommittee should craft guidance in a particular area such as partnerships, or should review guidance that NCHM develops. The Subcommittee could also be available if there are concerns regarding a potential relationship. They can be either reactive to developments or proactive.

- Mr. Rutz replied that both functions would be helpful. It is not fair to the Subcommittee for NCHM to ask them to create their guidance, but their viewpoints would be needed as NCHM makes progress toward partnerships. They hope to move forward quickly and deliberately. If it is possible to share materials in the formative stage, NCHM would welcome the Subcommittee's input. Further, if the Subcommittee could ponder the generic issues that NCHM is facing, their reactions can shape policy development. When policies and guidance are developed, then perhaps the Subcommittee can provide feedback on them.

- Dr. Barrett suggested that, as they have done with other topics, they identify a few Subcommittee members to form a workgroup to work with members of NCHM and the Internal Committee and other CDC staff. They could better refine the questions and form additional options for involvement.

- Dr. Macklin noted that they would need to address the question of members rotating off of the Subcommittee and taking on new projects.

- Dr. Hooyman and Dr. Thomas indicated their interest in participating.

- Dr. Magruder asked whether centers that are now in the process of developing relationships with private sector partners should utilize the guidelines of the CDC Foundation.

- Mr. Rutz said that guidelines are in place, but they were developed in different parts of the agency at different times. The reorganization of CDC has included consolidating these guidelines to make sense of their inconsistencies and to clear up confusion around them.

Public Health Ethics and Genomics

Review of the Best Practices Document

Dr. Mary Leinhos, PhD, Health Scientist, National Office of Public Health Genomics (NOPHG), offered a recap of the presentations made to the Subcommittee during their February 2007 meeting. The genomics session included four case studies illustrating ethical issues that have arisen in genomics work at CDC. The Subcommittee considered four discussion questions and provided input regarding the issue of returning genetic results to research participants:

- ❑ Is there an ethical duty to offer genetic research results to study participants? Questions regarding duty were considered, as were the rights of participants to receive information.

- ❑ What is the best way to report results? For example, the cancer cluster study reported aggregate results in a community meeting.

- ❑ How should the evolving clinical significance of genetic testing be dealt with as research is conducted over the long term? New candidate genes are discovered during the course of long studies.

- ❑ What are the ethical considerations for working with participants from special populations?

Additional ethical issues highlighted in February included biobanking. How long can or should data and samples be kept and linked? How long can samples collected for a study be kept? What is the scope of future genetic research on banked samples? What should be included for reporting to individuals as part of the informed consent process? Differential IRB requirements between localities and CDC are also an issue. The February session pointed out the need for an approach to developing best practices guidelines in genomic research at CDC. There is a general lack of existing, relevant guidance. Advances in public health genomics necessitate looking at this issue again. CDC scientific staff have requested assistance to answer these questions. In February, Dr. Leinhos also discussed the evidence base for best practices, and presented a list of proposed best practices topics.

The public health context for genetics is important to understand as well as the clinical research paradigm. Population-based genomic research has a few distinctive aspects. Its aim is to establish gene-disease associations, and clinically relevant information at the individual level is rarely gathered. Population-based research requires an extended chain of evidence. One study is only a link in that chain, so its implications are limited. Further, population-based research focuses on low-penetrance genes and relatively common variants, which have low relative risks compared to other factors for disease. Population-based research is related to understanding the role of environmental exposures and developing population-level interventions in public health. This research tends to raise more concerns about justice and group harm as opposed to individual harms.

Bringing epidemiology and genetics together requires finding common ground in the "rules" to be followed. Their cross-disciplinary conversation is characterized by overlapping interests, but there are differences in design, technique, emphases, and dialects. For instance, the term "confounding" has an important meaning in epidemiology, but in genetics and other areas, it does not have technical meaning. Similarly, there are missed distinctions between technical terms in genetics, such as the distinction between a gene and an allele. There are differences between observational and experimental study designs in epidemiology and genetics, which must be kept in mind when considering different studies. Experimental scientists are rarely trained in observational science methods, but observational scientists are typically trained in experimental methods. Therefore, experimental scientists may often not recognize that observational studies generally draw weaker inferences about causal connections, although they can be strengthened by accounting for confounding and bias—terms that are not often used in experimental designs. Detection technology may obscure the observational nature of data collection. That is, the more "high-tech" a project, the more experimental it may seem. For instance, some micro-array gene expression studies do not distinguish between observational

and experimental designs. It is important to use the design that is most appropriate to address a given research question, or to combine the designs.

An important element of the differences between epidemiology and genetics includes differential conceptions of genetics. For instance, Huntington's Disease is a dominant and highly penetrant trait. However, the majority of genetic diseases are not as penetrant and many are transmitted in a different manner from generation to generation. The concept of penetrance is the match between a genotype and its expected phenotype. The subtleties of penetrance, which is an important concept, are often not appreciated. For example, estimates of penetrance and prevalence have sometimes been inappropriately inferred from family studies, which are not representative of the general population. Regarding epidemiology and genetics, Dr. Leinhos observed an "investigative myopia." The disciplines are focused on describing and explaining this disease state versus the healthy state. Current technology and study designs are not well-suited to investigate protective genetic variants as opposed to susceptibility to various diseases. This perspective introduces bias into the questions that studies ask and are able to ask. These points have implications in the area of results notification. Genetics is highly complicated, and the implications of particular genetic findings for individuals or populations from one study may be limited in scope. Dr. Leinhos mentioned the National Health and Nutrition Examination Survey (NHANES) III DNA bank, which looks at the prevalence of genes of public health significance. NHANES collects information through interviews and collects specimens from a representative sample of the United States population.

Genomics is distinctive in public health in the area of field investigations. Field investigations such as disease outbreaks provide valuable and challenging opportunities to learn new things about disease transmission and cause. However, the field investigations often have other non-scientific goals that are important to the public as they explore the reasons for a cause of concern. Genomics will be increasingly integrated into public health investigations. This collaboration will help to better characterize environmental exposures, to better understand variation in disease outcomes, to assess the effectiveness and side effects of various interventions, and to refine those interventions. Public health has an interest in measuring and describing variation in both outcomes and inputs and in improving interventions to respond to those variations. She reviewed the major differences between clinical and public health contexts of genomics, adding that these have differential individual, social, and political implications.

Dr. Leinhos directed the group's attention to a revised outline for a "best practices" document and a draft section of the document. More detail and additional topics have been added to the outline since its presentation in February. She asked that Subcommittee members discuss general remarks about the outline and the draft section, indicating that specific comments should be e-mailed to her and Dr. Barrett by August 24th. The draft section includes an introduction and a biobanking best practices module. In addition, the genetic exceptionalism module is being developed but was not presented at this meeting.

The project has posed a few challenges. First, what is the best way to format and organize this best practices document so that it is useful to investigators and IRB members? There are several good models for best practices documents in the information technology (IT) industry. Another challenge is the size and the scope of the project. Initially, the plan was to create one large document, but it has subsequently been split into modular form to address major topics. Finally, a challenge is inherent in addressing multiple audiences and purposes in one document. The document aims to provide guidance to investigators and IRB members, but the document should also reflect justifications and ethical explanations to support the best practices.

Satisfying both of these goals is difficult, since a practical guidance should not spend a great deal of narrative on "why" as opposed to "how."

The biobanking module includes a brief introduction to the major questions that arise concerning biobanking. An executive summary includes conclusions and major points. The rest of the draft module provides best practice principles with specific explanations and examples for how to apply them. A small section of "related resources" is at the end of the module. This section has a number of strengths. The document is intended to be practical and systematic in how it addresses issues associated with biobanking. Results are divided into small, concrete tasks that investigators can consider as they think about protocols and study designs. The module provides illustrations from recent or current CDC studies. Other agencies have produced comparable documents, but they have different criteria and different goals.

Dr. Leinhos said she hoped to receive feedback on the draft introduction and biobanking module, specifically in content and presentation, but also on other issues. She also hoped to discuss practical challenges of the project, especially how to address the document's multiple audiences and purposes. She asked for reflections on addressing human subjects challenges associated with genomics research in the public health context as well as questions or comments about the best practices project.

Dr. Muin Khoury, Director of NOPHG, then addressed the group. He thanked Dr. Leinhos for her presentation and the Subcommittee for providing guidance and advice. The work of genomics has changed markedly, especially in the last year. The distinction between clinical and public health research is beginning to blur. These changes are due in part to NIH's new emphasis on the population-based approach and movement into large cohort studies. Another influence on, and change to, the field has come because of the "whole genome" approach. New chip technologies can measure one or two million genetic variants. A small variation contributes to susceptibility and protection from different diseases. New tools and technologies enable the measurement of many variants at the same time, which poses a number of challenges for biobanking and the overlay of the population-based approach. The NIH-driven research still focuses on discovering new genes, where public health hoped to figure out what genes mean for the health of a population or community that is affected by a cluster, for example. At the beginning, discussions focused on the "candidate gene approach." Now that nearly all genes can be measured on one chip, and there is little difference in price to measure 3000 variants or one million variants, the approaches must change. The first NHANES project measured the 50 genes that were related to the most diseases with public health significance. Now, NHANES could measure all genes and create a genome profile of the United States population. He said that the Subcommittee's guidance and input is needed in this rapidly-changing field. They hope to be able to explain public health problems, and learning about susceptibility will contribute to the control and prevention of public health problems in the community.

Dr. Koenig also thanked Dr. Leinhos for all of her work. The Workgroup decided to start with the practical approach of focusing on the research phase of genomics because these applications will probably not move into public health practice or into clinical practice and prevention right away. Although the document they are creating may be useful to CDC, it is constrained by elements of the bureaucracy and the human subjects enterprise in ways that may not be appropriate. However, in order to provide practical advice for the present, human subjects constraints must be understood. She expressed frustration that they did not "step back" and consider best practices for the moment, in the existing regulatory framework, and outline recommendations for reform of the system. They have not addressed the foundational question of exceptions to human subjects protections in the public health context. For example,

the genomic investigations of excess pediatric deaths in an influenza outbreak would demand a different set of guidance. She hoped that their discussion could move toward "next steps." The "Personalized Medicine" bill is before Congress now. The bill calls on CDC to conduct surveillance of the potential consequences, some of which could be negative, of the premature translation of genomics into the public sphere, especially because of direct-to-consumer issues. They should also be aware of the translational issues presented by the use of genomics in prevention and the use of predictive genomic risk information, which might be sold in a direct-to-consumer fashion.

Discussion Points

- Dr. Macklin opened the discussion, encouraging the group to provide feedback on the entire document, but to focus on the biobanking module.

- Dr. Levine agreed with the suggestion to develop a set of guidelines that would be useful today, but noted that even more important work might lie in creating what they think the guidelines should look like in the future. The documents should be careful to avoid confusion between current requirements and aspirations regarding future developments. Some codes of ethics fail to provide useful guidance because they fail to make such distinctions.

- Dr. Snider said that Dr. John Agwunobi would be leaving his post at HHS, which could pose a problem for them. Discussions concerning public health practice activities and their ethical review versus mechanisms used to review research activities were moving forward productively with the help of the Bern Schwetz, the Director of Office of Human Research Protections (OHRP), who is retiring. This situation could be unfortunate because both people have been helpful in making progress to resolve uncertainties as well as to address new issues. At the same time, changes can present opportunities. He was not sure that the leadership at HHS has these concerns "on their radar screen." There is a need to share the message that OHRP is an important entity within the department that needs good leadership, particularly with science evolving in new areas. He felt that the Subcommittee should be aware of these changes and the potential for growth or for deterioration.

- Dr. Koenig clarified that her concerns lay with whether the human subjects protection enterprise, which was designed specifically for clinical research, needs to be reworked and reconsidered for public health.

- Dr. Macklin said that this issue is not the same as their problem with the distinction between public health practice and public health research. The questions are related, but within the realm of research, there is still a disconnect between the clinical model and the needs of public health.

- Dr. Dixon asked about the extent to which the public has been engaged in this issue. If genomics represents a large departure from work in the past, structured engagement with the public about these profound questions might lead to the development of arguments to spur political change.

- Dr. Koenig said that they raised the idea of public engagement in February. There is a dearth of data regarding what the public wants. Community engagement pertaining to these issues will take place in Minnesota in September. There are some data from around the world about biobanking.

- Dr. Khoury said that NIH has funded a group to look at public engagement, especially as part of its cohort studies. A series of focus groups and large-scale surveys have been held about biobanking issues all over the country. Some data from this work is available. They have conducted small surveys in the past about the public's willingness to participate in biobanking, and reactions were mixed. Because of current interest in doing biobanking in large-scale studies, and because NIH is moving into the public health research domain, public engagement is becoming more frequent.

- Dr. Dixon noted that there is a difference between conducting surveys and focus groups and conducting formalized conversations based on scenarios, knowledge, and trade-offs. The latter approach will likely be more meaningful.

- Dr. Hooyman commented that with turnover in HHS leadership, they could have an opportunity for the Subcommittee to make a recommendation to the ACD. They could bring the issues within research and public health that are captured in genomics to formal recognition. The ACD could move the conversation forward. If there are new ways to review and consider the issues, then the Subcommittee should help that along. He then addressed the format and approach for the best practices document. In light of their discussions regarding health marketing, he commented that if the information is intended for a specific audience, the staff within NCHM could help package the information in appropriate ways.

- Dr. Thomas pointed to the Executive Summary, which acknowledges that it is not possible to assure the anonymity of genomic data. With the size of studies being conducted, and the speed of progression in the field, they may not be far from collecting genetic fingerprints for the entire population of the United States. In his work as an epidemiologist, he has obtained Certificates of Confidentiality from the federal government that protects his data from subpoena. This level assures participants that their data is protected. In the future, the options for deductive identification increase as genetic data are combined with marketing data, insurance data, and other sources. Of particular concern is genetic data that could affect whether a person is insured. An ethical issue of biobanking concerns the need for a "firewall" that will not just anticipate future studies, but will also anticipate the need to protect the data.

- Dr. Macklin understood that Certificates of Confidentiality protected against any governmental subpoena. However, there is no information about how protective the Certificates are, as they have not been tested.

- Ms. Kinlaw felt that the format of the biobanking module was good. The idea of breaking the issues into smaller questions, clarifying the principles, and providing illustrations made the document readable. On page five of the module's introduction, there is discussion of making the social value of studies to the community at large more explicit. She encouraged further exploration of this interesting idea. The clinical model for disclosure of information cautions against promising benefits to individuals, but public health genomics is a different realm. Several questions arise concerning how to share potential benefits well and how to

talk about them to the community at large as well as to individuals. Page ten of the introduction addresses disclosing in the informed consent process who has ownership of specimens and who controls their use. She wondered whether disclosure is adequate. Simply informing people about who has ownership does not justify the practice, and there are important concerns that need to be considered.

- Mr. Jennings complimented the work so far. He observed that the outline and framework of the best practices guidelines adhere to ideas regarding privacy, informed consent, harm to individuals, and harm to groups or communities. This framework is valuable, but may not include another dimension of public health genomics. Genetics incorporates a kind of "social epidemiology" in that in public health genomics, information is collected about relationships between genetic elements and disease susceptibility, prevalence, and patterns in a population. This kind of information touches not only on typical questions in epidemiology, but also on questions of individual and group identity and cultural meaning in new ways. The legacy of looking at genomics and genetics from a public health, population-based perspective as opposed to through a clinical lens necessitates raising the history and implications of eugenics. Because of issues around historical and cultural identity, and possible dangers that are not captured in references to stigmatization and other risks, he felt that more discussion was merited about these issues. The issues are more than risks and harms, but address the nature of how communities understand individuals and groups and what it means to be classified in terms of genetic makeup. There are serious implications in discovering that something in a person is "broken, wrong, or dangerous," as there are implications in discovering that a person is stronger, more powerful, or superior to the norm. As written, the framework of the outline could articulate these thoughts in Section I, particularly Number Four, and in the section on "Additional Considerations." That section includes other key points such as international research and race and ethnicity. In the international context, community engagement is a challenge. Race and ethnicity lead to questions regarding classification. He suggested that these points have more emphasis in the document.

- Dr. Coughlin commented on interest in the family history of cancer and different ways to assess it. Published literature on the validity of assessments of family history imply that first-degree information is better than information about secondary or tertiary family history, for which information is more likely to be inaccurate or incomplete. The ability to do biobanking for large populations to assess human genomes has only been available for a short time, but eventually issues will arise in which people may want genetic information about their ancestors; that is, past generations whose information is stored in a repository. That issue may not be of immediate importance, but it could arise in the future as more biobanking is done and more repositories are available, and could be anticipated in the informed consent procedure so that participants stipulate genetic information that could be available to their descendants.

- Dr. Leinhos thanked the group for their comments and invited them to send additional feedback to her. She particularly appreciated their comments about the document's framework and overarching issues that it should address. She noted that this framework was adopted in response to specific questions raised by investigators. The questions were constrained by the current regulatory requirements, which do not mesh well with the public health model for research. Until they grapple with these conflicts, they may not be able to tackle other issues. The issue of public engagement is important, and it is particularly important to reflect on specific projects rather than conceptions. Biobanking projects are ongoing at Vanderbilt, Kaiser Permanente in California, the Marshfield Clinic, and others.

These projects have included elements of public engagement and a great deal of background planning, both of which could inform the best practices guidelines. Some states are developing biobanks as well, and they are also interested in public engagement.

Dr. Koenig said that they should consider the issue of whether they should adopt the broader question of how public health investigations are different and in what ways they should be handled differently. For example, informed consent forms are quite unwieldy, with confusing verbiage and many "check boxes." Further, concerns about human subjects protections have constrained the use of NHANES data limiting usefulness and application.

Public Comment Period

Dr. Barrett noted that no members of the public had signed up to make publ c comment. She inquired whether anyone on the telephone wished to make public comment. Given that there were no responses, Dr. Macklin continued with the agenda.

Ethical Considerations for Non-Research Data Collections

Dr. Macklin turned the group's attention to a beginning outline for a guidance document for the collection, use, and storage of public health practice data. The document was created with input from members of the Subcommittee as well as CDC staff. This document re-raises questions regarding distinctions between public health practice and public health research. The Subcommittee had decided that it would be futile to try to make these distinctions, so the document should acknowledge the issue, but not grapple with it.

To create this outline, they assembled people and had three phone consultations. Different subgroups of the assemblage worked on different elements of the outline. The group that worked on legal issues wrote a piece for the outline. Dr. Macklin had asked for examples of ethical issues that arise. She recalled that the first meeting of the Ethics Subcommittee took place in February of 2005, and its focus was to organize the group rather than to tackle substantive issues. That meeting included a teleconference regarding a document that had been prepared for the CDC by a group of authors that was related to ethical issues pertaining not to research, but to the collection, storage, use, and sharing of HIV information. The Subcommittee was consulted to discuss whether it would be appropriate to broaden that document beyond HIV to include any and all types of information, thus turning it into a "CDC document."

It was concluded that the document was good for its purpose, but there were questions regarding whether it should be modified. Questions pertaining to this document arose again in this workgroup, with additional complications. There were questions regarding practical issues, such as whether the authors could remain the authors if the document changed. It was decided that the document should remain at CDC for the use of the HIV group, and features of it could be adapted or adopted with full credit given to its authors. Without examples, ethical analysis and the application of ethical principles cannot be applied, so the workgroup hopes that CDC will provide case examples. Dr. Macklin also asked for feedback on the outline: Missing

elements, major gaps, whether the order is appropriate, and whether any elements should not be included.

Discussion Points

- Dr. Levine asked whether beneficence, included as one of the public health principles, included non-maleficence.

- Dr. Macklin replied that they could treat "do not harm" separately or could explain that beneficence includes both "do good" and "do no harm."

- Dr. Levine was happy to leave the idea as a single principle. He asked about the meaning of the "precautionary principle."

- Dr. Macklin answered that this principle is addressed in the HIV document she mentioned. By itself, the principle means little; however, it could be useful in context. Any principle is difficult to explicate clearly without examples. The principle counsels not to go to reckless extremes when lesser methods or less risky approaches might be wiser.

- Dr. Levine commented that the meanings of other principles included in the document are well-understood. There could be disagreements over specific actions under the principles. The "precautionary principle" may not be widely understood in the realm of research ethics.

- Dr. Macklin replied that the principle does not appear in research ethics, but writings in public health ethics use the term. Any principle included in the document will be cited and explained.

- Dr. Coughlin clarified that the precautionary principle is stated often in the public health literature, most notably in the environmental sciences. Public health officials must often act in the absence of complete information. In environmental science, which has regulatory considerations, issues have arisen regarding whether officials should take steps to limit exposures to potential environmental hazards even when evidence is not absolute, or whether such decisions should be delayed until certain evidence is obtained. He then offered an example of the distinction between research and public health practice. There was concern about cervical cancer risk among populations of migrant workers. This group is difficult to reach for public health interventions for a variety of reasons. Only two surveys of large populations of workers could potentially include a module for women's health. One was the National Agricultural Workers Survey conducted by the Department of Labor. The National Institute for Occupational Safety and Health (NIOSH) had an ongoing relationship with the Department of Labor. They included questions regarding potential exposures to pesticides on this survey. His group contacted the survey about including questions regarding Pap testing. The questions were in Spanish and gleaned from another public health survey. One part of CDC viewed the questions as public health research; however, another part of CDC considered the questions to be surveillance. The requirements for informed consent are more elaborate under the federal guidelines for human subjects research. When the Department of Labor went to the Office of Management and Budget (OMB) to add questions pertaining to cervical cancer screening, OMB did not approve the women's health module.

- Dr. Macklin added that there are two main differences between research and non-research activities. One difference is the requirement for informed consent in research. In contrast,

formal informed consent is not required for surveillance. The other main difference is the need for IRB review. Surveillance and other public health activities are not reviewed by the IRB. These differences are arguments for making distinctions. Given the near-futility of that activity, however, they need to address how to approach this problem without making a hard and fast distinction.

- Dr. Lisa Lee suggested that the document should state clearly why it is needed. Federal regulation guides research, but no federal legislation protects people who undergo other public health practice activities such as surveillance, outbreak investigations, or program evaluation. The Subcommittee was asked to take up these questions because there have been discussions with OHRP regarding the definition of research, but no guidance was available regarding protections for other activities. She pointed out a section on page two regarding legal considerations relevant to collections and releases. In the surveillance world, there are beliefs about what should and should not happen regarding disclosures of data. These beliefs are sometimes counter to state laws which require release of surveillance or registry data for certain reasons. Guidance concerning the dilemmas that arise when state laws contradict ethics would be helpful. Further, she suggested expanding the discussion on page three about sharing public health practice data, specifically addressing whether data are being used as planned or as intended. Often, other uses for data become apparent after the data are collected. She wondered about their ethical obligations regarding using the data for other purposes that were unknown at the beginning of the data collection process. She also commented on retention and storage of data. There have been impacts as a result of Federal Records Retention regulations, and there have been questions regarding de-identifying data sets, which may go against those federal record regulations.

- Mr. Jennings commented that the precautionary principle is used widely in environmental policy and ethics, more so in Europe than in the United States. In Europe, the principle is reflected in the law and in international documents. The International Conservation Union produced a White Paper on the use of the precautionary principle in biodiversity conservation. Beyond choosing the least harmful alternative, the term flips the presumption that in order to stop an intervention, it should be shown to be harmful. Rather, this principle posits that in order to justify an intervention, it should be proven to be safe. It is designed for decision-making under uncertainty in complex systems.

- Mr. Jennings then turned to other potential issues that the document could address. He offered a situation in which public health surveillance is being conducted, and individually identifiable information is being collected in a database. The original intent of the work was surveillance and research, but the individuals in the database have been exposed to something that is potentially harmful to them. In this case, are the researchers obligated to notify the participants of their exposure when the intent of the collection was only epidemiological research? With time and effort, the participants could be contacted, since their information is identifiable.

- Dr. Macklin added an example that the Advisory Committee on Human Radiation Experiments discussed. This ethical dilemma concerned evidence that uranium miners had a higher incidence of lung cancer than the general population. The government was conducting research in this area, and in order to require the owners of the mines to ventilate the mines, thereby reducing risk to miners, they needed evidence from this study to show that miners were exposed to greater risk. In order to carry out the study, researchers had to go on private land, but the mine owners would not let the Public Health Service enter the

mines unless they promised not to give information regarding the study's purpose or impetus to the miners. This Advisory Committee debated the question at length and did not agree about what to do. A third option was to make a "lying promise" and to share information with the miners anyway.

- Dr. Levine observed that more than one IRB has to approve multi-centered research. In public health work, state and local IRBs are often involved as well. Any of the IRBs can propose amendments, which starts the approval process over again. For this reason, OHRP has expressed a willingness to entertain "alternate IRB models." A proposed Central Review Board (CRB) will perform the function of all IRBs. Under this model, each local institution would retain the option to conduct its own review. He then addressed the idea of individuals being able to provide information about their families. OHRP has issued a ruling to the effect that if sensitive information is sought about an individual who is not a research subject, for example, if a research subject is asked about afflictions or behaviors of his or her relatives, then that individual becomes a research subject and informed consent is required. Finally, he proposed adding medical records and the banking of surgical tissue specimens to the listed examples of non-research data collections. These areas frequently present problems.

- Dr. Thomas was not clear who the intended users of this document would be, and what they would need.

- Dr. Barrett replied that the document is primarily intended to be useful to CDC, but that it also should be useful to state and local partners and CDC-funded entities.

- Dr. Thomas commented that Section Six, Ethical Guidelines, is the intended product. Therefore, he wondered whether the guidelines should be stated as questions or whether they should be prescriptions.

- Dr. Macklin replied that the outline is preliminary, so some areas are presented as questions and others as "checklists." In the final guidance, these items will not be presented as questions, but as statements or checklists.

- Dr. Thomas hoped that the document would incorporate what the intended end users feel that they need. He noted that the document lists ethical and legal foundations and suggested that it also incorporate practical concerns. For example, an outbreak investigation includes the practical concern of timeliness, which has to be counterbalanced with other ethical concerns. If the leaders of an outbreak investigation were constrained to obtain informed consent with each person who was potentially exposed, then the resulting sample could be biased and not representative.

- Dr. Semaan addressed the end user of this product. Research protocols go from CDC staff and investigators to the CDC IRB members. The end users of this product are project officers and investigators as well as Directors for Sciences and Associate Directors for Science at the division and center levels at CDC. Clarity in the issues covered in the document is important because there are differences between and among centers, as described by Dr. Coughlin. Further, there may be variations between CDC and investigators outside the agency. She next clarified that in the document, "emergency response" in Section D applies to outbreak investigations. Categories A through E must be approved at the division level as well as the center level. The example of the traveler infected with tuberculosis does not fall into any of the mentioned categories. It was labeled as a case

contact investigation of sources who were exposed. Therefore, it was not reviewed and approved at the center level, only at the division level of two centers. For that reason, ethical concerns in public health emergencies need guidance. Other points in need of guidance include elements of the consent forms used in these methods of data collection. In a research protocol, it is usually agreed that at least eight elements should appear in the consent forms. In public health practice data collections there is disagreement regarding the elements of consent that should be included. State laws vary as well, and discussions regarding surveillance are confusing and should be considered.

- Dr. Lee clarified that the document is not meant to be guidance for determining research versus non-research. OHRP is providing guidance on that issue. The document is not intended to eliminate variation in research determinations across centers, but to provide guidance once a project is determined to be non-research.

- Dr. Semaan said that beyond the determination, there should be consistency, such as in the consent form contents, use of data, and others.

- Dr. Macklin said that in her institution, the IRB makes decisions regarding projects of quality assurance and quality improvement.

- Dr. Snider added that they have been in discussions with OHRP, and they are tackling the "impossible task" of distinguishing the difference between public health practice and research. These issues include outbreak investigations, quality assurance, and more. There are no concerns regarding institutions that conduct a great deal of research. Rather, there are concerns regarding local health departments and community health organizations that conduct surveillance. Given the possibility of avian influenza or pandemic influenza outbreaks, there are concerns that the IRB process will impair the ability of public health to react in a timely manner. These concerns underscore the need for this guidance from OHRP to make the issues clearer and to serve as the basis for institution-level decisions.

- Dr. Hooyman noted that the document focuses internally on public health professionals. He wondered whether it should include a section describing citizens' responsibility to participate in non-research data collection. If so, a principle regarding common good could support making that assumption.

- Dr. Koenig felt that the outline should address the issue of identifiability. Further, the document should also address the obligations of notification. She commented on the notion of "IRB creep." While OHRP is responsible for providing guidance and interpreting requirements for human research protections, if they do the wrong thing, then there is an obligation to point out their error. The introduction to the document can address the fact that often there is not a "firm line" between practice and research. Data collected for public health practice will often be used for research in the future because there is an obligation to continue improving processes and gathering knowledge, much in the same way that surgical pathology collections are used for research in the future. She felt that it was deceptive to state that data are only being collected for practice when in some instances, they will be needed for research.

- Dr. Lee said that once the data are proposed to be used for research, then the project goes under IRB review.

- Dr. Koenig replied that these regulations are not substantive. Their procedures should be governed by their needs.

- Dr. Lee agreed, noting that there are no regulations or guidelines for non-research activities, which is why this document is needed.

- Dr. Macklin said that issues of identifiability should remain constant across the documents that the Subcommittee should produce, so they should work together as the genomics document is created.

- Regarding the document's target audience, Dr. Snider suggested that it address the benefits versus the risks of these activities. He was not sure whether quality assessment and quality improvement was included under public health practice evaluation. Those efforts are considered in terms of overall evaluation, but as they move toward accrediting public heath organizations, then evaluation initiatives will be done. This activity involves data collection, so OHRP will be interested in whether it is research or non-research. Further, a great deal has been written about privacy issues, so they may be able to refer to existing literature and guidance rather than to "re-invent" guidance. He also suggested that the document should address the process of reviewing projects and situations. This document is organized to apply to CDC, but he hoped that it would be developed with an eye toward making it applicable to the entire public health community.

- With respect to sharing data, Chris Braden commented that the document would benefit from a discussion on data quality issues. Legal concerns arise as part of the Data Quality Act. In a practical sense, there are problems concerning what data to share and how to share it. They would like to be transparent and share the data that they have, but no data is perfect. Further, there are differences between raw data and clean data. How should they manipulate data, and are there ethical responsibilities associated with sharing raw data that could be misinterpreted, or even erroneous? Even if the data are good, the resources needed to create and support a public use data set might not be available.

Meeting Wrap Up and Next Steps

Dr. Macklin listed the Action Items that emerged from the meeting:

- ❑ Emergency Preparedness and Response: This document has 80 pages, and there will be more. The Subcommittee generated sufficient feedback and discussion to make progress. There is still a need for examples to improve the beginning of the document and the research section.

- ❑ Follow-up to Pandemic Flu: The Subcommittee is asked to present the concept of shared responsibility for antiviral drugs to stakeholders. Meetings with the stakeholders will begin within a few months. Suggestions and proposals on an individual basis, therefore, are needed in the next four to six weeks. Questions to consider include whether shared responsibility is an ethical concept, whether "responsibility" is a weak concept, and others. Those wishing to contribute to the conversation should do so through Dr. Schwartz and Dr.

Barrett.

- ❑ Proposal for an Annex to the Pandemic Influenza Paper: The paper has been vetted and approved by the ACD, but an annex might address ventilators specifically. In addition, Dr. Levine and Ms. Kinlaw will determine the utility of case studies as an aid to understanding the guidance document. Further, there was question regarding whether, and how, to respond to public comments regarding the document. One response is the proposed annex to address ventilators, but other comments may require attention.

- ❑ Travelers with Infectious Diseases: Dr. Cetron requested comments and suggestions on this subject. The Subcommittee tentatively agreed to consider the Pandemic Influenza paper and the paper on Emergency Preparedness and Response to ensure consistency and perhaps to craft a brief guidance for infected travelers.

- ❑ Health Marketing and Partnerships: Dr. Bernhardt and Mr. Rutz request assistance in some form. Dr. Snider asked to clarify whether the Subcommittee should take information and craft guidance, whether the Subcommittee should review guidance developed by CDC, or whether the Subcommittee should be available for consultation if there are concerns about a potential relationship. Dr. Macklin wondered whether the Subcommittee should consider the scenarios presented by Mr. Rutz. Analysis of the scenarios could help them determine how to shape the guidance.

- ❑ Genomics: Dr. Leinhos has requested feedback on the biobanking module and on the best practices document. From there, she will take "next steps" with Dr. Koenig and Dr. Hooyman.

- ❑ Ethical Considerations for Non-Research Data Collections: This paper is in its incipient stages and will progress.

- ❑ Procedural Issues, Specifically Rotation Off of the Subcommittee: What, if any, will be the continued roles of those who rotate off of the Subcommittee, especially for those who are committed to activities?

Discussion Points

- Dr. Barrett said that they could explore using people who rotate off of the Subcommittee in a "consultant role."

- Ms. Kinlaw inquired about whether they should make additional recommendations to the list of potential new Subcommittee members.

- Dr. Hooyman suggested that the November meeting include sufficient time to address procedural issues, especially given that the February 2008 meeting will include new members.

- Dr. Barrett indicated that she welcomed input from Subcommittee members on additional recommendations for new Subcommittee members.

- Dr. Hooyman noted that the rest of the Subcommittee will rotate off in December of 2008, so if they take a chair from the existing group, then the term will not be long. He reiterated that they should take time to think through procedures.

- Dr. Barrett added that members could be extended for six months beyond their terms, which could be an option for members who are in the midst of a project and only need a short amount of time to complete it.

- Dr. Macklin wondered whether a meeting could include some "overlap" of members, in which some members attend as consultants. This approach would be especially helpful if a chair is selected who is a new member of the Subcommittee.

- Dr. Hooyman raised the question of public comment at their meetings. He had understood that public comments were restricted to items on their agenda. Otherwise, any person with an ethical "gripe" could come to the meeting.

- Dr. Barrett explained that her understanding is that the intent of the public comment period is to provide an opportunity for members of the public to provide input to the Subcommittee. It would seem inappropriate to stipulate what that input should be as long as the commenter stays within the allotted time frame. She will contact the Committee Management Office to obtain additional guidance.

- Dr. Macklin recalled that in her experience, members of the public who speak to the committee focus on subjects that the committee is addressing. She wondered whether they could stipulate a framework in which the public provides comments.

Closing Session

Dr. Barrett requested that those who did not have the opportunity to make comments at the meeting e-mail comments to her, and she would share them with the Subcommittee members. She also asked that they complete their evaluation forms.

Dr. Macklin thanked the Ethics Subcommittee and the PHEC members for their excellent input, and for contributing their valuable time to the joint meeting.

With no further business brought before the Ethics Subcommittee or PHEC, Dr. Macklin adjourned the meeting at 3:30 PM on August 10, 2007.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

_____
Date

_____
Ruth Macklin, Ph.D.
Chair, Public Health Ethics Subcommittee

ATTACHMENT 1
Meeting Participants

August 9, 2007

Ethics Subcommittee Members:
Dr. Ruth Macklin, Chair, Albert Einstein College of Medicine
Dr. John Arras, University of Virginia
Dr. Georges Benjamin, American Public Health Association
Dr. Mary desVignes-Kendrick, University of Texas Health Science Center
Dr. Thomas Hooyman, Ethically Speaking and Regis University
Mr. Bruce Jennings, Center for Humans and Nature
Ms. Kathy Kinlaw, Emory University
Dr. Barbara Koenig, Mayo College of Medicine
Dr. Robert Levine, Yale University
Dr. James Thomas, University of North Carolina, Chapel Hill

Drue Barrett, Ethics Subcommittee Designated Federal Official, OCSO

CDC Public Health Ethics Committee Members:
John Araujo, OCSO
Karen Bouye, OSI
Chris Braden, NCZVED
Steven Coughlin, NCCDPHP
Richard Dixon, NCHM
Barbara Ellis, COTPER
Debraelee Esbitt, COTPER
Roberto Garza, OCSO
Gail Horlick, OCSO
Annie Latimer, NCEH/ATSDR
Marinda Logan, COTPER
Charles Magruder, NCIPC
Josephine Malilay, NCEH/ATSDR
Kathleen McDuffie, NCHM
Jeff Peddicord, OCSO
Lee Sanderson, NIOSH
Scott Santibanez, NCHM
Salaam Semaan, NCHHSTP
Adam Skelton, NCHM
Anne Sowell, NCEH/ATSDR
Mark White, COGH

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Lauren Broussard, NCEH/ATSDR
Jacqueline Chmar, OCSO
Catherine Chow, CPTPER
Laurie Dieterich, NCPDCID
Betsey Dunaway, OCSO
Kimberly Geissman, OCWD

Leslie Gross, NCID
Peg Haering, CCID
Lisa M. Lee, OCSO
Dan McDonald, OWCD
Priscilla Patin, OD
Benjamin Schwartz, DHHS
Dixie Snider, OD
James Stephens, OCSO
Patricia Sweeney, NCHHSTP
Guijing Wang, OCSO
Mark Wooster, COTPER

Members of Public:
James Fessenden, The Lillie Center
Emily Meyer, Albert Einstein College of Medicine
Daniel Stockin, The Lillie Center

August 10, 2007

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Members of Public:
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