NIH Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Disease Laboratory at Boston University Medical Center

Working Group of the Advisory Committee to the Director

Summary of

Public Meeting

May 16, 2008

The NIH Blue Ribbon Panel for the Risk Assessment of the National Emerging Infectious Disease Laboratory (NEIDL) at Boston University Medical Center (BUMC) (Blue Ribbon Panel [BRP or "the Panel"]), a working group of the Advisory Committee to the Director (ACD) of the National Institutes of Health (NIH), was convened for its third meeting at 9:00 a.m. on May 16, 2008, in the Gardner Auditorium of the Massachusetts State House, Boston, Massachusetts. Dr. Adel Mahmoud (Chair) presided. In accordance with Public Law 92-463, the meeting was open to the public from 9:00 a.m. until 11:55 a.m. on May 16, 2008. Notice of this meeting was published in the *Federal Register* on May 7, 2008 (73 FR 25753). The purpose of this meeting was to summarize the BRP's work to date and to accept public comments.

Panel Members Present

Stephen Eubank, Ph.D., Virginia Polytechnic Institute and State University
Vicki S. Freimuth, Ph.D., University of Georgia
George Friedman-Jiménez, M.D., Bellevue Hospital Center
Margaret A. Hamburg, M.D., Nuclear Threat Initiative
Karen A. Holbrook, Ph.D., University of South Florida
Dennis L. Kasper, M.D., Harvard Medical School and Brigham and Women's Hospital
Johnnye Lewis, Ph.D., DABT, University of New Mexico
Adel Mahmoud, M.D., Ph.D., Princeton University (Chair)
Mary E. Northridge, Ph.D., M.P.H., Columbia University/*American Journal of Public Health*
Mark Gregory Robson, Ph.D., M.P.H., Rutgers, The State University of New Jersey

NIH Staff Members Present

Amy P. Patterson, M.D., Office of the Director (OD), NIH

Moderators for the Public Comments

John T. Burklow, OD, NIH
Alfred C. Johnson, Ph.D., Director, Office of Research Services, OD, NIH

Others

Approximately 123 people attended this BRP meeting.

I. Welcome and Opening Remarks: Purpose of the Blue Ribbon Panel/Dr. Mahmoud

Dr. Mahmoud, BRP Chair, called the meeting to order at 9:00 a.m. on May 16, 2008. BRP members introduced themselves with name, professional affiliation, and primary area of professional activity.

Dr. Mahmoud reviewed the purpose of this meeting, which was to summarize the BRP's work to date and to accept public comments, and he provided an overview of the agenda. Regarding the public input

session, Dr. Mahmoud explained that the BRP is gathering data and therefore will listen carefully and consider all remarks but that BRP members would not become part of the dialog.

This panel is a working group of the ACD, and as such, the BRP's initial recommendations will be conveyed to the NIH Director through the ACD at its next meeting on June 6, 2008. Dr. Mahmoud explained the BRP's charge from NIH Director Dr. Elias Zerhouni as providing independent scientific advice regarding the scope of additional necessary risk assessments and strategies for effective risk communication. The BRP is mindful of issues related to national environmental concerns, environmental justice (EJ), community liaison, and risk communications.

The procedures for the public input portion of the meeting, which was approximately 2 hours long, were reviewed. Mr. Burklow and Dr. Johnson facilitated the session. Individuals who wished to speak were asked to sign up at the table outside the room, and additional comments were noted as possible if all the registered remarks were completed within the allotted timeframe. Oral statements were limited to 3 minutes, but individuals were encouraged to submit their remarks in writing if more time was needed. Dr. Mahmoud stated that all oral and written remarks would be part of the official record of the BRP.

The Panel's Web site is considered the public reading room for all of the materials the BRP has received and reviewed. That Web site is http://nihblueribbonpanel-bumc-neidl.od.nih.gov/index.htm. In addition, materials will be provided in the local public library for those who do not have Internet access.

II. Panel's Approach to Its Tasks/Dr. Freimuth

Dr. Freimuth discussed the BRP's approach to its tasks. The Panel has reviewed background materials that include previous studies of the Massachusetts Environmental Policy Act and the National Environmental Policy Act (NEPA), judicial materials, safety and emergency preparedness plans, epidemiologic and demographic data, and oral and written public input. On May 2, 2008, the BRP convened its second public meeting, which focused on dialog with the National Research Council (NRC) committee and discussion of the NRC's letter report and additional findings.

The BRP is currently assessing (1) which additional studies would help identify the potential risks and public health consequences of accidental or malevolent releases of infectious agents and (2) whether exposure to infectious agents would materially differ in urban vs. less populated locations. Defining the key elements of those studies—infectious agents, scenarios, and methodologies of risk assessments—is also under way.

Dr. Freimuth further explained that the BRP would review strategies to minimize the chances of release and mitigate potential public health consequences in the event of a release. In addition, the Panel will assess the characteristics of the surrounding community and relationships with the community and will advise on the conduct of risk assessment studies and final reports.

III. Panel's Preliminary Findings/Dr. Mahmoud

Dr. Mahmoud shared the BRP's preliminary findings in two categories: (1) Additional risk assessment studies should be performed to address judicial requests and public concerns, and (2) it is important to allow transparency in conducting and communicating all additional studies. The additional risk assessment studies should involve an array of infectious agents that vary in their ability to infect people and cause disease and in their manner of transmission. Studies should be reality based and scientifically accurate and likely will vary in the ways in which they address the concept of "worst case." In addition, these studies should use proven methods and reflect known epidemiologic and demographic data related to EJ populations, should take into account the characteristics of the surrounding community, and should address the risk of agent release, probability of occurrence, and what happens when safety measures and emergency plans do and do not operate as expected. Transparency is particularly important to

maintain credibility and public trust. Any additional studies should be transparent in their design and conduct, and the final results and their interpretation should be made widely available.

The methodology to assess the consequences of a release or exposure event must include both a qualitative analysis, which uses relevant data to assess the likelihood of a release and its effect, and a quantitative analysis, which includes epidemiologic and other relevant data as well as mathematical modeling, if appropriate. All methodologies must have been tested and accepted by the scientific community, and these results also must be communicated in a transparent fashion.

IV. Panel's Next Steps/Dr. Mahmoud

Dr. Mahmoud discussed the BRP's next steps. On June 6, 2008, the BRP will present its work plan to the ACD; this meeting is open to the public and will be webcast; until that date, the BRP will allow a continuing opportunity for public comments. The BRP will advise the NIH on the conduct and analysis of studies through the latter half of 2008, obtain public input on the draft study report, and review and advise on the final report through the first half of 2009.

Written comments to the BRP may be submitted via e-mail at NIH_BRP@od.nih.gov or may be mailed in writing to NIH Blue Ribbon Panel, National Institutes of Health, 6705 Rockledge Drive, Suite 700, MSC 7985, Bethesda, MD 20892.

V. Input From the Citizens of Boston, Surrounding Communities, and the General Public/Mr. Burklow and Dr. Johnson

Mr. Burklow requested that individuals wishing to make remarks sign in at the check-in desk for this meeting. He explained that comments would be limited to 3 minutes per individual to allow enough time for all individuals to speak. A total of 39 comments were offered to the BRP at this public meeting.

Public Commenters

Although this list of commenters includes the affiliations of most of the speakers, in most cases it was not clear whether the individual was speaking for herself/himself or for her/his organization. Names are listed alphabetically within the appropriate group.

Speaking *in support of* the NEIDL were the following individuals:

- James Coyle, Metropolitan Boston Building Trades
- George B. Donahue, Plumber's Union Local 12
- Mark Klempner, BUMC
- Paul Lynch, Iron Workers
- Robert McCarron, Association of Independent Colleges and Universities of Massachusetts
- Bob Rio, Associated Industries of Massachusetts
- Michael J. Spillane, Massachusetts Association of Nonprofit Schools and Colleges

Speaking *in opposition to* the NEIDL were the following individuals:

- Klare Allen, Safety Net
- Maryann Colella, Stop the Biolab Coalition
- Michael Cote, Safety Net
- Louise Dunlap, Cambridge citizen
- Sandy Eaton, Massachusetts Nurses Association
- Joan Ecklein, Women's International League for Peace and Freedom
- Susan Gracey, Women's International League for Peace and Freedom

- Nelson Ham, citizen
- Alice Kast, Pax Christi
- Joseph F. Kebartas, South Boston Residents for Peace
- Heather Spurlock Kennedy, McRoberts, Roberts, and Rainer
- Phoebe Knopf, citizen
- Ernesta Kraczkiewicz, Watertown Citizens for Environmental Safety
- Eloise Lawrence, Conservation Law Foundation
- Laura Maslow-Armand, Boston Bar Association
- Elliot Mishler, Harvard Medical School
- David Mundel, resident of Boston's South End
- Adrienne Naylor, Stop the Biolab Coalition
- Carmen Nazario-Vega, Safety Net
- Teddi Richman, Safety Net
- Vicky Steinitz, United for Justice with Peace (read into the record by Susan Lees)
- Cornelia Sullivan, Pax Christi
- Chuck Turner, City Councilman
- Joseph Whight, Safety Net
- Katie Zappala, citizen

The following individuals expressed *neutral opinions* about the NEIDL:

- Barbara Ferrer, Boston Public Health Commission
- David Ropeik, Harvard University

In addition, five individuals who had not signed up ahead of time offered comments at the end of this session; four comments were against the NEIDL, and one commenter supported the NEIDL.

Summary of Issues

The following list of issues is not exhaustive; the full issues list will be contained in the minutes of this meeting. These comments are presented here, within each category, in the order in which they were offered at the meeting.

Issues in support of the NEIDL:

- Biosafety level 4 (BSL-4) labs can operate safely; there has never been a community incident or environmental release.
- The NEIDL will include the latest safeguards, and the researchers will be among the most experienced in the world.
- Boston has an outstanding reputation for biomedical research, and the BUMC has a long history of infectious disease research.
- The NEIDL will provide needed jobs and will generally be good for Boston's economy.
- Boston has a ready-made talent pool of educated people who will be able to operate this lab safely.
- The NEIDL is expected to create 1,200 construction jobs and 660 permanent jobs.
- The NEIDL was designed and is being built in accordance with stringent safety standards. Safety will be maximized.
- The NEIDL will be in close proximity to other research organizations and to other scientists, and the research conducted at the NEIDL will benefit all of society and will meet all regulatory requirements.

Issues in opposition to the NEIDL:

- Community concerns have not received a fair, open response and have not always been deemed important.
- The BSL-4 lab within the NEIDL will be a bioterror lab.
- The BSL-4 lab will be a dangerous military project in the middle of residential neighborhoods.
- The BRP should look at the no-action alternative under the NEPA.
- Treatments for the diseases that will be studied in the proposed BSL-4 lab are in development, so the BSL-4 lab at the NEIDL is not needed.
- Critical and immediate public health needs of the population are being ignored (*e.g.,* HIV/AIDS).
- Locating a high-risk facility in a dense, low-income, predominantly minority, EJ community is a violation of the civil rights of that community, and is an example of environmental racism.
- There is no justification for a BSL-4 lab being located in downtown Boston.
- Evacuation plans and routes are inadequate.
- No quarantine plan exists.
- Holding this meeting at 9 a.m. on a weekday makes it difficult for a majority of community residents to attend.
- The NEIDL is built on landfill with a storm drain that, when not filled with water, could provide unsecured access to the facility.
- The surrounding community is a densely populated area with a large number of medically challenged individuals.
- Failure to build this BSL-4 lab will not harm Boston's biomedical research industry.
- Failure to conduct comprehensive alternative site analyses is of concern.
- A distrust of government and industry exists within the community surrounding the NEIDL.
- Members of the community should be included on this panel, along with scientists and BUMC representatives.

Other issues:

- Relationships between the BUMC and the community have been badly damaged.
- Lack of respect and trust between the BUMC and the community.

VI. Wrap-Up/Dr. Mahmoud

Dr. Mahmoud stated that public input is critical to the BRP's understanding of the issues and that the input received today would be reflected in the minutes of this meeting. Written comments provided by e-mail or the U.S. Postal Service are welcome and need to be received by May 30 to be considered as part of the report to the ACD on June 6, 2008.

Dr. Mahmoud thanked all of the public participants at this meeting.

VII. Adjournment

Dr. Mahmoud adjourned the meeting at 11:55 a.m. on May 16, 2008.

[Note: This summary is based on notes taken at the meeting by a science writer and NIH staff members. More detailed information will be available in the minutes of this meeting. Actions approved by the BRP are considered recommendations to the ACD; therefore, actions are not considered final until approved by the ACD.]

Additional information about this Blue Ribbon Panel can be found at: http://nihblueribbonpanel-bumc-neidl.od.nih.gov/index.htm.

Attachment: Roster
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