

NATIONAL INSTITUTES OF HEALTH

MEETING OF THE COMMITTEE ON TECHNICAL INPUT
ON THE NIH'S DRAFT SUPPLEMENTARY RISK ASSESSMENTS
AND SITE SUITABILITY ANALYSES
FOR THE NATIONAL EMERGING INFECTIOUS DISEASES
LABORATORY, BOSTON UNIVERSITY

Washington, D.C.

Friday, October 19, 2007

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1 PROCEEDINGS

2 (8:30 a.m.)

3 DR. AHEARNE: -- your
4 institutional- organization connection and
5 then I will ask the same thing of the people
6 around the room. So I'm John Ahearne. I'm
7 retired from Sigma Xi and the Scientific
8 Research Society.

9 DR. JOHNSON: Barbara Johnson. I'm
10 a private consultant on biosafety and
11 biosecurity.

12 DR. RICHMOND: Jonathan Richmond,
13 also a biosafety consultant.

14 DR. ARMSTRONG: I'm Tom Armstrong.
15 I'm the industrial hygienist currently
16 working with ExxonMobil Biomedical Sciences.

17 DR. GRONVALL: Gigi Kwik Gronvall,
18 Center for Biosecurity, the University of
19 Pittsburgh Medical Center.

20 DR. NORTH: Warner North, private
21 consultant with NorthWorks, Incorporated, in
22 Belmont, California, in risk analysis.

1 DR. CHOWELL: I'm Gerardo Chowell.
2 I'm an assistant professor at the School of
3 Human Evolution and Social Change at Arizona
4 State University.

5 DR. HARVILL: Eric Harvill. I'm an
6 associate professor at Pennsylvania State
7 University.

8 DR. SMITH: Hello. I'm Gary Smith.
9 I work at the University of Pennsylvania
10 School of Veterinary Medicine.

11 MS. COLEMAN: My name is Margaret,
12 or Peg, Coleman and I work for Syracuse
13 Research Corporation as a microbiologist.

14 DR. LOCKE: I'm Paul Locke. I'm an
15 associate professor at Johns Hopkins
16 Bloomberg School of Public Health in
17 Baltimore, Maryland.

18 (Recess)

19 MR. TONKISS: John Tonkiss.

20 MS. SUPERNAVAGE: I'm Sherry
21 Supernavage. I'm a fellow at NBBPT
22 Fellowship and (off mike).

1 MR. TUOHEY: Kevin Tuohey, Boston
2 University.

3 MR. TAHMASSIAN: Ara Tahmassian,
4 Boston University.

5 MR. GIEDT: Anton Giedt, United
6 States Department of Justice.

7 MR. LANKFORD: I'm David Lankford
8 and I work at the Department of Health and
9 Human Services.

10 MS. BIAN: I'm Ling Bian, (off
11 mike).

12 MR. VANDERSLUIJS: Patrick
13 Vandersluis. I'm (off mike).

14 MR. KURILLA: I'm Mike Kurilla,
15 NIAID.

16 DR. WILSON: Debbie Wilson, (off
17 mike).

18 DR. AHEARNE: Okay, let me (off
19 mike) minutes.

20 REPORTER: He's lost power.

21 DR. AHEARNE: He's lost power?

22 REPORTER: It seems that it was

1 working when I tested it and now (off mike).

2 DR. AHEARNE: I'm sorry. We're
3 going to have to continue.

4 REPORTER: Yes, let me grab this
5 microphone, put it on here.

6 DR. AHEARNE: The purpose of this
7 meeting is to help this committee prepare a
8 letter report. A letter report goes through
9 the same procedures that the National Academy
10 has for all its reports, except the letter
11 report tends to be much smaller. It's 15 to
12 20 pages usually.

13 We are going to hear this morning
14 from presenters, then we'll go into closed
15 session. This afternoon, this evening, and
16 tomorrow, we will be writing our report.

17 The report is going to be focused
18 on a narrow set of questions: To determine
19 if the scientific analyses in this most
20 recent NIH study are sound and credible;
21 determine whether the proponent has
22 identified representative worst-case

1 scenarios; and determine based on this
2 study's comparison of risks associated with
3 the alternative locations identified in the
4 study, whether there's a greater risk to
5 public health and safety from the location
6 facility in one or another proposed location.

7 We are not going to look at many
8 broader issues. For example, we're not going
9 to look at should there be many BSL-4
10 facilities? We are not going to come up with
11 a recommendation for the state of
12 Massachusetts. We are going to answer those
13 three questions. And I recognize some of you
14 may see that as narrow, but that's the task
15 we have.

16 The other thing I have to comment
17 on, and I assume Deborah Wilson will comment
18 in the beginning of it, yesterday we were
19 advised that NIH cannot answer any questions
20 in this meeting because of VBA. So that will
21 somewhat restrict the interaction between the
22 committee and NIH.

1 Marilee, something else we should
2 (off mike)?

3 MS. SHELTON-DAVENPORT: I'm sorry,
4 (off mike) technical issues, so I didn't hear
5 everything that you said, but did you tell
6 them not to take anything that committee
7 members said out of --

8 DR. AHEARNE: Go ahead.

9 MS. SHELTON-DAVENPORT: So this is
10 an open session. It's an information
11 gathering session for the committee members.
12 Anything that the committee members say or
13 ask should not be taken as an indication of
14 the committee members' opinions on the
15 particular issues. It would be inappropriate
16 to take any opinion -- take back anything
17 from this open session like that until the
18 final report is out. That will state the
19 committee's opinion.

20 Also, I already covered that this
21 session is going to be recorded and there's a
22 recorder on the telephone. We'll having a

1 little bit of a technical issue. We've tried
2 to do several technical things at the same
3 time, as you can see. So, hopefully, we'll
4 see what happens (off mike).

5 DR. AHEARNE: I wonder why a
6 National Academy of Sciences building has so
7 much difficulty with telecommunications, but
8 that's (off mike).

9 MS. SHARPLES: You don't want to go
10 there.

11 DR. AHEARNE: Right. It's not part
12 of scope.

13 MS. SHELTON-DAVENPORT: Are the
14 people on the teleconference able to hear us?

15 SPEAKER: Yes.

16 MS. COLEMAN: Could you just let us
17 know who's on the teleconference, please?
18 Please state your names.

19 MS. SMITH: Stephen Smith with the
20 Boston Globe.

21 MR. NICKSA: Gary Nicksa with
22 Boston University.

1 MR. WILLIAMS: Steve Williams from
2 Boston University.

3 MR. MOORE: And Tom Moore from
4 Boston University.

5 SPEAKER: HHS Office for Civil
6 Rights.

7 MR. FAYE: Jamie Faye.

8 MS. SHELTON-DAVENPORT: So I'll
9 just say again for those that are on the
10 line, I'm not sure if you heard the earlier
11 announcement that anything in the open
12 session that the committee is asked should
13 not be construed as the committee's opinion
14 on any of these particular topics. They may
15 ask questions in a leading way to get
16 answers, but that does not represent their
17 opinion on the particular issues. And it
18 would inappropriate to take anything out of
19 this open session as such an opinion.

20 DR. AHEARNE: Okay. Mr.
21 Babb-Brott?

22 MR. BABB-BROTT: Good morning.

1 DR. AHEARNE: You get your full
2 half-hour, but we'll be starting late, so go
3 ahead.

4 MR. BABB-BROTT: I don't think I'll
5 need it. So good morning, folks. On behalf
6 of Ian Bowles, the secretary of the
7 Massachusetts Executive Office of
8 Environmental Affairs, my name is Deerin
9 Babb-Brott. I am the assistant secretary for
10 environmental impact review for
11 Massachusetts. In that capacity I direct the
12 office that reviews major development
13 projects in Massachusetts under the
14 Massachusetts Environmental Policy Act, or
15 MEPA, which is the state analog to the NEPA
16 federal process.

17 Sec. Bowles would like to thank the
18 National Academies and the distinguished
19 committee members for their work (off mike)
20 on this project.

21 I'd like to thank Fran Sharples,
22 Evonne Tang, Marilee Shelton-Davenport, and

1 Rebecca Walter for helping us to bring this
2 contract to fruition.

3 My brief presentation this morning
4 will include a very brief background on how
5 we arrived at where we are now with our
6 review in the project before you, the current
7 status, and then the charge from the sponsor.
8 And then I understand we'll be opening this
9 up for questions and discussions.

10 DR. AHEARNE: (off mike)

11 MR. BABB-BROTT: Thank you.

12 MS. SHELTON-DAVENPORT: If you need
13 help, we can also flip it from back there.

14 MR. BABB-BROTT: Great, thank you.
15 Boston University addressed the potential
16 environmental impacts of the biosafety lab in
17 a final EIR, Environmental Impact Report,
18 which is our analog to the Environmental
19 Impact Statement, and submitted that for
20 review.

21 MS. SHELTON-DAVENPORT: You can
22 disconnect.

1 MR. BABB-BROTT: Submitted for that
2 review under the Environmental Policy Act.
3 The final EIR assessed potential impact to
4 human health and safety using the worst-case
5 scenario based on accidental or malevolent
6 release of anthrax -- excuse me, the
7 accidental release of anthrax. The secretary
8 of EEA at the time determined that the final
9 EIR adequately demonstrated that Boston
10 University had avoided, minimized, and
11 mitigated potential environmental impacts to
12 the maximum extent practicable, which is the
13 fundamental test under MEPA of an EIR's
14 adequacy.

15 That determination was subsequently
16 challenged in State Superior Court, which
17 invalidated the secretary's certificate. The
18 Court remanded the review to the secretary.
19 Finding that the worst-case scenario should,
20 rather than being based on anthrax, should be
21 characterized as an accidental or malevolent
22 release or a contagious pathogen. And he

1 found that environmental review should
2 include an assessment of the comparative risk
3 of setting the BSL in an alternative less
4 densely populated location.

5 The secretary of EEA issued a scope
6 for a supplemental final EIR that
7 incorporated those two components of the
8 Superior Court's direction. Simultaneously,
9 BU appealed the Superior Court's order, and a
10 decision on the appeal is pending currently
11 before the State Supreme Judicial Court.

12 As folks are aware, the National
13 Institutes of Health has published for review
14 the Daft Supplementary Risk Assessments,
15 which are the focus of this effort. The
16 National Institutes study is designed in part
17 to address the state requirement that the
18 supplemental final provide information about
19 the worst-case scenario and comparative
20 levels of risk.

21 The National Institutes study will
22 form the scientific basis of the supplemental

1 final EIR.

2 There will be additional materials
3 that will be incorporated through Boston
4 University. EEA has contracted, as folks are
5 aware, to provide an independent peer review
6 of the NIH study to inform the state's
7 review. In addition, EEA will file the NRC
8 report with the National Institutes of Health
9 during the current public comment period.

10 The charge from the sponsor, as has
11 already been walked through, is to determine
12 if the scientific analyses in the NIH study
13 are sound and credible; to determine whether
14 the proponent has identified representative
15 worst-case scenarios; and to determine, based
16 on the comparison of risk, whether there is
17 greater risk to public health and safety from
18 the location of the facility in one or
19 another proposed location. And I guess I
20 would summarize all of that, and particularly
21 the second bullet, by asking in the
22 alternative did the National Institutes of

1 Health omit a more plausible, realistic, or
2 appropriate scenario?

3 And with that, I'll conclude.

4 Thank you.

5 DR. AHEARNE: I have a question.

6 You mentioned that the Court said the
7 worst-case scenarios should be characterized
8 as accidental or malevolent release. The
9 charge from Massachusetts to us said
10 determine whether (off mike) has identified
11 representative worst-case scenarios. Did
12 Massachusetts intend for that to also include
13 malevolent?

14 MR. BABB-BROTT: I think not
15 because Massachusetts is interested in
16 specifically the contents of the NIH study.

17 DR. AHEARNE: But your statement to
18 -- Massachusetts issued a scope for the
19 preparation supplemental and that includes --
20 Massachusetts asked for at least one
21 additional worst-case scenario analysis
22 rising from the next (off mike) or malevolent

1 release.

2 MR. BABB-BROTT: There's a
3 distinction between the scope of the
4 supplemental final EIR and the materials that
5 we -- or the questions that we've asked the
6 National --

7 DR. AHEARNE: No, I understand
8 that. I'm just --

9 MR. BABB-BROTT: I guess then I'd
10 hedge and I'd say -- I'd go back to did the
11 study omit a more plausible, realistic, or
12 appropriate scenario?

13 Since the focus of the effort is on
14 the NIH study, I think that --

15 DR. AHEARNE: And my question goes
16 back, at Massachusetts' request do you
17 include malevolent scenarios as being
18 appropriate and realistic?

19 MR. BABB-BROTT: I apologize, but
20 I'm going to play ping-pong.

21 DR. AHEARNE: Okay. Other
22 committee -- Paul?

1 DR. LOCKE: I would like, just on
2 your expertise as a leader in the
3 Massachusetts Environmental Agency, and
4 perhaps you could tell us if there is
5 something in the Massachusetts statutes or
6 the Massachusetts regulations or the
7 Massachusetts core of decisions that define
8 the term "worst-case scenario?"

9 MR. BABB-BROTT: There is not that
10 I am aware of. I am not a lawyer and I am
11 not thoroughly versed in case law associated
12 with this. As far as the regulations are
13 concerned, under the environmental
14 secretariat, I am not aware of "worst- case
15 scenario" being defined formally. I am not
16 fully versed in regulations which underlie
17 the Department of Public Health secretariat.

18 DR. LOCKE: Can I just follow up
19 with another question then? The sense I'm
20 getting is the definition of "worst-case
21 scenario," is that a definition that has some
22 -- all technical components that -- or it's

1 not -- it doesn't sound like -- from what you
2 said, it's something that has a legal
3 definition, so is it a technical definition?

4 MR. BABB-BROTT: We have
5 incorporated the phrase "worst-case scenario"
6 based on the language and the judge's order.
7 And I guess in that regard it's the latter.
8 We are not asking the question from a
9 specific position grounded in an actual
10 definition. We rely on the expertise of the
11 committee to find their way to that.

12 DR. LOCKE: Thank you.

13 DR. AHEARNE: Any other questions
14 from the committee? Marilee, any question
15 from you? Fran?

16 MS. SHARPLES: Can you amplify a
17 little bit, Deerin, on what the state is
18 hoping to get out of this? I mean, we have
19 these words that describe it, but can you
20 sort of flesh that out a little bit or is
21 there nothing more to be said beyond --

22 MR. BABB-BROTT: I don't think

1 there's more to be said beyond that. We are
2 looking to the committee of experts to
3 provide an independent peer review of the NIH
4 study predicated on and framed by the three
5 questions that we posed.

6 DR. AHEARNE: All right. Thank
7 you.

8 MR. BABB-BROTT: Thank you.

9 DR. AHEARNE: Since we're running
10 ahead, we can shift to NIH.

11 DR. WILSON: Oh, we can shift to
12 NIH when the technical problems have been
13 resolved.

14 DR. AHEARNE: Could you use a
15 microphone, please?

16 DR. WILSON: Well, they've not
17 loaded my presentation yet.

18 DR. AHEARNE: Well, while they're
19 waiting to load your presentation, could you
20 explain, as I understand it, yesterday we
21 were informed that we cannot answer any
22 questions?

1 SPEAKER: I can clarify that for
2 you.

3 MS. SHELTON-DAVENPORT: Could you
4 come to the table?

5 SPEAKER: Can you use a mike,
6 please?

7 MS. SHELTON-DAVENPORT: And
8 actually we need everybody to use the
9 microphones and to state your names. We've
10 got a message from the folks on the telephone
11 that they're not hearing questions very well.

12 MR. LANKFORD: Yes, my name is
13 David Lankford. I'm with the General
14 Counsel's Office for the NIH.

15 DR. AHEARNE: Okay. You -- but
16 then since you're answering it, you can also
17 answer this meeting has been scheduled for
18 three weeks. Yesterday we were told NIH
19 cannot answer questions.

20 So I'm a little puzzled by the
21 timeframe, but go ahead and answer the
22 question, please.

1 MR. LANKFORD: All right. Well, as
2 we discussed with the NAS yesterday, the NIH
3 will not be able to answer questions at this
4 session today or this morning. If the panel
5 members wish to submit questions, they can do
6 so through NAS in writing to the NIH. The
7 NIH will review the questions and then decide
8 if NIH is able to answer them, hopefully,
9 this afternoon, so that you have the benefit
10 of the answers as you do your closed session
11 discussions.

12 DR. AHEARNE: You haven't answered
13 my question as to why you can't answer the
14 questions.

15 MR. LANKFORD: There are
16 restrictions under the National Environmental
17 Policy Act that limit our ability to do that
18 today.

19 DR. AHEARNE: Could you say what
20 they are?

21 MR. LANKFORD: Well, I'm not sure
22 it's appropriate to get into that discussion

1 here, but we have sorted through these issues
2 and that's basically what we can do today,
3 and we're certainly trying to be cooperative.

4 DR. AHEARNE: It probably would
5 have helped had you sorted through those
6 issues and told us several days ago, but all
7 right. Is it loaded?

8 MS. SHELTON-DAVENPORT: Yes, she's
9 loading it.

10 DR. WILSON: Thank you.

11 MS. SHARPLES: That is not
12 intuitively obvious, how to use (off mike).

13 DR. WILSON: And the pointer, I've
14 got it, but the pointer is at the top?

15 SPEAKER: Yes, but it doesn't --
16 wherever you are in the room, it will (off
17 mike).

18 DR. WILSON: Thank you. Good
19 morning, everyone. I'm Deborah Wilson. I'm
20 director of the Division of Occupational
21 Health and Safety at the National Institutes
22 of Health in Bethesda, Maryland.

1 And I'm here today to discuss with
2 you in particular the additional risk
3 assessments that were done by the NIH
4 regarding the National Emerging Infectious
5 Diseases Laboratory, so-called NEIDL, that is
6 located or being built on Albany Street in
7 Boston. Now, the NEIDL in particular, and
8 the reason that we're here today, is that
9 this laboratory contains a maximum
10 containment laboratory, a BSL-4 laboratory,
11 which is the point of these risk assessments.

12 I would like to mention and thank
13 very, very much our collaborators. Dr. Ling
14 Bian from the State University of New York at
15 Buffalo and the National Center for
16 Geographic Information and Analysis. This is
17 one of the three national centers in the
18 United States. Dr. Bian's an associate
19 professor and she has a particular research
20 interest in individual-based epidemiologic
21 modeling.

22 Pat Vandersluis was president of

1 HealthRx Corporation from Fairfax, Virginia.
2 And his work includes modeling, simulation
3 research, clinical IT solutions using high
4 dimensional biomedical data visualization.

5 And Dr. Murray L. Cohen,
6 consultants in disease and injury control
7 from Atlanta, Georgia, has retired from the
8 Centers for Disease Control after a 21-year
9 career there. And he has a broad background
10 in public health, community health, and
11 worker safety from previously being at NIOSH.

12 And I want to say publicly how much
13 I thank these wonderful people for working
14 under incredible deadlines. Dr. Bian
15 mercilessly worked her graduate students day
16 and night for a period of four months to
17 create the work that you (off mike).

18 DR. AHEARNE: You should also thank
19 the graduate students?

20 DR. WILSON: I do. It's just that
21 I don't have their names written down and I
22 can't remember them all, but I heartily thank

1 them.

2 Now, the purpose of the overall
3 study here was to take an additional hard
4 look at the NEPA issues to ensure that equal
5 consideration was given to alternative sites.
6 We were to perform risk assessments to
7 investigate the extent, if any, to which
8 exotic diseases if accidentally released may
9 spread into the communities where the NEIDL
10 may have been built. We wanted to compare
11 the impacts on these three different sites
12 and to determine if there would be a
13 disproportionate health impact on any
14 environmental justice communities that were
15 present.

16 The report has two main parts.
17 First, the risk assessments, which are what
18 I'm going to address this morning. The
19 second was the additional site analyses,
20 which I don't intend to discuss, but are
21 clearly laid out in the report.

22 I think there are two important

1 questions as we go forward and listen to what
2 I have to present: How are the diseases that
3 we study chosen and how are the scenarios
4 developed?

5 NIH felt it was just critically
6 important that the public have input into
7 this study, so we offered a number of
8 outreach activities, including public
9 meetings in Boston, set up e-mail addresses
10 where people could send comments, and a
11 special telephone line and special number for
12 people to call to give verbal input. From
13 all of that, the public comments we received
14 gave us this list of situations that the
15 public was more concerned about with the
16 siting and operating of a Biosafety Level 4
17 laboratory in and around a particular
18 neighborhood.

19 First was a transportation accident
20 with subsequent release of an infectious
21 agent, release of a vector-borne disease,
22 release of an infected insect, a laboratory

1 incident that concerned either mislabeling a
2 specimen or a stock culture, release of a
3 recombinant organism, a laboratory incident
4 involving Ebola virus, a laboratory incident
5 involving a poxvirus. And I'll digress for a
6 moment there.

7 The community, even after our last
8 public presentation in Boston, some members
9 of the community have concerns that smallpox
10 will be used in this facility. They continue
11 to look at a particular table in the final
12 EIS, which is labeled "Agents That Will Be
13 Studied Looking Into the Characteristics of
14 Smallpox," or something to that nature. And
15 that has caused a great deal of confusion and
16 it remains to this day. So we included a
17 poxvirus. Not smallpox because we didn't
18 find that to be realistic, and so we have
19 chosen another one.

20 An incident involving a school or
21 school- aged children and an incident
22 involving requiring transport of an

1 infectious patient. Now, that's a lot to try
2 and do.

3 Additionally, we received this
4 public comment and we think it is very cogent
5 and goes right to the point of the risk
6 assessment that needed to be done,
7 specifically the portion that says, "True
8 life complexity cannot be left out of the
9 model for the sake of making the problem
10 tractable." We really took that to heart as
11 I think you will see in a few moments when I
12 discuss the models used.

13 The diseases we selected for study.
14 The very first one, because there's just
15 major interest in it, was the Ebola virus.
16 It was chosen because it is probably the most
17 notorious of the viral hemorrhagic fever
18 viruses. Hemorrhagic fever viruses assigned
19 to Biosafety Level 4 containment. They're
20 very high mortality rates and we don't know
21 yet absolutely the reservoir of disease.
22 There are many books, articles, movies in the

1 popular press, and there have been outbreaks
2 of severe hemorrhagic disease in African
3 towns and villages. And, of course, this
4 causes a great deal of concern to people who
5 read or hear about it and, in fact, there is
6 an ongoing Ebola outbreak at this time.

7 The second disease, and the example
8 of the poxvirus that we chose, is monkeypox
9 virus. This disease closely resembles
10 smallpox. It's transmitted in a similar way.
11 Scientists use it, in fact, as a surrogate
12 for studying the characteristics of smallpox.
13 It is indeed communicable from person to
14 person. And there was an outbreak caused in
15 the United States in 2003, when pet prairie
16 dogs crossed paths with an African rodent
17 that was imported as an exotic pet into the
18 United States, and people, adults and
19 children, were infected through six states in
20 the Midwest. So we have included monkeypox
21 as an orthopox virus example.

22 The next disease we included was

1 Sabia virus. This is a New World or Western
2 Hemisphere hemorrhagic fever virus. It is a
3 member of the arenavirus family. It causes
4 hemorrhagic disease. As a matter of fact,
5 most of the South American hemorrhagic fever
6 viruses cause hemorrhagic disease more
7 quickly and perhaps more intensely than the
8 African ones. There have been two known
9 human cases originated from laboratory
10 settings. And, in fact, we included it
11 because this particular area in the Northeast
12 has some experience with Sabia virus when a
13 Yale researcher became infected while working
14 in the laboratory as the result of a
15 centrifuge spill.

16 And this individual did indeed
17 travel to Boston, and so we thought that
18 there probably would be memory of that. And
19 so wanting to include a South American virus
20 in our group as well, a virus that's normally
21 assigned to Biosafety Level 4, we have chosen
22 Sabia virus, most particularly because it

1 lends itself very, very well to
2 laboratory-acquired infections.

3 And then the next disease we chose
4 for study is the Rift Valley fever virus.
5 There currently is an ongoing epizootic or an
6 epidemic in animals in Africa. And as of May
7 of this year, there were over 1,000 confirmed
8 human cases and 315 deaths. I have not
9 looked up the most recent figures, but
10 they'll be up.

11 Humans are highly susceptible to
12 this virus. It is enormously infective in
13 aerosols. It has caused a number of
14 laboratory-acquired infections. And most
15 recently, to my knowledge, Paragas and Endy
16 have done a survey of that. A hundred and
17 three laboratory-acquired infections and four
18 deaths in the scientific literature. And
19 scientists worry that Rift Valley fever, if
20 introduced into this country from the African
21 continent, would really have a severe impact
22 on human animal health and the U.S. economy.

1 Now, why do I say that? Obviously
2 other than the impact on human health, we
3 have a \$3 billion industry in beef, just beef
4 alone in this country, and over \$6 billion a
5 year in export of beef, all which would be
6 impacted as well.

7 Rift Valley fever was also chosen
8 because it is transmitted by mosquitoes. And
9 wanting to make sure that we could spread
10 this disease as far as possible in our model,
11 a mosquito lent itself to that much more than
12 a tick that is limited to being transmitted
13 by its host. The mosquitoes, of course, can
14 -- many species can fly great distances, they
15 can be blown by wind, they can be carried in
16 containers, so on and so forth. And so we
17 thought this offered a better vector for
18 worst-case modeling.

19 A few things I would like for you
20 to remember if you would, please, while I go
21 through the description of the models and the
22 results. These scenarios are indeed

1 fictitious, but we base them on the available
2 science and recommended public health
3 practice. Where it was available, we did use
4 information and data, but if we didn't have
5 it, we made decisions that would overstate
6 risks and overstate the negative outcomes in
7 all simulations.

8 Now, the data and information that
9 was in the literature we also used in a way
10 that would overstate risk significantly. And
11 when I say that, if there were -- I'll give
12 you an example, Ebola virus. In the
13 literature there are fatality rates anywhere
14 from 40 or 50 to 90. You know, mostly it's
15 85 percent. We chose 85 percent. Whenever
16 we had a range, we would take the worst or
17 the more conservative approach. Okay.
18 Wherever we made a decision like that, the
19 same set of circumstances were, of course,
20 applied across all three communities in every
21 simulation.

22 And these scenarios were designed

1 to force an infection beyond the laboratory.
2 So in every scenario there would be at least
3 one laboratory or event-related infection and
4 at least one secondary infection that was
5 forced into the community and then we modeled
6 from there. So keep that in mind that we set
7 these scenarios up to purposely force
8 infection in the communities so we could then
9 compare how these diseases acted in the
10 communities and compare the impacts and
11 negative outcomes on each community.

12 When we developed the models
13 probabilities of disease occurrence were
14 assigned to events that have not occurred in
15 nature, again, to force infections and give
16 more weight to negative outcomes and
17 infections in the community. An example: We
18 assigned a probability to respiratory
19 transmission of Sabia virus that has not been
20 documented in the literature nor have we seen
21 it in the natural history of the pathogenesis
22 of the disease.

1 No public health interventions at
2 all were included in these simulations. We
3 took away all immunizations. Where we used
4 mosquitoes, there's no insect repellent. For
5 the most part we have immunologically naive
6 populations simply because these are indeed
7 exotic agents. And where for the orthopox
8 virus assumed no immunity by smallpox
9 immunization.

10 The A-BEST simulation provides
11 millions of interactions during an explicit
12 individual movement, simulating daily-life
13 activities within these towns and cities that
14 we're creating, optimizing the exposure
15 potential, and it results in worst-case
16 modeling opportunities. Collectively, we ran
17 over 2,500 simulations to demonstrate for you
18 the reliability and reproducibility of the
19 models that we used.

20 Now, if you recall that list of
21 situations that the public was most concerned
22 about, we included every one of those things

1 in complex scenarios, four scenarios as a
2 matter of fact, so there are numerous layers
3 of risks built in. The Ebola, and I'm not
4 going to go in and describe each scenario
5 because that's written in great detail in
6 your reports, but just know in the Ebola
7 virus scenario we studied familial contacts;
8 occupational exposures; sexual transmission,
9 again, something that has not been seen in
10 nature, but we gave it probabilities to study
11 that in our simulations; and patient
12 transport.

13 Monkeypox. This was the example of
14 the poxvirus. This was the scenario where we
15 introduced the recombinant aspect. We put a
16 green fluorescent protein this orthopox
17 virus. It involved schoolchildren. It
18 involved patient transport. Also here is,
19 and I'll point out, an opportunity where we
20 used public health practice and introduced a
21 pocket pet, so-called pocket pet, a hamster,
22 and looked at that as well in the scenario.

1 Now, know that nowhere in the
2 literature has it ever been reported that man
3 has transmitted monkeypox to an animal. But
4 the Centers for Disease Control very strongly
5 warns against handling these so-called pocket
6 pets if you think you've been exposed. This
7 was part of multiple guidance documents that
8 came out in 2003.

9 And then the Sabia virus scenario.
10 This was the laboratory accident scenario.
11 It's a centrifuge accident. This one
12 involves the mislabeled specimen and aerosol
13 transmission in the laboratory. And for this
14 one we also assumed a person-to-person
15 respiratory route of transmission as I
16 mentioned earlier. That has not happened in
17 nature, but we gave a small but finite
18 probability of that to study how it would
19 transmit through the community.

20 Rift Valley fever. This one
21 involved the transportation accident. And
22 just so you understand how we made that

1 happen, those of you who are familiar with
2 the actual shipping containers that are
3 required for select agents and this level of
4 infectious agent will know that they're
5 pretty close to indestructible. So in order
6 to have this released because of a
7 transportation accident when these devices
8 are made to withstand airplane crashes and
9 transportation accidents, the scenario
10 involved a postdoctoral student -- excuse me,
11 a postdoctoral fellow who couldn't read and
12 put dry ice in the container, which resulted
13 in an explosion when the truck hit a pothole.
14 The additional energy caused it to explode
15 and create an aerosol. And really that's
16 about the only way we could figure out to do
17 that.

18 This is the vector-borne disease
19 where there is an infected insect as part of
20 it. And in this particular scenario, because
21 Rift Valley fever really has kind of two
22 modes of transmission, it's certainly a

1 zoonotic agent, but it also is an
2 occupational exposure for veterinarians,
3 farmers, people who may have contact with
4 infected body fluids, materials of
5 parturition, so on and so forth.

6 So as you can see, these scenarios
7 in and of themselves are extremely complex.
8 And we tried very, very hard to address all
9 of the comments that were given to us and the
10 major concerns about these agents that may
11 indeed be used in the NEIDL.

12 We used to risk assessment models
13 to get our data. First, the Agent-Based
14 Explicit Spatial and Temporal Model, what we
15 have named the so-called A-BEST Model, and we
16 studied four infectious diseases. And then
17 the multilayer agent-based simulation tool,
18 MLAB, which we studied the vector- borne
19 disease only. Which, of course, begs the
20 question why did we use two different models?

21 The vector-borne disease issues or
22 anybody who has attempted to study

1 vector-borne disease and the natural history
2 of these diseases knows that there are unique
3 challenges associated with it. In order to
4 force Rift Valley fever in our A-BEST Model
5 it was necessary to load the model with
6 10,000 Rift Valley fever-infected mosquitoes
7 at a given density per acre of appropriate
8 water habitat for that mosquito. And we did
9 this to ensure that we got vast overstatement
10 of the risks. And during something, and I
11 didn't finish that sentence.

12 MLAB modeling, however, allowed the
13 simulation to begin with one infected
14 mosquito and then we could track that over a
15 period of two cycles. Two years, basically
16 18 months through the MLAB Model. It took
17 into account the natural biology of the
18 vector, which the A-BEST Model could not do.
19 The A-BEST Model is data-driven. Data, data,
20 data, data, data-driven. You have to have a
21 data point for everything. We don't have the
22 data on the mosquitoes, where they go, what

1 they do, how they spend their spare time, you
2 know, that sort of thing. So in order to
3 validate one model, we created another, and
4 then we compare the results of those two
5 models as well. And they're very different
6 models, but I think you'll find the data very
7 interesting. And then we did indeed compare
8 the results using these two different models.

9 The risk assessment data that I'm
10 going to present to you was derived from
11 three simulated communities named Boston,
12 Tyngsborough, and Peterborough, New
13 Hampshire. In our simulated community,
14 Boston, the South End, that represents a very
15 urban environment, we had loaded into the
16 model about 245,000 -- no, 246,000
17 inhabitants, which live in a 2-mile radius of
18 the Albany Street site. Now, that's exactly
19 the number that was in the U.S. Census from
20 2000. There's 104,000 households there and
21 there are indeed environmental justice
22 communities present.

1 Now, in Tyngsborough,
2 Massachusetts, which is pretty much a suburb
3 of Boston, in our simulated community there
4 are 30,000 inhabitants in a 2-1/2- mile
5 radius of the alternative site, 11,000
6 households, no environmental justice
7 communities. Now, immediately the question I
8 would ask if I were in your seat is why are
9 the radiuses different? And I'll just answer
10 that right now since you can't ask me. We
11 had to vary the radiuses to get enough data
12 points to stabilize the model.

13 Now, in Peterborough, New
14 Hampshire, is the example of our rural
15 environment. Nine thousand inhabitants
16 within the 3-mile radius of the alternative
17 site, 3,500 households, no environmental
18 justice communities present in either the
19 real or the simulated town.

20 Now, let's focus on the A-BEST
21 Model for a moment, if we can. It's
22 predicated upon a laboratory worker who

1 sustains a laboratory-acquired infection and
2 subsequently leaves the laboratory, entering
3 the community surrounding the laboratory. In
4 the Rift Valley fever model it is the
5 transport accident that causes the infection,
6 so it's actually outside of the laboratory
7 when it occurs. The potential diseases
8 caused by these infectious agents, all
9 transmitted through close contacts, are
10 occupationally acquired infections throughout
11 the A-BEST Model. And the simulation employs
12 an individual-based and spatially explicit
13 modeling approach. And it predicts both
14 where and when transmission will occur
15 throughout the model.

16 Simulation components. Now, I'm
17 not going to take a lot of time going over
18 all of these slides because I'm told it's
19 really boring. But having said that, the
20 simulation components of the A-BEST Model
21 involve a nighttime population, which in your
22 mind think of as that's where people live and

1 sleep.

2 Okay? So in our model we know who
3 lives with whom and where they live. The
4 daytime population in your mind, this is
5 where people work. Okay? And actually in
6 the model is built two shifts into each
7 workplace. And this is who works, where they
8 work, and with whom they work. There are
9 data sets describing that in the model.

10 Then we have the pastime.
11 Obviously -- or some of us have lives other
12 than work and sleep. This is what the
13 pastime is. I used the word in quotes
14 "shops." It happens to be what I like to do,
15 but it could be anything: Bowling, going out
16 to eat, any service you might need. So
17 pastime is anything but work and home and
18 sleeping.

19 And then we loaded in disease
20 transmission. You know, who is infected,
21 when they're infected, where they're
22 infected, and actually the outcome of each

1 infection in the simulation.

2 Now, I'd like to take a minute for
3 those of you who may not be used to networks
4 and modeling.

5 I certainly wasn't until Dr. Bian
6 instructed me. But basically, the A-BEST
7 Model is based on both an analytical and
8 conceptual framework that Dr. Bian and her
9 co-workers developed. Basically it's called
10 the multi-population two-layer network.

11 Layer 1 is right here, the home.
12 Each of these -- this is not a very strong
13 pointer or I can't see and it might be both.

14 DR. AHEARNE: It's there.

15 DR. WILSON: All right. There's a
16 home and each of these nodes represents an
17 individual. This is a very simplistic model.
18 At the top, the top layer is anywhere other
19 than the home. The populations are those
20 that I just described: Nighttime, daytime,
21 and pastime. So you can see if an individual
22 left this home, went to this place, maybe a

1 day care center, which in my experience were
2 the worst places ever to go if you wanted to
3 stay free of infectious diseases, and then
4 left that center potentially carrying the
5 disease to another place. It's very
6 simplistic, but I think gives you a good idea
7 of what's happening in the A-BEST Model.

8 Those of you who have children may
9 remember a number of years back, when mine
10 were younger, something called SIM City. It
11 was a game where kids learned social
12 structures and networking and they could
13 build cities. This is an enormously complex
14 SIM City that we've developed here to study
15 infectious disease transmission in
16 communities.

17 You want to forward that for me,
18 please? There, okay. Now, just so you know
19 what data we threw into the model, the 2000
20 Census Bureau data for population in
21 households, we acquired data from a company
22 called Reference USA where we got household

1 data. Business data was acquired from ESRI,
2 Incorporated. We used the East Massachusetts
3 Travel Diary. And we used both the
4 Massachusetts and New Hampshire state and
5 county data for agriculture in 2002. And
6 this is a program of the U.S. Department of
7 Agriculture.

8 Okay, very quickly, the nighttime
9 population. Remember this is where people
10 sleep? This is how we have their homes. We
11 used 2000 Census data, 227 block groups are
12 actually located within 2 miles of the BU
13 Medical Center. Block groups is a census
14 term. Basically it includes about 1,000
15 people. We disaggregated all of this data
16 and then the Monte Carlo method was used to
17 apply it throughout the simulation, to
18 populate our simulation with homes, people,
19 relationships, and so on. We used additional
20 data, adding additional attributes, but most
21 interested in these common attributes on the
22 right-hand side of the slide. And basically

1 after you do all of that, you now have all of
2 the homes, these 104,000 homes, placed on a
3 map.

4 Okay? Now, daytime population.
5 This is how people work. So if people are
6 sleeping and they have a home, they have to
7 be able to afford it. So we put all of the
8 businesses and the employers that could
9 possibly be within a 1-hour drive of any of
10 the 3 communities, and there are over 310,000
11 businesses or places of employment in this
12 model.

13 We also have character of the study
14 population. That means the simulated
15 individuals have these attributes as workers.

16 Okay. When you put on all of the
17 businesses within a one-hour travel, this is
18 what it looks like. Each one of those small
19 dots is a place where our simulated
20 individuals can work and do work in our
21 model. Focusing just on the area around the
22 Boston University Albany Street, this would

1 be the number of workplaces that were in 59
2 minutes travel time.

3 Daytime population, we also involve
4 the transportation considerations, how do
5 people get to work. You know, is it the
6 subway? Did they drive a car? Did they
7 walk, so on and so forth? All of that's in
8 the model. And placing people in homes and
9 workplaces, we actually used the travel
10 diary. It's reversed, used the travel diary
11 to place people in homes and workplaces.

12 These are the data sources we used
13 for the other activities other than work and
14 home sleeping.

15 We knew the -- we assigned the
16 number of trips that someone might take, who
17 took them, how old they were, your income
18 because that's really just spending, how many
19 trips you might take, how many vehicles you
20 have, how many workers, so on and so forth,
21 number of trips, whether it was a multi-
22 person or a multipurpose trip. We knew where

1 -- we assigned where people shop by their
2 transportation modes, all of the businesses,
3 so on and so forth.

4 Now, just as one visualization,
5 because there are hundreds of these things,
6 this happens to be where all the retail
7 businesses are in the Boston -- around the BU
8 Medical Center site. So they're available
9 both as employment sites and service sites.

10 And finally, disease transmission.
11 Who's infected, when, and where are they
12 infected? It occurs by time and location and
13 by mixing pattern. You know, if you've got
14 people at home, whether they're leaving home,
15 whether they work at home, so on and so
16 forth. Disease transmission depends on the
17 infectious rate in the simulation. The --
18 excuse me, the infectious agent, the rate of
19 transmission primary, secondary, tertiary,
20 and then an infection period.

21 Health status of the individual
22 that we loaded into the models follows

1 basically a very standard epidemiologic
2 model, the SEIR Model, susceptible, exposed,
3 immune, or removed by a variety of means.

4 And so the output from A-BEST after
5 this very complex building is the location
6 and time of the infection and the outcome of
7 the infection. And here's the data.

8 Basically for the diseases that
9 would be worked with in this maximum
10 containment laboratory, diseases that require
11 that or a surrogate for a disease that
12 requires that, there was really no difference
13 in the number of infections that occurred
14 across these three communities, independent
15 of the population or whether they were urban,
16 suburban, or rural. And it's pretty clear
17 from the numbers, it's easy to see. But
18 statistically, there was no significance
19 except in the Rift Valley fever model where
20 the numbers are really statistically
21 significant and show that Peterborough or
22 Tyngsborough are much more likely to have

1 more negative outcomes than Boston in that
2 situation. Now, this, of course, is due to
3 the fact that there are reservoir hosts
4 available in those two sites for a zoonotic
5 disease that is not the case in Boston.

6 And this is what the data would
7 look like just temporally. All right. So we
8 have complete data sets -- a complete data
9 set for you in the report as an example.

10 And if you would click on that
11 link, please. Okay? All right. If you'll
12 move that to the center of the screen,
13 please. Thank you.

14 Let's see, Ebola virus is chosen
15 and the BU site, so if you click "Animation,"
16 this is a very simple graphical interface of
17 the A-BEST Model. In the center is the BU
18 university facility. And in this case, we
19 see -- I think it's -- I can't really see
20 from here, but two -- a workplace infection
21 and a household infection, and you'll see
22 them up here on the right. We have a

1 counter. It's an interactive summary table.

2 The first workplace infection is
3 the laboratorian. The second workplace
4 infection that occurred in this case happened
5 to be a friend of his, who he had intimate
6 relations with in Town B. And 62 days later,
7 the other household infection is -- excuse
8 me, that's not true. In this workplace, at
9 21 days for this simulation, it was a health
10 care worker who sustained a needle-stick injury.
11 It's an occupational injury. And at 62 days,
12 it was the lady over in Town B. And the
13 outcomes are there: Two dead and one alive. Of
14 course, the alive was forced, too, because we
15 needed to push the disease out into the
16 community.

17 Okay, you may close that. Thank
18 you. Next slide, please.

19 So moving on to the MLAB Model.
20 This one's very different. It also -- yeah?

21 DR. AHEARNE: Let me interrupt for
22 a minute.

1 DR. WILSON: Am I taking up all my
2 time?

3 DR. AHEARNE: You've got about 10
4 minutes.

5 DR. WILSON: Got it. No problem.
6 Would you go back a slide for me, please?
7 Okay.

8 This is the multilayer agent-based
9 simulation tool developed by Dr. Vandersluis
10 or in collaboration with Dr. Vandersluis.
11 This takes into consideration the human
12 population, the ruminant populations, and the
13 mosquitoes populations, and the biology of
14 those three populations. And without going
15 into great detail, as you can read it for
16 yourself, we assume a just slightly less than
17 1 percent of infected humans also will suffer
18 a hemorrhagic form of the disease. That's
19 consistent with the literature. And of those
20 people, 50 percent will die.

21 And the ruminant population is also
22 described. These guys are infected by

1 mosquitoes. And ruminant infectivity is 21
2 percent at 7 days, 58 percent at 14 days,
3 based on the work of Gargan, Bailey, et
4 cetera; and takes into consideration that the
5 mosquitoes become more infectious with
6 subsequent blood meals because the virus
7 replicates within the mosquito.

8 Also within the MLAB, we take into
9 consideration the population dynamics of the
10 mosquito. We used and chose a mosquito
11 actually for both models, *Aedes canadensis*.
12 And *Canadensis* was chosen because it's a
13 very, very aggressive biter. It's an
14 aggressive biter of both humans and animals,
15 which may not be the case for all mosquitoes.
16 They usually have a preference. It is
17 univoltine, which means it has only one --
18 lays only one generation of eggs a year. And
19 these eggs do indeed over-winter or live
20 females can over-winter. They can transmit
21 the disease vertically. And, most
22 importantly, in real life this particular

1 vector is present in all three communities.
2 And this just describes further the mosquito
3 population.

4 Now, MLAB is very different than
5 A-BEST. As I told you earlier, Dr.
6 Vandersluis is very interested in graphical
7 visualization of data. And the way he did
8 this was -- ran this simulation was by using
9 a bunch of layered maps. And for every
10 attribute of these three populations, there's
11 a different layer of map. The dark drawings
12 on the lower maps we've marked out water
13 bodies. We place in constraints on each
14 layer of map that keeps, for instance, cows
15 from getting outside their fences and people
16 from walking on water, and the mosquitoes
17 basically can go anywhere they want within
18 the constrained areas. If you line all of
19 these maps up, think of them all as pixels,
20 which they are. Drill down, and so every
21 time a mosquito lines up with a cow or a
22 person, there is an opportunity to transmit

1 the disease. Okay, that's it in a nutshell.

2 This is an example of the output.

3 And I'm going to show you very quickly a
4 simulation, but I just want to orient you
5 because several things will be happening.
6 You will notice that the changes will occur
7 here. You'll be able to see ruminants go
8 from susceptible to infected to recovered or
9 otherwise. You can follow what's happening
10 in terms of numbers of the three populations
11 -- human, ruminants, and mosquito -- on this
12 graph. And then on the right lower side we
13 have an actual counter of disease following
14 whether they are susceptible, infected, or
15 recovered or removed.

16 Yeah, the first one, and you can
17 watch. This happens to be Tyngsborough. If
18 you can move it over. There you go.

19 Now, watch what's happening there.
20 You can see that after the accident occurred
21 we have our ruminants that are infected going
22 up, the number of infected mosquitoes -- or

1 the number of overall mosquitoes is going
2 down because that's part of the natural
3 biology of the disease. And you can watch
4 down here where the actual -- we now have 19
5 cases of infections in humans in
6 Tyngsborough. And you can see what's
7 happening to the ruminants. The number of
8 ruminants in each community was set at 10
9 percent of the total county that that
10 community was in. Okay, you may close that.

11 Open the bottom one, please, very
12 quickly. This is Boston. And basically what
13 this is going to show if we let it run for
14 the 18 months is because there is no
15 amplification host available in Boston, the
16 disease cannot establish itself and infect
17 the human population, and because there are
18 really no agriculturally based occupations in
19 that area either that would lend itself to
20 coming in contact with it. Okay, next. You
21 can close that.

22 And next slide. Not surprisingly,

1 here's the data. It shows that both
2 Tyngsborough and Peterborough are indeed at
3 greater risk should a release of Rift Valley
4 fever occur. Next slide, please.

5 And here are the conclusions.
6 Using the data derived from both models, we
7 can say that there wasn't any difference in
8 simulated disease transmission among the
9 urban, suburban, or rural sites for Ebola,
10 monkeypox, or Sabia virus. There was indeed
11 a significant difference for Rift Valley
12 fever, which said that the sites other than
13 Boston were at a greater risk. The
14 population size in each community did not
15 affect the simulated number of cases of each
16 disease in the community's model. And the
17 environmental justice communities that are,
18 therefore, near Boston, could not have been
19 disproportionately affected by the presence
20 of the NEIDL, either -- the operation of the
21 NEIDL on the Albany Street site.

22 And that's it. And thank you all

1 for your very kind attention.

2 DR. AHEARNE: Now, I realize we
3 can't ask questions, but I did have one
4 question. The NIH draft, who wrote it?

5 DR. WILSON: Well, that depends on
6 whether you like it or not. I didn't answer
7 that. You have to put that in writing.

8 DR. AHEARNE: So let me make sure I
9 understand, the information of who wrote the
10 report is sufficiently sensitive under NEPA
11 that we can't have an answer? Thank you.

12 DR. WILSON: No, I will not answer
13 it unless my lawyer says I can.

14 DR. AHEARNE: Your lawyer is
15 sitting over there.

16 DR. WILSON: The report says on the
17 front page that it was prepared by the
18 Division of Occupational Health and Safety at
19 NIH.

20 DR. AHEARNE: We understand that.

21 MR. LANKFORD: Dr. Wilson, you can
22 go ahead and indicate -- answer that

1 question.

2 DR. WILSON: I wrote the report.

3 DR. AHEARNE: You wrote it. Thank
4 you. All right.

5 DR. WILSON: And it was worse than
6 my dissertation.

7 DR. AHEARNE: In what sense? No,
8 never mind.

9 DR. WILSON: Thank you all very
10 much.

11 DR. AHEARNE: All right. We move
12 on to -- now, Boston University is very
13 well-represented here as I understand. But
14 I'm not sure who is now going to --

15 MS. SHELTON-DAVENPORT: Mark
16 Klempner.

17 DR. KLEMPNER: If you don't mind,
18 I'm going to sit here so I can see the same
19 set of slides.

20 DR. AHEARNE: Of course.

21 (Recess)

22 DR. KLEMPNER: Are you all set with

1 your AVs?

2 MS. SHELTON-DAVENPORT: Do you want
3 to flip them yourself or would you like for
4 us to flip them?

5 DR. KLEMPNER: If this works, I'm
6 an old hand at this.

7 MS. SHELTON-DAVENPORT: It should
8 work.

9 DR. KLEMPNER: Okay. Good morning,
10 you all. Mr. Chairman and distinguished
11 members of the panel, thank you for the
12 opportunity to come before this panel to
13 provide comments regarding the NIH's Draft
14 Supplementary Risk Assessments and Site
15 Suitability Analyses for the National
16 Emerging Infectious Diseases Laboratories, or
17 the NEIDL, currently under construction at
18 the Boston University medical campus. My
19 name is Mark Klempner and I serve as the
20 director of the NEIDL and the associate
21 provost for research at the Boston University
22 medical campus. I'm an infectious diseases

1 physician scientist who has been trained in
2 and practiced clinical infectious diseases
3 for the past 28 years. Also for the past 28
4 years, I have conducted peer-reviewed,
5 NIH-funded, laboratory- based, and clinical
6 research on multiple infectious diseases,
7 including Yersinia pestis, Borrelia
8 burgdorferi, Leishmania donovani, and several
9 highly pathogenic Gram-positive cocci such as
10 the ones that are in the news this morning.

11 My remarks will address the
12 following question, which is contained in the
13 charge to the panel and that is, namely, to
14 determine whether the proponent has
15 identified representative worst-case
16 scenarios. I will briefly discuss the
17 development of an organism-specific risk
18 assessment matrix that was developed by the
19 Centers for Disease Control and Prevention,
20 and adopted and expanded by the National
21 Institutes of Health. This risk category
22 matrix assigns infectious agents into risk

1 categories according to their potential
2 public health impact should such agents be
3 released into the population.

4 I'm not -- did I do that?

5 MS. WALTER: No, sorry about that.

6 DR. KLEMPNER: Thank you very much.

7 I will discuss the elements that have been
8 considered for risk assessment to the
9 public's health of these infectious agents,
10 how the organism's chosen for the
11 supplemental risk assessment fit into that
12 matrix, and, finally, I will discuss
13 important facility and personnel safety
14 features that have been incorporated into the
15 NEIDL.

16 MS. SHELTON-DAVENPORT: I think you
17 have to point it back not at the screen, but
18 up this direction.

19 DR. KLEMPNER: Next slide, please.

20 As part of a congressional initiative begun
21 in 1999, a distinguished expert panel was
22 convened to review and comment on the threat

1 potential of various infectious agents to
2 civilian populations or to the public's
3 health. Included in this panel were academic
4 infectious diseases experts, national public
5 health experts, Department of Health and
6 Human Services agency representatives,
7 civilian and military intelligence experts,
8 and law enforcement officials. The citation
9 for the published results and the full list
10 of the distinguished panel participants is
11 shown on this slide.

12 Following the meeting, the Centers
13 for Disease Control personnel identified the
14 objective indicators in each of the areas
15 that were considered in order to formulate a
16 framework for an objective agent-specific
17 risk matrix analysis. Based on the overall
18 criteria and weighting, agents were placed
19 into one of three priority categories
20 according to their potential adverse public
21 health consequences of a release into the
22 civilian population, what are now referred to

1 as the Category A, B, and C priority agents.

2 Agents in Category A are assigned
3 the highest potential for adverse public
4 health impact.

5 Category B agents were considered
6 to have some potential for large-scale
7 illness, but generally cause less illness and
8 death. And Category C agents were not
9 believed to present a high risk to the
10 public's health from a release. Next slide,
11 please.

12 The elements that were considered
13 in formulating the risk assessment for each
14 infectious agent as it related to public
15 health risk included a number of parameters.
16 Scientifically sound, factual information,
17 and empiric evidence about each of the agents
18 was used to inform the development of the
19 risk assessment matrix.

20 Also considered was the morbidity
21 and mortality of specific agents with higher
22 priority given to agents for which there is

1 no effective outpatient treatment and,
2 therefore, could result in illness that
3 requires hospitalization. Agents were also
4 given higher priority in proportion to
5 untreated mortality of the specific
6 infectious disease. The higher the case
7 fatality rate, the higher the priority of
8 public health concern.

9 The overall potential for initial
10 dissemination to a population and the
11 potential for continued propagation in the
12 population by person- to-person transmission
13 was also considered. Agents with highest
14 potential for initial dissemination and
15 highest reproductive number were considered
16 of higher risk to the public's health.

17 Risk assessments of infectious
18 agents have also included whether the
19 infectious agent of concern is already
20 present in and readily available in nature,
21 whether the agent is being used or can be
22 produced in large quantities, and whether the

1 agent is in a form that is compatible with an
2 effective route of infection. The main route
3 of infection is also considered since
4 pathogens that cause infections via the
5 respiratory and oral routes have the
6 potential for greater dissemination to the
7 public than do pathogens that require
8 intimate contact with blood and bodily
9 fluids. Environmental stability of the
10 infectious agent may also be considered,
11 although it is often difficult to assign a
12 precise duration of stability for most
13 infectious agents since most agents have a
14 wide range of stability that depends on the
15 form of the agent and the environmental
16 conditions. In the risk assessments of
17 infectious agents, public awareness and
18 concern for a particular infectious agent was
19 also considered since heightened awareness
20 and concern could contribute to mass public
21 health fear or panic in the event of a
22 release of the agent.

1 Finally, the special health
2 measures that would be required to prepare
3 for the release of a specific agent was
4 considered since containment of cases might
5 result from release of an agent -- that would
6 result from release of an agent would be more
7 difficult if a combination of public health
8 measures, such as stockpiling of
9 therapeutics, augmentation of laboratory
10 capacity for rapid diagnosis, and a need for
11 enhanced public surveillance and education,
12 were required for adequate public health
13 mitigation.

14 Beginning with the factual empiric
15 data, in over 92 collective years of
16 operating Biosafety Level 4 laboratories and
17 5 different laboratories in the United States
18 and Canada, with hundreds of thousands of
19 person-hours working in Biosafety Level
20 laboratories, there has never been a primary
21 laboratory-acquired infection. Of course,
22 this means that there have never been any

1 secondary transmitted cases to the public
2 since secondary transmission requires an
3 index case. These Biosafety Level 4 research
4 laboratories in the United States and Canada
5 have an unblemished record for laboratory
6 worker and public health safety. Next slide,
7 please.

8 This slide shows how the expert
9 panel depicted their criteria and weighting
10 for the elements of public health risk
11 assessment that I have just described. As
12 noted in the first footnote, each specific
13 agent was ranked from highest, three pluses,
14 to lowest, zero, according to the potential
15 for causing morbidity and mortality, which is
16 listed in this table as whether the agent
17 caused disease or death under "Public health
18 impact."

19 The dissemination potential of the
20 pathogen is shown in the next two columns and
21 this category is subdivided into
22 considerations of the ease of production of

1 quantities of the pathogen in a transmissible
2 form, so-called P-D here with footnote b, and
3 considerations of whether there was
4 person-to-person transmission of the
5 infectious agent and by what route
6 transmission occurred, listed here as P-P
7 with footnote c. The public's perception and
8 concern for the agent was also taken into
9 consideration for the reasons that I have
10 mentioned. And finally, the complexity of
11 public health measures to mitigate release of
12 an infectious agent is listed as special
13 public health preparations that would be
14 required for countermeasures. Using this
15 matrix each agent was assigned to a risk
16 category group of A, B, or C. Next slide,
17 please.

18 Shown here are the results of the
19 expert panel's prioritization of each of the
20 specific agents or groups of agents. There
21 was consensus that variola major, the agent
22 that causes smallpox, had the highest

1 potential for an adverse effect on the
2 public's health. As you know, this agent has
3 been eradicated from the natural environment
4 and the only known stocks are contained at
5 the Centers for Disease Control and
6 Prevention and a high- containment laboratory
7 in Russia. Variola major is not available
8 for study outside the Centers for Disease
9 Control high-containment laboratories, and we
10 have emphatically stated repeatedly that we
11 cannot and will not study and do any research
12 on the smallpox virus.

13 Bacillus anthracis, the agent that
14 causes anthrax, was considered by consensus
15 as the worst- case pathogen that was
16 available and accessible for study. From
17 this assessment and several others, anthrax
18 was selected as the pathogen to model the
19 worst-case scenarios for potential adverse
20 public health impact of a release of an
21 infectious agent. As is the case for the
22 National Emerging Infectious Diseases

1 Laboratory, the NEIDL, the environmental
2 assessments and statements from each and
3 every one of the high-containment facilities
4 being built around the country used anthrax
5 as the worst-case scenario to model potential
6 adverse public health impact for a release of
7 an infectious agent from the laboratory.
8 This includes the environmental impact risk
9 assessments for the National Institute of
10 Allergy and Infectious Diseases' Rocky
11 Mountain Laboratories in Hamilton, Montana;
12 the NBAC Homeland Security Department
13 facility at Fort Detrick, Maryland; and the
14 Galveston National Lab in Galveston, Texas.

15 In the case of Rocky Mountain Labs,
16 the quantitative risk assessment modeled the
17 worst-case scenario as anthrax, citing the
18 risk assessment matrix that I have just
19 presented. The NBAC facility modeled three
20 anthrax release scenarios, which they labeled
21 as the maximum credible event, or MCE. And
22 Galveston's quantitative risk assessment used

1 a maximum possible risk model with accidental
2 release of powdered anthrax spores as their
3 worst- case scenario. I have supplied you
4 with the records of decision for each of
5 these NEPA findings as well as the anthrax
6 release worst-case scenario that was done for
7 the initial FEIS of the NEIDL. In each case,
8 the results of modeling the public health
9 risk of a release of anthrax from any of the
10 biocontainment laboratories, including
11 scenarios that modeled complete HEPA
12 filtration failure of the facilities and work
13 on anthrax spores in powdered form,
14 demonstrated a negligible risk that
15 approached zero for risk to even one
16 individual in the community. Next slide,
17 please.

18 Somehow the color has been deleted,
19 but it will be okay. On this slide the four
20 additional organisms that were chosen for
21 study for the supplemental risk assessment
22 are listed within the framework created by

1 the expert panel for evaluation of the public
2 health risks associated with biothreat
3 organisms. All four of these infectious
4 agents are Risk Category A agents and are
5 listed among the other Risk Category A
6 agents.

7 Monkeypox, the second one that you
8 see up there, is a Risk Category A virus that
9 is a member of the same Poxviridae group as
10 smallpox. It was chosen as a surrogate for
11 smallpox since smallpox cannot and will not
12 be studied in the NEIDL. Community input
13 specifically requested modeling of the
14 release of a poxvirus as has been indicated
15 by Dr. Wilson.

16 While the clinical disease of
17 monkeypox causes much less morbidity and
18 mortality than smallpox, monkeypox is
19 communicable from person to person. The
20 clinical illness appears to affect and be
21 more severe among children, and an outbreak
22 of monkeypox into the community has the

1 potential to cause widespread panic and
2 concern, as it did in 2003, when pet prairie
3 dogs became infected from an African rodent
4 imported as an exotic pet. Disease was
5 reported in adults and children from six
6 states.

7 Concerned citizens expressed a
8 desire that the additional risk scenarios
9 include a select agent that would affect
10 school-aged children.

11 Rift Valley fever virus is a Risk
12 Category A agent that is a member of the
13 Bunyaviridae. The virus is a
14 mosquito-transmitted zoonotic infectious
15 disease to which both humans and animals are
16 susceptible. Concerned citizens requested
17 that the additional risk scenarios include an
18 insect- transmitted infectious disease. Rift
19 Valley fever virus is placed in this table
20 next to tularemia since tularemia is another
21 Category A priority pathogen that can be
22 transmitted by insects, although not by

1 mosquitoes. And Rift Valley fever is placed
2 alongside and just above viral hemorrhagic
3 fever viruses since the human clinical
4 illness shares common features with these
5 viral diseases. In this regard, Rift Valley
6 fever is a representative of a Risk Category
7 A risk group pathogen that can be transmitted
8 by insects.

9 Ebola and Sabia viruses both fall
10 within the group of viral hemorrhagic fever,
11 and you'll see it right under the VHF there,
12 Ebola virus and Sabia virus, and, therefore,
13 both of these are Risk Category A agents.
14 While Ebola is a filovirus and Sabia virus is
15 an arenavirus, they share many of the
16 characteristics of the other hemorrhagic
17 fever viruses. Through multiple media
18 outlets and through my experience with over
19 350 community meetings regarding the NEIDL,
20 the I believe the public has come to know
21 Ebola virus as the quintessential Category A
22 pathogen and concerned citizens specifically

1 requested modeling of an Ebola virus
2 infection.

3 In summary, the highest Risk
4 Category A agent that is accessible for
5 study, namely Bacillus anthracis or anthrax,
6 was chosen for our initial quantitative risk
7 assessment worst-case scenario as it was for
8 the quantitative risk assessments of the
9 other BSL-4 laboratories under construction.
10 All of the organisms chosen to model in the
11 supplemental risk assessment are Category A
12 agents and representative of these pathogens,
13 namely those pathogens which are considered
14 to have the highest potential for negative
15 public health impact if they are released
16 into the population either accidentally or
17 intentionally. Next slide.

18 In my final few minutes I would
19 like to comment on the extensive design and
20 construction safety features that have been
21 incorporated into the NEIDL and then on to
22 the people with extensive Biosafety Level 4

1 experience that have been recruited to help
2 operate the NEIDL. Next slide.

3 The team that is building the NEIDL
4 has extensive national experience in building
5 Biosafety Level 3 and 4 laboratories as well
6 as extensive experience building in the city
7 of Boston. All critical systems are designed
8 to be redundant, so- called N+1 systems,
9 meaning that we have the required number of
10 each type of equipment plus a spare, so
11 building operations will not be affected by
12 maintenance or repair of any piece of
13 equipment.

14 The building's waste processing
15 tanks are a good example. We need two and we
16 have three.

17 Another example is our redundant
18 electrical system where we can buy or make
19 our own power. The building is fed by four
20 different electrical mains from two different
21 substations even though it requires no more
22 than one or two feeds at any given time. The

1 building can also be powered by on-site
2 diesel-powered generators and there's
3 uninterruptible power-supplied battery backup
4 for critical safety and security systems.

5 Air supply systems are
6 HEPA-filtered on the intake side and double
7 HEPA-filtered on the exhaust side to ensure
8 that what leaves the building is cleaner than
9 when it came in.

10 Safety engineering elements include
11 blast- proof exterior walls and windows, and
12 a structurally segregated BSL-4 laboratory
13 designed to withstand high-intensity seismic
14 activity with extremely dense concrete,
15 multilayer epoxy coatings, airtight
16 submarine-style doors, increasingly negative
17 airflow moving into the labs, and
18 negative-pressure biosafety cabinets that are
19 inside the airtight labs where the actual
20 handling of most infectious agents will be
21 done.

22 Activity within the building will

1 be physically and systematically monitored
2 through highly integrated security access
3 systems using combinations of proximity
4 cards, biometric devices, and a
5 closed-circuit television system to ensure
6 appropriate access and adherence to standard
7 operation procedures, including the
8 two-person rule.

9 In your packets I have provided a
10 more extensive list of the state-of-the-art
11 safety and security features that have been
12 incorporated into the design and construction
13 of the NEIDL. Next slide, please.

14 There can be little question that
15 the most important safety feature in any
16 biomedical research laboratory is the
17 experience of the people working in those
18 laboratories. We have been fortunate to have
19 successfully recruited a substantial group of
20 scientists and staff with extensive
21 experience working in Biosafety Level 4
22 laboratories.

1 Dr. Tom Geisbert was recently the
2 associate director and high containment
3 coordinator for the NIAID's Integrated
4 Research Facility. He brings over 20 years
5 of BSL-4 experience to his role as associate
6 director of the NEIDL and director of the
7 Specimen Processing Core in the NEIDL.

8 Joan Geisbert is currently a senior
9 biologic science laboratory technician at
10 USAMRIID and brings over 26 years of BSL-4
11 experience to her roles in the NEIDL as
12 director of the Training Simulator Core
13 Facility and associate director of the
14 Specimen Processing Biosafety Level 4
15 Laboratory. She is one of the nation's most
16 experienced training mentors to research
17 scientists and staff in how to work in a
18 Biosafety Level 4 laboratory environment.

19 Dr. Elke Muehlberger is one of the
20 leading molecular virologists working on the
21 filoviruses, Ebola and Marburg viruses. And
22 she will be joining us in the spring from

1 Marburg, Germany. Dr. Muehlberger has over
2 16 years of BSL-4 experience working at the
3 Virology Institute where Marburg virus was
4 discovered. She also has extensive
5 experience training staff to safely work in
6 the Biosafety Level 4 environment.

7 Each of these individuals will be
8 recruiting additional faculty and staff that
9 already have Biosafety Level 4 experience.
10 Next and last slide.

11 In conclusion, it is our belief
12 that the Draft Supplemental Risk Assessment
13 by the NIH modeled an appropriate array of
14 Category A agents. The public had requested
15 scenarios that included a variety of possible
16 exposures, accidents, and dissemination
17 events, and the NIH appropriately
18 incorporated those requests in their
19 scenarios. We believe that the analyses in
20 the NIH report, coupled with our earlier
21 anthrax scenario, represent a robust and
22 representative set of worst-case scenarios.

1 Taken as a group, these analyses indicate
2 that the NEIDL constructed in the Albany
3 Street location will conduct its work with
4 negligible risk to the surrounding community.

5 Again, I appreciate the opportunity
6 to offer these comments and thank you for
7 your attention.

8 DR. AHEARNE: Questions?

9 DR. LOCKE: Thank you for your
10 presentation. I want to ask a question. I'm
11 sorry if this is going to be redundant. I
12 think you pretty much answered it, but I want
13 to just make sure. And if I have the chance,
14 I'd also ask this question to NIH. But what
15 is your definition of a "worst-case
16 scenario?"

17 DR. KLEMPNER: I am going to defer
18 that question to -- since it's already being
19 asked of the NIH, and let them answer for
20 that in writing since it is a comment on
21 their document.

22 DR. WILSON: I'm writing these

1 questions down and we will answer them
2 posthaste.

3 DR. AHEARNE: Let me follow up.
4 Dr. Locke's question was not what NIH's
5 definition is. It's what does Boston
6 University use as their definition of a
7 worst-case scenario?

8 DR. KLEMPNER: For the purposes of
9 the Environmental Impact Report and
10 Statements we used -- we followed the lead of
11 the state and --

12 DR. AHEARNE: You heard the answer
13 from the state.

14 DR. WILSON: That's why you're
15 following him.

16 DR. AHEARNE: I guess, Paul, there
17 is no definition.

18 DR. LOCKE: In that case, can I ask
19 another question?

20 DR. AHEARNE: Go ahead.

21 DR. LOCKE: I appreciate your
22 explaining to us Table 2 and 2A (off mike)

1 analysis. And I just wanted to ask you, this
2 is sort of from, you know, the one side, the
3 side of the agent itself, from the population
4 side what things do you think about when you
5 think about how many of these agents would
6 disseminate or propagate in a population?
7 And I'm particularly interested in, you know,
8 issues of children, the elderly, immune
9 compromised, and how those would play into
10 the way the disease transmits.

11 DR. KLEMPNER: Again, I think those
12 are questions that specifically relate to the
13 NIH supplemental risk scenarios, and so I'm
14 going to have to defer to them to answer
15 them. As an infectious disease physician I
16 think about all of those characteristics that
17 were incorporated into the risk analysis
18 matrix. And they have been incorporated into
19 the characterization of the agents, which I
20 believe are representative.

21 MS. SHELTON-DAVENPORT: Can I just
22 make a small note just in case we have any

1 late joiners on the teleconference, and this
2 wasn't anything about Dr. Locke's comments.
3 But I just want to remind those that are
4 listening on the telephone this is an open
5 session in which the committee members are to
6 ask questions, but their questions are not to
7 be construed as any kind of opinions of the
8 committee.

9 This is merely for them to ask
10 questions and any conclusions of the
11 committee will be in the final report, and no
12 conclusions should be made from this open
13 session. That would inappropriate to do.

14 DR. RICHMOND: Jonathan Richmond.

15 SPEAKER: Wait.

16 DR. RICHMOND: I'm Jonathan
17 Richmond. Mark, very impressive three people
18 that you gave CVs to on your Level 4. Have
19 you already appointed a biological safety
20 officer for your facility?

21 DR. KLEMPNER: We have Dr. Ara
22 Tahmassian here, who is the head of research

1 compliance. And we have -- I think I'll
2 defer to him to answer the question because
3 it involves a recruitment, which is under his
4 umbrella.

5 MR. TAHMASSIAN: I'm Ara
6 Tahmassian. I'm the associate vice president
7 for research compliance and I'm also the core
8 director for the Environmental Health and
9 Safety. We actually have a national search
10 going on. In fact, it's an international
11 search going on. We have a number of
12 candidates. And as we speak actually I
13 believe one candidate is being interviewed by
14 a search committee today with a number of
15 others over the next couple of weeks.

16 DR. KLEMPNER: I would add to that
17 that we've also sent additional people, a
18 person, to the Biosafety Level 4 high
19 containment training courses, the two-year
20 courses, at the NIH. Dr. John Tonkiss, who I
21 believe is in the room, will return; was a
22 17- year faculty member at Boston University;

1 has wide experience with both animals and
2 laboratory experience; and has come to spend
3 an additional 2 years here in the fellowship
4 program, which I know has been referred to by
5 name already and perhaps you could restate
6 what the name is. It's not a question to
7 you, but the name of the training program.

8 DR. AHEARNE: You sure you don't
9 have to ask your lawyer?

10 DR. KLEMPNER: The National
11 Biosafety and Biocontainment Training
12 Program, which he's scheduled to finish in
13 January 2009.

14 DR. AHEARNE: Tom?

15 DR. ARMSTRONG: I was wondering if
16 you could -- my name's Tom Armstrong. I was
17 wondering if --

18 DR. AHEARNE: Speak into the
19 microphone.

20 DR. ARMSTRONG: I was trying. Tom
21 Armstrong. Could you tell us a little about
22 the risk assessment review that the anthrax

1 scenarios were put through? What kind of
2 peer review did that go through?

3 DR. KLEMPNER: I think that the
4 review -- are you asking about the NEIDL one
5 or for each of the ones that I referred to
6 for all of the other facilities?

7 DR. ARMSTRONG: I believe I will
8 just put the NEIDL one on the table this
9 time.

10 DR. KLEMPNER: Yes. So the report
11 is in your packet. And the report modeled a
12 powered anthrax scenario, despite the fact
13 that we have said repeatedly that powered
14 anthrax is not the storage form that we will
15 use anthrax, so we were trying to maximize
16 the worst case part of the worst-case
17 scenario. And it modeled a complete system
18 of failures of all building components that
19 related to air handling. It also further
20 modeled a downwind person who had been a --
21 someone who must have been exercising heavily
22 because they were breathing at 30 times a

1 minute, I hope no one in here is doing that
2 as a physician, but the usual breathing rate
3 is somewhere around 12, and so that they were
4 actively breathing with lots of air movement.
5 They were kept in one location so that they
6 didn't move out of the maximum place where
7 the wind wake modeling had the potential
8 spore deposition from a release from the lab.
9 And with all of those contrived conditions,
10 it resulted in a zero to negligible chance.

11 DR. AHEARNE: But the question was
12 --

13 DR. KLEMPNER: I'm coming to it.

14 DR. AHEARNE: -- what kind of a
15 peer review did it go through?

16 DR. KLEMPNER: The review that it
17 went to was to the state. This was part of
18 our submission to -- as part of the NEPA
19 process and it went to the reviewers at MEPA,
20 who made the determination of its
21 sufficiency. And that's the peer review that
22 it went through.

1 DR. AHEARNE: Could -- Dr.
2 Babb-Brott, could you explain what kind of a
3 peer review Massachusetts did of that?

4 MR. BABB-BROTT: Deerin Babb-Brott,
5 Massachusetts. I was not the director at the
6 time.

7 To my knowledge the office did not
8 conduct an independent peer review of the
9 science behind the project. The MEPA office
10 instead, as is typically the case, relied on
11 written comments from all public folks who
12 submitted comments to the office.

13 DR. AHEARNE: Thank you. Warner?

14 DR. NORTH: Warner North. You have
15 mentioned that your organization is on record
16 that it will not use smallpox virus in this
17 laboratory. And I believe you have just
18 mentioned and is included in the document you
19 described that there will be a restriction on
20 the type of anthrax, that certain forms will
21 not be used in the laboratory. Could you
22 tell us and could you provide documentation

1 on what other restrictions you have agreed to
2 in terms of agents listed in Table 2 and also
3 pathogens that are considered very high
4 threats to public health, but not biological
5 threat agents?

6 That might include SARS, 1918
7 influenza virus, mutated avian flu, et
8 cetera. Just what restrictions have you
9 agreed to in terms of what agents will not be
10 used in this BSL-4 laboratory?

11 DR. KLEMPNER: As you probably
12 know, there is widespread study of influenza,
13 avian influenza, already ongoing in multiple
14 locations in the United States, including in
15 Boston, so there's -- to that specific point.
16 And, in fact, some of the most active
17 research on avian influenza is currently
18 going on about 50 yards from Dr. Lipsitch's
19 office.

20 In terms of the restrictions that
21 we have agreed to, there is no agreement in
22 -- there's no stipulation in the NIH/NIAID

1 contract that -- of the agents that we can
2 and cannot work on other than that they must
3 be Category A, B, and C agents. That was a
4 stipulation of the broad agency announcement
5 and we will follow that.

6 The specific restriction on
7 smallpox is both imposed on us by the Centers
8 for Disease Control since it's a select agent
9 and we can only acquire select agents through
10 the Centers for Disease Control in general or
11 with their permission.

12 And we have put out a public
13 document, which I would be happy to supply
14 you, that said in 2004, and it has been
15 repeated at almost every one of the 357
16 public venues, that we will not use -- study
17 smallpox and we are not permitted to that.

18 With regard to other agents there,
19 other than what I've stated, that they have
20 to be among the Category A, B, and C agents,
21 there are no particular restrictions for
22 which there is written policy.

1 DR. AHEARNE: Margaret?

2 DR. KLEMPNER: Oh, yes, I think it
3 -- there is one other piece that we've stated
4 and I'll state it again here. There is a
5 widespread misconception also that we will do
6 secret research or so-called classified
7 research. We have repeatedly made the
8 statement and we emphasize it here again that
9 every piece of research that is done at the
10 National Emerging Infectious Diseases
11 Laboratories will be peer reviewed by inside
12 and outside. It will be reviewed by the
13 Boston Public Health Commission. It will not
14 be classified. There is -- we will not do
15 any classified research in the National
16 Emerging Infectious Diseases Laboratories.

17 Similarly, there is a restriction
18 in Boston about using recombinant DNA
19 organisms in a BSL-4 environment. And
20 despite the inclusion of that and the many
21 other features in the risk scenarios that are
22 not credible from the standpoint of either

1 biology or possibility, namely restrictions,
2 we will not do any recombinant DNA- related
3 research on Biosafety Level 4 organisms,
4 namely we will not insert any genes into
5 Biosafety Level 4 organisms that express a
6 protein.

7 DR. AHEARNE: Margaret?

8 MS. COLEMAN: Margaret Coleman. I
9 had a follow-up question. I have in front of
10 me the publication from CDC where Table 2
11 originated, and it lists emerging threats as
12 Category C. Do you envision any of the
13 organisms that Warner North mentioned as
14 emerging agents?

15 DR. KLEMPNER: Yes, I do.

16 MS. COLEMAN: So they could be part
17 of the research program in your facility?

18 DR. KLEMPNER: Yes, many of those
19 agents, as you know, are currently under
20 study widely around the country. In
21 particular, right at the top of the list
22 there and also on the NIAID Category A list

1 is, for example, Nipah virus. And we do
2 intend to study Nipah virus because one of
3 our incoming investigators has expertise and
4 interest in studying Nipah virus, which is
5 considered a Category C agent.

6 MS. COLEMAN: But would you also
7 consider SARS and avian flu viruses as
8 emerging threats?

9 DR. KLEMPNER: Oh, absolutely. I
10 think that these are Category C agents that
11 are emerging infectious diseases, that are
12 widely present in nature, as you well know.
13 And I think most everybody believes that if
14 there is going to be a change in influenza
15 virus, it's going to occur in nature. It
16 might also be worth mentioning that influenza
17 virus is not handled at BSL-4, avian
18 influenza included.

19 DR. AHEARNE: Any other questions?

20 DR. GRONVALL: Gigi Gronvall.

21 DR. AHEARNE: You need the mike.

22 DR. GRONVALL: Sorry. Thank you.

1 Gigi Gronvall. My question is about the
2 animal facility, animal use in the
3 facilities, and what will be done at BSL-4.

4 DR. KLEMPNER: Yes. We have
5 extensive vivaria. As you know, one of the
6 main goals, I would say the most important
7 goal of the National Emerging Infectious
8 Diseases Labs is to do what most of us have
9 been trying to do our whole careers, and that
10 is to develop diagnostics, treatments, and
11 vaccines against emerging infectious
12 diseases. In order to do that, one needs to
13 ultimately work towards having a product that
14 can be delivered to the American public and,
15 for that matter, to the worldwide public.

16 In order to have any agent become
17 any therapeutic or diagnostic, for that
18 matter, but mostly therapeutic or vaccine,
19 one needs to suffice the FDA. The FDA has
20 created the two-animal rule that requires
21 that one demonstrate efficacy in at least two
22 animals, usually one being a non-human

1 primate. So we are well set up to evaluate
2 and to perform the need of the nation to
3 study these agents and fulfill the mandate in
4 order to study them in animals, both for
5 pathogenesis purposes and ultimately to
6 supply data that could be used for protective
7 product development.

8 DR. AHEARNE: Anyone else? Minor
9 question. Can the Rift fever be transmitted
10 by a mosquito biting a rat?

11 DR. KLEMPNER: I do not believe
12 that a rat is an amplification host. It
13 really requires ovine intermediate host. But
14 I will be absolutely sure of that, if you'd
15 like, and perhaps that might be a question.
16 But in my infectious disease expertise I
17 believe that a rat is not an amplification
18 host.

19 DR. AHEARNE: Deborah, you're
20 writing that down as a question?

21 DR. WILSON: Yes, sir.

22 DR. AHEARNE: Thank you. All

1 right. Any other questions? All right.

2 With that, then thank you very much.

3 DR. KLEMPNER: Thank you.

4 DR. AHEARNE: And we will take a
5 15-minute break until 25 of.

6 (Recess)

7 MS. SHELTON-DAVENPORT: Okay. The
8 room is no longer on mute, just so everyone
9 knows.

10 DR. AHEARNE: All right, we're
11 reconvening now.

12 SPEAKER: I don't think that was
13 supposed to happen.

14 DR. AHEARNE: Is it possible that
15 the people on the videoconference on the
16 lower screen could identify themselves?

17 SPEAKER: They don't know that
18 they're the lower screen probably.

19 DR. AHEARNE: Well --

20 MS. SHELTON-DAVENPORT: The ones
21 that are not us are on the lower screen. So
22 if you're not us, maybe you could identify

1 yourself. I think we have Boston University
2 on the left of the big shiny table. And the
3 one with the yellow wall, I think that's at
4 Harvard. So maybe Boston University first?

5 MS. SHARPLES: They keep freezing
6 up.

7 MS. SHELTON-DAVENPORT: Okay, maybe
8 we should go with the Harvard folks first.

9 SPEAKER: Hello?

10 MS. SHARPLES: Yes, we can hear
11 you.

12 MR. NICKSA: Hi. This is Boston
13 University, Gary Nicksa speaking. Would you
14 like us to just identify those people in the
15 room?

16 DR. AHEARNE: Yes, please.

17 MR. NICKSA: We have Tom Moore, Tom
18 Robbins, Ed King, Bob Donohue, Steve
19 Williams, Jamie Faye, Robida Fullon
20 (phonetic), and Willis Wang.

21 DR. AHEARNE: And then the other I
22 guess it's Harvard?

1 MS. ORMOND: I'm Laura Maslow
2 Ormond, staff attorney at the Lawyers
3 Committee for Civil Rights.

4 MS. LAWRENCE: I'm Eloise Lawrence,
5 staff attorney at the Conservation Law
6 Foundation. And Laura and I are both
7 co-counsel representing the clients in -- but
8 we also have Dr. Ozonoff here.

9 MS. SHARPLES: Oh, good.

10 SPEAKER: Oh, so we could stay on
11 schedule.

12 MS. SHELTON-DAVENPORT: Dr. Ozonoff
13 is scheduled to be next so we could go with
14 him immediately or we could go ahead and go
15 with Dr. Lipsitch.

16 SPEAKER: We're ahead of schedule.

17 DR. AHEARNE: My schedule has Dr.
18 Ozonoff next if he's (off mike).

19 DR. OZONOFF: I'd be glad to. I
20 just walked in the door. Once I get settled
21 I'm at your convenience.

22 DR. AHEARNE: Then go ahead.

1 MS. SHELTON-DAVENPORT: Committee
2 members should have a copy of his statement
3 on your chair.

4 DR. OZONOFF: Let me begin by
5 apologizing for having a statement rather
6 than a PowerPoint presentation. I was once
7 on a panel I think probably in the very
8 building that you're in now at the Academy
9 and there were three epidemiologists and a
10 lawyer on the panel. All of us
11 epidemiologists had PowerPoint presentations.
12 The lawyer had a written statement like the
13 one I'm about to give you. And he said it's
14 not because as a lawyer he doesn't understand
15 that a picture's worth a thousand words, it's
16 just that he preferred a thousand words.

17 Well, I don't. I actually wish I
18 had a PowerPoint presentation for you. But
19 the same obligations that prevented me being
20 with you in person prevented me from doing
21 that, so I do have a statement. There is, I
22 think, a copy that I sent off within the last

1 hour or so, complete with typos, available to
2 you.

3 DR. AHEARNE: We have it.

4 DR. OZONOFF: Okay. I'll try not
5 to read the entire thing because you have it
6 available to you, but there are points in it
7 that I want to make that are important for me
8 to say orally.

9 My name is David Ozonoff. I'm a
10 physician. I'm a chronic disease
11 epidemiologist and I'm professor of
12 environmental health at Boston University
13 School of Public Health. And I've been at
14 that institution for 30 years, and 26 of
15 those years I served as chair of the
16 Department of Environmental Health. And when
17 I look out my office window I can see the
18 laboratory under construction.

19 And let me state very clearly at
20 the outset that I feel quite strongly that we
21 must do research on dangerous organisms of
22 public health importance. We don't have

1 Ebola, we don't Marburg, Rift Valley in the
2 United States, but there are countries where
3 these diseases are important -- disease of
4 public health importance. So my opposition
5 to this laboratory is not opposition to
6 pursuing a public health mission with
7 organisms that are difficult and dangerous to
8 work with. And Dr. Klempner knows this as
9 I've expressed this view to him and have
10 expressed it to the community, to both of
11 them both privately and publicly.

12 But I do oppose this particular
13 facility and I've been asked to present my
14 views on the Draft Risk Assessment because
15 the committee charge regarding the evaluation
16 of the methods and the analysis of the
17 assessment do fall within my areas of
18 interest and experience. I teach risk
19 assessment, for example, and I currently
20 teach a course in mathematical modeling of
21 infectious diseases using the usual tools of
22 difference equations and ordinary

1 differential equations.

2 I also have experience with the
3 problem of bioterrorism. After 9-11, I
4 served on the first NRC Committee on Water
5 System Security Research. This was a
6 committee that was commissioned by the
7 Environmental Protection Agency's National
8 Homeland Security Research Center,
9 specifically to review the research agenda
10 and plans they had going forward to do
11 research in the very area that's the subject
12 of today's meeting. After the initial report
13 from the committee which I served on, I was
14 then asked to chair the successor committee
15 on water security system research, and our
16 NRC report came out I think in February of
17 this year.

18 So I've sat in your chairs. I take
19 the subject of bioterrorism seriously. I've
20 thought about it for years and I've discussed
21 it with colleagues like yourself and done it
22 often.

1 In addition, I'm principal
2 investigator of an NIH environmental justice
3 grant, which is now in its fifth year. I've
4 written on the topic of environmental
5 justice, worked on the issues of concern to
6 the very neighborhood where this facility is
7 located and I can see out my office window,
8 and I feel a special responsibility to the
9 people in whose neighborhood I've been a
10 guest for so many years as I've come over
11 from my home in Cambridge to work at this
12 medical center.

13 Opposing an official project of my
14 institution, a place that's been a
15 comfortable and satisfying place for me to
16 work for so many years and a great portion of
17 my career, brings me no joy at all. I'm
18 happy to say that I've had no pushback from
19 my dean, from my administration, from my
20 colleagues who respect my opinions, I hope
21 and I believe. And they have continued to
22 call on me for matters within my area of

1 expertise, which includes emerging infectious
2 diseases. And I've recently co- chaired at
3 the request of the president of the
4 university a task force on avian influenza
5 and institutions' response to it.

6 So that's by way of background and
7 now to the matter at hand. Your charge on
8 how well the NIH contracted risk assessment
9 addressed three questions: Were there any
10 risks from this facility?

11 Is the location in the densely
12 populated area of the urban South End of
13 Boston posing any additional risk? And are
14 there any environmental justice communities
15 subject to a disproportionate risk from this
16 facility?

17 As to Question 1, it's my view that
18 the analysis and the draft assessment is not
19 optimally relevant, it's incomplete in a very
20 troubling way, and I think it's misleading.
21 The relevance issue will be discussed
22 actually in more detail by Dr. Lipsitch, who

1 follows me. He's going to discuss the choice
2 of agents in the model and whether it fairly
3 reflects that are inherent in a facility of
4 this nature.

5 But I do want to point out that the
6 review is not limited to the BSL-4 section of
7 the building.

8 As it's stated and as is required
9 by Executive Order it encompasses risks from
10 the laboratory in general. And that makes
11 actually a great deal of sense because there
12 are many potentially dangerous agents that
13 can be handled at the BSL-3 level, including
14 agents of high lethality for which there is
15 currently no vaccine or any treatment. And
16 some examples are avian influenza, H5N1, the
17 H1N1 1918 flu, and the SARS human
18 coronavirus. In fact, two of these agents,
19 the SARS virus and the H5N1 virus, are the
20 only emerging infectious diseases that are
21 explicitly mentioned in the first paragraph
22 of the introduction to the risk assessment.

1 So it would seem that they would
2 have made a logical and appropriate set of
3 agents to include in the model and failure to
4 include these agents or agents like them is a
5 glaring omission, but it engenders an
6 incompleteness in this analysis which is
7 troubling in another way. There is, in fact,
8 some evidence that influenza was included in
9 an earlier version. I don't know this for a
10 fact, but here's the evidence that I think
11 indicates it.

12 In Chapter 6 on page 16, and again
13 in Appendix 3 on page A5, influenza is listed
14 as one of the agents under consideration.
15 However, there are no analyses and no results
16 from the use of this agent. And regardless
17 of whether it was dropped at some point or it
18 was never considered in the first place, it
19 is quite clear, and Dr. Lipsitch will speak
20 to this, that agents that are transmissible
21 from person to person and likely to be
22 present at this facility should have been

1 part of the analysis, and the analysis is,
2 therefore, seriously incomplete on these
3 grounds alone. But there are many more
4 grounds.

5 I also believe that it's
6 misleading. There's frequent repetition that
7 the scenarios that are considered are
8 worst-case scenarios, designed to force
9 infections into the community. But in
10 reality that's how these analyses are done.
11 These are analyses of conditional
12 probabilities, probabilities conditional upon
13 the infection. And the probabilities of that
14 infection or of the agent emerging from the
15 laboratory are unknown. Right? That's a
16 good reason for not estimating them.

17 The laboratory-acquired infection
18 via accident, in fact, is not the only
19 scenario by which agents emerge from
20 laboratories. And, in fact, it's not even
21 the most likely one. Misjudgment and other
22 human error are the usual causes, not

1 accidents.

2 Dr. Lipsitch will have much more to
3 say about Question 1 and let me go on to
4 Question 2, whether the South End location is
5 worse than other locations. And again, in my
6 view, the assessment presents insufficient
7 information to make the case that there's
8 negligible risk to this community,
9 specifically by it being in that location.

10 I read the very lengthy description
11 of this model several times and I was still
12 not completely confident that I understood
13 exactly how it was done. It seemed to me
14 that the final conclusion, however, the
15 conclusion that the number of people exposed,
16 the number of people in the neighborhood,
17 makes no difference to the end result, is, in
18 fact, hard-wired into this model. If you
19 seed a large population with one or only a
20 few cases that transmit very poorly, as the
21 agents in these scenarios do, the way the
22 model runs can't distinguish between small

1 populations and large populations. The
2 transmission rates, as far as I can tell,
3 were not density-dependent and I was unable
4 to tell if the contact rates were density-
5 dependent. So it seems to me then that the
6 answer was preordained. An analysis for a
7 truly transmissible disease would have
8 brought us closer to a complete analysis, but
9 that analysis wasn't done.

10 I had some remarks about the
11 unsuitability of vector-borne diseases, but
12 I'll skip them in the interest of time. I
13 think Dr. Lipsitch will discuss it.

14 DR. AHEARNE: You have time.

15 DR. OZONOFF: Okay. Well, let me
16 just say that using a mosquito-borne disease
17 and making it depend upon ruminants, which
18 are not present in urban areas, but are only
19 in rural areas, also preordains the outcome.
20 There are other vector- borne diseases that
21 could have been considered and other hosts
22 that could have been considered that are more

1 common in an urban environment. Intermediate
2 hosts, like cockroaches, mice, and rats, for
3 example, small land-based birds like
4 starlings and pigeons of which we know, in
5 fact, are competent hosts for some of the
6 viruses that will be considered there, could
7 have been considered. But instead it was an
8 exotic mosquito-borne disease that had a host
9 in ruminants. And Dr. Lipsitch will talk
10 about this further.

11 But I'd like to spend most of my
12 time on the third question that the draft
13 assessment analyzed and that the committee
14 has been asked to consider because it's one
15 of the core questions that bothers the
16 community the most and was the central
17 question addressed by the draft assessment.
18 I want to be very blunt about the analysis
19 that was done there. I don't think it's
20 serious. In fact, it borders on being
21 perfunctory. It displays a blindness and a
22 lack of concern about environmental justice

1 communities that is rightly infuriating to
2 them. And let me go through some of it with
3 you. I'm not going to go through all of it
4 in the interest of time and just because it
5 would be repetitive, but I do want to make
6 some points and make some specific points so
7 that I won't be seen as just waving my hands
8 about this. You can find most of this
9 material summarized in Chapter 8, from page
10 17 onwards, where there's a summary of what's
11 purported to be an analysis of differential
12 impacts in the three different kinds of
13 communities, that is the inner-city
14 community, the suburban, and the rural
15 community.

16 As the report acknowledges, only
17 the area around the existing proposed
18 facilities can be fairly called an
19 environmental justice community on the basis
20 of race and income, which is the criterion
21 for designation.

22 DR. AHEARNE: Oops. We've lost

1 him.

2 MS. SHARPLES: I wonder if they
3 even know that.

4 DR. AHEARNE: Dr. Ozonoff, I don't
5 know if you can hear us. We can't hear you.

6 MS. SHELTON-DAVENPORT: Or see you.

7 SPEAKER: Hi. We lost one of our
8 videoconferences (off mike) have to call us.

9 MR. NICKSA: This is BU. Do you
10 hear us?

11 DR. AHEARNE: Yes.

12 MR. NICKSA: Our picture is frozen.

13 MS. SHARPLES: We can hear you,
14 though.

15 MR. NICKSA: But we hear you.

16 MS. SHARPLES: Yes. Dr. Ozonoff,
17 can you hear us? No, we just totally lost
18 the connection.

19 SPEAKER: (off mike) buys these
20 cheap damn systems.

21 DR. AHEARNE: Now, he made a strong
22 point that you had not discouraged him in any

1 way. Did you pull the plug?

2 DR. KLEMPNER: I note that we have
3 not had any humans walking on water (off
4 mike). It was mentioned in Dr. Wilson's
5 summary.

6 MS. SHARPLES: Ah-ha.

7 DR. AHEARNE: Ah-ha what?

8 MS. SHARPLES: Well, I was hoping
9 that was going to tell us something useful,
10 but.

11 DR. LIPSITCH: Continuous presence.

12 MS. SHARPLES: Yes.

13 DR. AHEARNE: If he doesn't come
14 back on shortly I'll shift over and ask you
15 --

16 MR. NICKSA: This is -- hi. This
17 is Boston University again. Is there
18 anything that we can do from our end just for
19 tech support to help reestablish the
20 connections?

21 MS. SHELTON-DAVENPORT: We're
22 working on it. Just hang on.

1 MR. NICKSA: Okay, thank you.

2 DR. AHEARNE: Dr. Lipsitch?

3 DR. LIPSITCH: Yes?

4 DR. AHEARNE: If we don't get him
5 in about five minutes, I'm going to ask you
6 to -- and then --

7 DR. LIPSITCH: I have his cell
8 phone number here (off mike) helpful.

9 MS. SHARPLES: Oh, that would be
10 good.

11 DR. AHEARNE: Go ahead.

12 DR. LIPSITCH: Let me see if I can
13 -- he probably won't be listening --
14 answering it because he's busy talking, but.

15 SPEAKER: He knows you're here,
16 though, right?

17 DR. AHEARNE: Yes.

18 DR. LIPSITCH: I don't know if he
19 could see me since I'm hiding over here.

20 DR. AHEARNE: He knows he's here
21 because he referenced --

22 DR. LIPSITCH: He promised that I

1 would give about 78 minutes of speech.

2 SPEAKER: Yes, we noticed that.

3 MS. WALTER: There's some sort of a
4 firewall that they have set up that won't
5 allow us to call them.

6 DR. LIPSITCH: If somebody wants to
7 call him, his cell phone number is --

8 DR. AHEARNE: Why don't we move on
9 to his colleague?

10 MS. SHELTON-DAVENPORT: Are we
11 going to go ahead and (off mike)?

12 SPEAKER: Yes.

13 MS. SHELTON-DAVENPORT: Doctor, I
14 think he might have talked about (off mike)
15 prior presentation. Does it make any
16 difference if you go now?

17 SPEAKER: Are the microphones
18 muted?

19 MS. SHELTON-DAVENPORT: Yes, right
20 now they are.

21 SPEAKER: Unmute them?

22 MS. SHELTON-DAVENPORT: Yes.

1 DR. LIPSITCH: Good morning. My
2 name is Marc Lipsitch. And I'm a member of
3 the faculty at Harvard School of Public
4 Health where I'm a professor of epidemiology
5 and hold a joint appointment (off mike)
6 epidemiology and infectious diseases. I am
7 not here representing them. I am here
8 representing my own views.

9 And I should say that my
10 experience, my research experience, involves
11 mathematical modeling of disease
12 transmission. It also includes laboratory
13 experimental work with infectious pathogens
14 at the BL-2 level. I am here having been --
15 at the request of the Lawyers Committee on
16 Civil Rights representing the opponents of
17 the biolab. I am not here myself as an
18 opponent of the biolab. I haven't come to an
19 opinion about the relative merits and
20 demerits of the biolab. In fact, I hadn't
21 given it much thought until about a month
22 ago, when people on a number of sides asked

1 me to look at this risk assessment and give
2 my views. So my views are really on the
3 narrow issues raised by the risk assessment
4 and charged to the committee. And I'll try
5 to limit myself to that without judging the
6 issue of whether the L-4 lab or the
7 laboratory as a whole should be gone ahead
8 with because I haven't come to a view.

9 The risk assessment basically can
10 be seen -- sorry, that should say "Agent 2"
11 in red -- as taking several agents, making a
12 series of assumptions about them, putting
13 them into a model, which is appropriately
14 shown as a black box, and that model then
15 comes out with a series of predictions. And
16 possible concerns about this model could come
17 at each of those stages, from the choice of
18 so-called worst-case agents to the
19 assumptions about particular agents to the
20 nature of the model, its structure, its
21 assumptions, its analysis and its
22 presentation, and, of course, the predictions

1 that come out of that. So I'll go on that in
2 reverse order, starting from the model and
3 going back to the agents. And as I'll
4 indicated, I think some of these concerns are
5 more serious to the ultimate conclusions than
6 the others, but I think each of them are
7 serious on its own terms.

8 So concerns about the model. And
9 Dr. Ozonoff made this quite clear and I'll
10 echo it, there's an extraordinary lack of
11 transparency in this model. About --
12 virtually everything in a standard infectious
13 disease model would be sort of primary
14 characteristics of the model. It's unclear
15 in, for example, the vector-borne aspects,
16 how mosquito, human, and ruminant densities
17 translate into biting rates. It is unclear
18 how the scenarios with their narrative detail
19 relate to the simulation runs using the
20 entire population. There are hundreds of
21 pages of statistics about the construction of
22 the population, which are irrelevant. And

1 I'll define what I mean by irrelevant in a
2 moment.

3 And even the notion of a contact is
4 not well-defined. We heard in the
5 presentation this morning that there's a mean
6 of 10 contacts, I believe, for individuals in
7 the model. It was not stated whether those
8 are contacts per day, contacts per infectious
9 period, or contacts were just total contacts
10 of each person. And, of course, all of those
11 are critical to understanding both the input
12 parameters and the outputs that are derived
13 from them.

14 So when I say statistics that are
15 reported are irrelevant, if I were trying to
16 explain to someone what I had done in an
17 infectious disease model, as I often do and
18 as I often request as an editor and peer
19 reviewer of infectious disease models, these
20 are the sorts of quantities that one wants to
21 know in order to evaluate a model: The
22 number of contacts per day by type of contact

1 and by type of individual; the relative
2 infectiousness of those; the inferred
3 transmissibility as measured by the
4 reproduction number for the pathogen; the
5 probability of a large outbreak given, which
6 is a function of that reproduction number and
7 the distribution of number of contacts; and
8 it is standard practice, especially in
9 agent-based modeling and certainly in any
10 sort of policy modeling, to perform a
11 sensitivity analysis of the various parameter
12 values and, ideally, of the structure of the
13 model. None of which is done in this model.

14 Dr. Ozonoff already mentioned the
15 issue of the frequent references to the claim
16 that the probability of an accident is
17 understated. This is overstated. This is a
18 standard approach, as he said, of
19 conditioning on the occurrence of an
20 introduction and then trying to figure out
21 the consequences of that. Things that are in
22 light blue here are things that are slightly

1 different from what are on your handouts.
2 You don't have handouts yet, but I have given
3 them -- a version of this to make handouts
4 with and these are small additions hat I made
5 after that. So you'll have all of this in
6 writing.

7 Given that infections with BL-3
8 pathogens have occurred at several
9 universities without prompt reporting. And
10 moreover, given that biocontainment lab
11 accidents have been classified -- or the
12 reports of these accidents have been
13 classified, as noted in the Boston Globe of
14 October 3rd, our confidence in claims of low
15 or no risk must be limited. It's, therefore,
16 not credible to state that such infections
17 are extremely unlikely.

18 The report also states that no
19 public health interventions are assumed in
20 the estimates of parameters -- or in the
21 scenarios, yet the parameters, such as the
22 transmission probabilities, which are

1 included in those reports, are drawn from
2 real events, such as those in African
3 outbreaks of Ebola. And in those events real
4 precautions were taken.

5 Second is some concerns about the
6 agent- specific assumptions of this model.
7 In the mosquito model, for example, and I
8 believe this is the A-BEST version of the
9 mosquito model, a fixed density of infected
10 mosquitoes per acre of suitable habitat is
11 assumed. As the report states, this
12 overstates the risk. However, it especially
13 overstates the risk for the rural
14 communities, which have more water habitat.
15 And finally, it casts doubt on the notion
16 that this is a transmission model since the
17 density of infected mosquitoes in a
18 transmission would, of course, depend on the
19 ongoing transmission.

20 So this is an example of doing two
21 things at once that are, in some sense,
22 contradictory, making so-called worst-case

1 assumptions tends, when those worst-case
2 assumptions are made for the vector-borne
3 illness, to prejudge the issue of the rural
4 versus the urban communities. Because more
5 worst-case assumptions for the vector-borne
6 diseases tend to bias towards the world
7 communities.

8 A second issue that I've raised is
9 that among directly transmitted infections,
10 the first three, there's an arbitrary that
11 secondary cases are less infectious than
12 primary cases. In other words, the second
13 round of human-to-human transmission is
14 tenfold less likely to happen than the first
15 round. And to my knowledge, there's no
16 evidence for such a phenomenon in natural
17 infections. It certainly is a phenomenon
18 that human-to-human transmission is rare
19 relative to the risk of primary human
20 infection, but the notion that the disease
21 becomes less transmissible through
22 transmission chains is not, to my knowledge,

1 supported.

2 A general concern, and I would say
3 on the whole my concerns are getting larger
4 as I go on in terms of their ultimate impact
5 on the quality of the conclusions in the
6 model, for each of these agents it's assumed
7 that the strains used have the same
8 characteristics as the strains that have
9 causes previous outbreaks, which ignores
10 natural strain variation which is a known
11 property of infectious agents, including some
12 of these. It ignores the possibility of
13 weaponization, although we've heard some
14 assurances that that would not be done here.
15 It ignores genetic modification. And as I
16 read at least the Boston Public Health
17 regulations, the rule is that agents that are
18 required to be used in BL-4 may not be then
19 used in a recombinant form. But it does not,
20 to my understanding, preclude, for example,
21 the use of modified BL-3 agents, which then
22 become BL-4 by virtue of their modifications.

1 It's not clear, but I would say it's at least
2 a loophole if I were looking for loopholes.
3 It ignores human error and it ignores the
4 possibility of unapproved experiments, which
5 as the Texas A&M case at least shows us that
6 was reported in Science in the last few
7 weeks, is something we should expect to
8 happen from time to time in biocontainment
9 labs.

10 My most serious concerns are about
11 the choice of agents. In general, the
12 Category 4 agents -- and now we're moving
13 from the ABC, which are categories that Dr.
14 Klempner described in terms of their
15 biological threat potential as a malicious
16 agent, and that's clearly stated in the
17 report from the group that designated the
18 original A, B, and C, to now the
19 biocontainment level. So Category 4 agents
20 as they have been listed tend to have limited
21 communicability in humans, including, of
22 course, the ones that were defined in this

1 risk analysis.

2 On the other hand, the definition
3 of Risk Group 4 agents, oddly enough, is
4 those for which preventive or therapeutic
5 interventions are not usually available,
6 including viruses not identified.

7 So perhaps because the specific
8 list of BL-4 agents at the present time does
9 not include, for example, influenza and
10 XDRTB. These were not included among the
11 risk assessment. I think that's a very
12 important omission.

13 Influenza pandemic strains as well
14 as reassortants between pandemic and current
15 strains meet the criteria of potentially
16 having few or no good therapeutic options.
17 And while they have been used in BL-3 to
18 date, I think there's a case for using them
19 in BL-4. And indeed the recent report in
20 Nature, in 2004, of the human glutenin from
21 1918 being reassorted with other H1 -- or
22 with other influenza viruses was, in fact,

1 performed in a BL-4 facility. So influenza
2 is done in BL-4, at least some of the time.
3 It's also done in BL-3 and 3+.
4 Drug-resistant variants of influenza would be
5 another example. Extensively drug-resistant
6 tuberculosis also meets the definition I read
7 before of something for which few or no
8 therapeutic options are available, although
9 it also has not been placed in a BL-4
10 specific list.

11 Similarly, enhanced agents that
12 might be used for biodefense or biooffense,
13 but might be studied for biodefense, may be
14 more transmissible than their wild type
15 precursors. And certainly novel pathogens
16 not currently known under the category of
17 Category C, emerging infections, many of them
18 should be correctly treated as BL-4 until
19 their transmissibility and the risks are
20 better understood. So the idea that the
21 current list of BL-4 agents is a closed list
22 and the one from which these worst cases

1 should be selected strikes me as naive.

2 This repeats what I've just said.

3 A few more general considerations and then

4 I'll conclude.

5 I think in general we should
6 consider that our current estimate of
7 accident risks should be seen as lower
8 bounds, both because it's unlikely that the
9 public record is complete given the
10 government's efforts to classify accident
11 reports on biocontainment facilities and
12 given the pattern that's been seen even
13 following the CDC investigation in Texas A&M
14 of cover-up of accidents, which then only
15 later became available. So while we, of
16 course, don't know all of these things, I
17 think it would be appropriate to expect that
18 our current estimates are lower bounds.

19 Human factors, as Dr. Ozonoff
20 mentioned, should be considered and failures
21 expected, including unapproved experiments as
22 done at Texas A&M, failures in containment as

1 found in the foot- and-mouth release from the
2 Pirbright Laboratory in the United Kingdom,
3 lack of timely reporting, and malicious
4 intent. This is consistent with the
5 testimony from the Government Accountability
6 Office earlier this month in which Keith
7 Rhodes -- this doesn't work -- but if you
8 read the part that's circled, the risks due
9 to accidental exposure release can never be
10 completely eliminated. And even the most
11 regulated and sophisticated ones have had and
12 will continue to have safety failures.

13 Conclusions. And here I'll try to
14 address the three issues that are asked of
15 the committee and my own views on these
16 topics.

17 The first question is whether the
18 scientific analyses in the study are sound
19 and credible. In response I would say that
20 the model is poorly described, the parameters
21 are poorly justified, and sensitivity
22 analyses are lacking; that the pathogens

1 considered are assumed to resemble strains in
2 epidemiologies seen in previous outbreaks,
3 which is not appropriate in considering
4 worst-case scenarios; that this study would
5 not pass peer review at a quality infectious
6 disease journal.

7 However, having said that, I think,
8 and this is sort of an opinion based on
9 experience rather than a carefully -- rather
10 than going through every aspect of every one
11 of these pathogens because I've not had time
12 to do that, but my impression, given what I
13 know about these pathogens, is that despite
14 these failures of the model, the conclusions
15 are probably what a good model would get.
16 Because the model -- the agents chosen are
17 ones of very low transmissibility. They are
18 ones assuming modest transmissibility as they
19 should. And that any model, good or bad, is
20 likely to conclude if you put in very well
21 values for transmission, that a few people
22 will be infected.

1 The second question is to determine
2 whether the proponent has identified
3 representative worst-case scenarios. And I
4 would argue that best- case scenarios have
5 been assumed on several dimensions. First,
6 the deceptive rhetoric about the vast
7 overestimation of the risks. Again, the
8 notion that conditioning in a single
9 individual becoming infected is a vast
10 overestimation of risk; the limitation to the
11 current list of BL-4 pathogens, specifically
12 those of low transmissibility, which is
13 essentially the entire list apart from
14 smallpox; the assumption of non-modified,
15 non-weaponized, non- aerosolized versions of
16 these pathogens.

17 And finally, the question about the
18 comparison of risk associated with
19 alternative locations. I have not directly
20 addressed this issue, in part, because I lack
21 expertise on vector- borne infections and, in
22 part, because I found that description of

1 that part of the model particularly difficult
2 to follow and poorly defined. But I would
3 make a couple of comments.

4 First, that the large number of
5 so-called conservative assumptions to favor
6 the vector-borne transmission tend,
7 therefore, to make Boston look better than
8 the outlying sites. So they're conservative
9 only in one sense, but not in terms of the
10 Boston versus outlying site comparison.

11 I think it's possible, though I
12 don't have the expertise, that the choice of
13 vector species may do the same. Again, if a
14 vector species is particularly abundant in
15 those outlying areas compared to vector
16 species in Boston. But again, this is a
17 speculation.

18 And the lack of scenarios involving
19 a failure of containment or a human-human
20 transmissible pathogen, of course, minimizes
21 the relevance of location, and such scenarios
22 should be considered.

1 For a more realistic assessment I
2 think we should expect that laboratory
3 workers in the biocontainment laboratory will
4 become infected with some of the pathogens
5 under study. We should expect departures
6 from protocol, unapproved experiments, and
7 failures of reporting of exposure to happen,
8 at least as a possibility. With the current
9 list of BL-4 pathogen in known forms I think
10 the risks would probably be limited to the
11 individual and immediate contacts. But with
12 modified, weaponized, or novel pathogens,
13 greater risks exist which are difficult to
14 define a priori. Modified versions of
15 existing BL-3 pathogens, such as influenza
16 which may then, by virtue of their
17 modification, meet BL-4 definitions are of
18 particular concern.

19 So I conclude that the report
20 understates the risk of the laboratory in
21 general and the BL-4 facility in particular,
22 and that decisions on the building and siting

1 of this laboratory should be based on more
2 realistic assessment, knowing that some of
3 them may be unquantifiable. And I should
4 just note here that the model is we're given
5 an essentially impossible task if they were
6 asked to define worst-case scenarios because
7 the list of agents is open. Category C
8 includes emerging infections "such as," and
9 two examples are given. It does not include
10 an exhaustive list. And, of course, if this
11 is to be a useful facility, that list will
12 grow as new infections emerge.

13 Again, I think this may be an
14 acceptable risk. I think it may be something
15 that should be done, but that our credibility
16 as a scientific community and as risk
17 assessors requires that we assess these are
18 realistically as possible. Thank you.

19 DR. AHEARNE: Questions?

20 DR. SMITH: This is Gary Smith.
21 Can you help me out? Your specific concern
22 no. 2, the one in which you said the models

1 appear to assume that secondary transmission
2 was much less.

3 DR. LIPSITCH: Yes.

4 DR. SMITH: Can you help me out?
5 Where did you find that here? Is this
6 something other than the assumption that, you
7 know, the next case has occurred? I couldn't
8 see anywhere in there --

9 DR. LIPSITCH: No, there are
10 tables, and I don't have the page number.

11 DR. SMITH: Section 7.7, I believe.
12 Are those the tables?

13 DR. LIPSITCH: They're blue at the
14 top, if that's helpful. They're tables of
15 parameters. No, it's 5 -- sorry, 6 -- for
16 example, page 6-8, the A-BEST simulation
17 assumptions for recombinant monkeypox,
18 similarly for other agents. If you look at
19 that table the primary infection rate is
20 stated as 100 percent, meaning 1 person gets
21 infected with 100 percent probability, then
22 under that, two down from that, it says

1 secondary transmission is .4 percent for
2 health care worker and 8.3 percent among
3 contacts. And then tertiary transmission is
4 0.03 percent.

5 And similarly, under Ebola on the
6 previous page, 0.4 percent for a health care
7 worker, and then tertiary transmission 0.003
8 percent, although that's a casual contact.
9 If you look in the text, and I can try to
10 find the reference, it says beyond tertiary
11 transmission, no transmission was assumed to
12 be possible. So it goes down ten- or more
13 fold and then it goes down infinity beyond
14 that, which the low levels may be appropriate
15 for these agents, but the notion that each
16 link in the chain becomes less transmissible
17 I think is not well justified.

18 DR. SMITH: Is it your impression
19 that that's exactly what they did or is it
20 just that the tables have been poorly
21 labeled?

22 DR. LIPSITCH: I can't tell.

1 DR. AHEARNE: Other questions?

2 Paul?

3 DR. LOCKE: I wondered if you could
4 offer us some information about how you would
5 think about doing a risk model looking at a
6 population, I think Dr. Ozonoff was just
7 about to talk about the Boston population, to
8 make sure that we understand the comparative
9 aspects of this. That's one thing you
10 brought up. The three populations are
11 different. How would you be thinking about
12 that if you were the modeler?

13 DR. LIPSITCH: Well, it would
14 probably depend very much on the choice of
15 the agent being considered because of the
16 routes of transmission and the risk factors
17 for transmission, all those being different.
18 As I said, I think that sort of anything you
19 do with these agents and these approximate
20 assumptions will give the same approximate
21 answer.

22 If I were doing something like

1 influenza and I were choosing to use an
2 agent-based model of this sort, several such
3 models have been published by other groups in
4 Science and Nature recently. Among their
5 most important conclusions was that outbreaks
6 in isolated areas of influenza, such as
7 outbreaks of a new strain in Thailand, might
8 be containable. And if they were in a rural
9 area, it would be impossible to contain if
10 they reached a big city. The reason for that
11 is assumptions in those models about the
12 rates at which people are contact, the
13 degrees of geographic -- the geographical
14 scale on which they have contact, the ability
15 to find those contacts because of the
16 geographical scale, et cetera. I have
17 problems with some of those models, but the
18 essential factor of population density for a
19 directly transmitted disease is certainly
20 relevant.

21 I would try to consider the
22 relative contact rates and also

1 infectiousness of individuals, different
2 types of individuals, such as by age,
3 occupation, et cetera. All of these, again,
4 require assumptions they're not -- we don't
5 know the answers to all these things, but
6 these are the ingredients that one would
7 consider if one wanted to go into tremendous
8 detail with something like this.

9 I would like to say that I think
10 the general approach, which was perhaps
11 requested by the community -- I don't know
12 the history; that certainly is what people
13 have suggested -- but the general approach of
14 exquisite detail is not something that I
15 would particularly favor. I think it tends
16 to hide things. And Lord May of Oxford, who
17 at the time was the chief scientist for the
18 UK government, recent president of the Royal
19 Society, and mathematical modeler, wrote
20 these words in Science in 2004. He said,
21 "Most common among abuses in mathematical
22 models are situations where they're

1 constructed with an excruciating abundance of
2 detail in some aspects while other important
3 facets are misty or vital parameters and
4 certain to within (off mike) order of
5 magnitude. It makes no sense to convey a
6 beguiling sense of reality with a relevant
7 detail when other equally important factors
8 can only be guessed at.

9 So to me, and again, I don't fault
10 anyone for this because this may have been
11 what was asked for, but I think the -- I
12 think detail is not the same as
13 understanding.

14 DR. NORTH: I have a question.

15 DR. AHEARNE: Warner?

16 DR. NORTH: Warner North. I
17 believe Dr. Klempner described the four
18 pathogens that were chosen as being an
19 appropriate array of Category A.

20 We looked at Table 2 in two forms
21 and I noted double plusses with respect to
22 piece C, transmissibility for plague. I

1 wonder if you would like to comment a bit on
2 your view of whether plague should have been
3 included in the analysis?

4 DR. LIPSITCH: I'll say from the
5 outset I don't know very much about the
6 transmission of pneumonic plague, but
7 certainly among the high-level threat agents
8 and -- it is one of the more transmissible
9 ones, like they said in the literature. My
10 guess is that it was not included because
11 it's not listed as a BL-4 agent, it's listed
12 as a BL-3 agent. There are no bacteria
13 listed among the stated BL-4 agents, just
14 emerging pathogens, which, of course, could
15 include things in the future.

16 So I would -- my own view is that
17 the analysis should include agents that are
18 -- well, my own view as a citizen of the area
19 is that one should look at the biggest risks,
20 not only -- and to me the biggest risks are
21 communicable diseases. The agents included
22 were those which are currently listed as BL-4

1 and which are, by definition almost, not very
2 transmissible. So I would be interested in
3 plague, especially if it were going to be
4 used in the BL-4.

5 But I think one question that I
6 can't answer that Dr. Ozonoff also mentioned
7 is, is this an analysis of the worst-case
8 from a biocontainment laboratory or from the
9 BL-4 component? If it's only the BL-4 and
10 (off mike) doesn't become BL-4, then that's
11 why it was excluded, I suspect.

12 DR. JOHNSON: Barbara Johnson.
13 We've asked some of the previous speakers for
14 a definition of "worst-case scenario," and
15 you've used the term, but if we get a
16 definition from them we'd like to be able to
17 baseline and compare what the expectations
18 should be. Do you have a reference frame
19 you'd like to provide us for worst-case
20 scenario, your definition?

21 DR. LIPSITCH: Well, I don't want
22 to come to a definition that I have to stick

1 by either, but I would say that a component
2 of that would include reasonably foreseeable
3 changes in the list of agents or changes in
4 the list of risks. In other words, it's not
5 -- should not only include the risks which we
6 can name and quantify now, but should include
7 risks which we can reasonably expect may
8 emerge. In my own view, recombinant
9 influenza or even novel strains of influenza
10 may well end up on a BL-4 list and, if a BL-4
11 lab is being built, should absolutely be
12 priority agents for study there because it's
13 an important problem. The omission of that
14 strikes me as not thinking about the
15 worst-case scenario, but as thinking of a
16 sort of constrained list.

17 DR. AHEARNE: Anyone else? Now,
18 I'm told we do have Dr. Ozonoff back.

19 SPEAKER: On the phone.

20 MS. SHELTON-DAVENPORT: Dr.
21 Ozonoff, are you on the telephone?

22 DR. OZONOFF: Dr. Ahearne?

1 DR. AHEARNE: Yes.

2 DR. OZONOFF: Can you hear me?

3 DR. AHEARNE: Yes, clearly.

4 DR. OZONOFF: Can you hear me?

5 SPEAKER: Yes.

6 MS. SHELTON-DAVENPORT: Yes, very

7 loud.

8 DR. AHEARNE: Yes, very clearly.

9 DR. OZONOFF: Okay. I did hear Dr.
10 Lipsitch and I --

11 DR. AHEARNE: We lost you just as
12 you were moving into the discussion of
13 environmental justice.

14 DR. OZONOFF: Okay, very good. May
15 I continue?

16 DR. AHEARNE: Please.

17 DR. OZONOFF: You can find their
18 summary of the environmental justice part on
19 page 17 onward of Chapter 8. In addition to
20 the comparison only between Boston University
21 locations, I don't know why it was only
22 confined to Boston University locations and

1 only two amongst those. But even the
2 comparisons that are made just with those
3 locations suggests that the arrow had already
4 been shot and the assessor went through the
5 motions of painting the target around it.
6 And rather than just state that baldly, let
7 me see if I -- let me try and support that by
8 considering some examples. Some of these are
9 perhaps minor in consequence, but they all
10 betray an orientation and attitude which I
11 think adds up to something quick significant.

12 Even the simple location of the
13 site in description where it was concluded
14 that a location in the middle of a large
15 medical center is more convenient and more
16 suitable than a more distant setting in terms
17 of support for a large biomedical research
18 enterprise is irrelevant. Other laboratories
19 and research facilities are, in fact, located
20 away from the main institutions, sometimes in
21 very wealthy communities. We have an example
22 of it here in Boston, where the MIT's Lincoln

1 Laboratory, which is a biodefense laboratory,
2 is situated in the town of Lincoln,
3 Massachusetts, one of the wealthiest towns in
4 the area and many, many miles away from the
5 parent institution.

6 Visual quality was assessed. And
7 this seemed like perhaps a no-brainer when
8 you're looking at it, but it's not so much a
9 no-brainer if you look at it through the
10 spectacles of the community. It's true that
11 a large multi-storied building is more a part
12 of the scenery in an urban environment than
13 it would be elsewhere. That hasn't stopped
14 developers from putting up large industrial
15 parks and office centers in suburban
16 locations, however. And the conclusion that
17 the building is not going to adversely the
18 visual quality of the site is also, I think,
19 revealing.

20 In this building, because of
21 security concerns, there'll be none of the
22 usual ground floor amenities, such as retail

1 establishments or other facilities like
2 meeting rooms that are open to the public.
3 And, in fact, from the ground level, the
4 level that's exterior and (off mike)
5 neighborhood pedestrians. It's just a dead
6 space. It invites nobody in, but, in fact,
7 excludes the neighborhood for security
8 concerns.

9 Large buildings, especially those
10 with so much notoriety attached to them, do
11 make a difference in every community in which
12 they're situated, perhaps in different ways,
13 but they do have an impact and they have an
14 impact everywhere. The idea that
15 neighborhood residents who spent years trying
16 to organize a rational development plan don't
17 care or won't be affected by the building,
18 but suburban and rural residents will, shows
19 both a lack of empathy and a lack of insight.

20 It gets worse. Consideration of
21 noise impacts. The alleged analysis here in
22 this document of the noise problem shows even

1 more clearly the (off mike) issue. It says
2 that the location already exceeds the city's
3 noise limits, so adding more noise isn't
4 going to matter. By contrast, the other
5 locations would require exceptions from the
6 town's zoning exceptions, exceptions not
7 required in Boston because the limits are
8 already being exceeded. It's almost like
9 they're saying to the community if you're in
10 pain, you're not going to mind a little bit
11 more pain. The conclusion that a site that's
12 already exceeding the sound level is the most
13 appropriate place for more construction and
14 operation noise betrays a troubling, almost
15 dismissive attitude towards the community.

16 Even simple things, like utility
17 availability, show presumptions here.
18 Boston, of course, does have an urban
19 infrastructure and the other two locations
20 don't. But that shouldn't prevent the
21 construction of the laboratory someplace
22 where there is an adequate utility

1 infrastructure. The assessors limited
2 themselves to only two sites that were owned
3 by Boston University. There are, in fact,
4 other university properties on other
5 campuses, in non-environmental justice urban
6 communities that do have an infrastructure as
7 well as a very large array of non-Boston
8 University sites, none of which were
9 considered. The assessment was not and
10 should not have been confined to those two
11 Boston University properties.

12 Transportation access. The
13 assessors' assumption was that people coming
14 to the facility will take public
15 transportation. That's absolutely not true.
16 I can tell you not only from my own personal
17 experience, but from data that's been done by
18 transportation planners. The document, in
19 fact, provides no support because no support
20 is possible for this assertion and it's
21 almost certainly untrue.

22 The public transportation system is

1 already at full capacity and the location is
2 poorly served by it. Workers will drive
3 there. The impacts on the neighborhood are
4 going to be more severe because there are
5 more cars, fewer parking spaces, the cars
6 will move more slowly, they'll idle longer,
7 they'll add to an already overburdened and
8 congested area. In comparison, the impact on
9 the other areas would be considerably less in
10 almost every way.

11 Despite all this, and I think the
12 considerations are obvious on their face, the
13 assessors still conclude the Boston site is
14 the best choice. It's a clear case where the
15 decision was made in advance and, in this
16 particular instance, barely concealed.

17 The fact that Boston is a major
18 transportation node, which was put forth as a
19 good reason to have a facility like this in
20 Boston, also gives one some pause. This
21 analysis only considered local spread, but
22 the status of Boston as a highly connected

1 node in a realistic network topology that may
2 have a small world or a scale-free
3 configuration to it, argues strongly against
4 Boston as compared to the other locations if
5 you go beyond local spread.

6 Air quality. I mention air quality
7 because the reasoning used for the air
8 quality is just the noise reasoning turned
9 upside down, used now to justify the
10 preordained conclusion. The alternate sites
11 are both ozone nonattainment areas, so more
12 cars would increase the problem, as the
13 report suggests. But Boston is also an ozone
14 nonattainment areas, so the assessors had the
15 problem of squaring that particular circle.

16 So they claim, first of all, again,
17 as I note without support, that cars coming
18 to the alternate sites would be coming from
19 Boston. Not true and no evidence for it.
20 And that people coming to the site in Boston
21 would be using public transportation. Also
22 very doubtful.

1 Contention that extra traffic would
2 exacerbate the nonexistent carbon monoxide
3 problem on the alternate sites, but not in
4 Boston, is also completely the reverse of
5 what the situation would really be. Carbon
6 monoxide is a localized pollutant unlike
7 ozone. And the more congested and slower
8 moving traffic in Boston would make the CO
9 impact much worse there than it would in the
10 rural alternative sites.

11 There is also -- I won't go into
12 the details here, but they suggest that the
13 ozone nonattainment is okay around the
14 laboratory because the closest monitors show
15 that it's in compliance even though the area
16 is not in compliance. That ignores the fact
17 that ozone levels are usually worse in the
18 middle of the city. There's something called
19 a rural high ozone effect. It's because the
20 ozone precursors are eating up the ozone with
21 an additional free radical reaction. When
22 you see lower ozone levels surrounded by

1 higher ozone levels, what you're seeing is
2 the effect of very high pollution levels.

3 There's no mention in all the talk
4 about air quality or any of the other things
5 that are considered about the high asthma
6 hospitalization rates in this community in
7 comparison to the alternate sites or, for
8 that matter, the extraordinarily high
9 prevalence, the highest in all of Boston, of
10 immunosuppressed people in the South End.

11 It's four times the rate of Boston, twice as
12 high as any other neighborhood. And this
13 comparison of impacts in the context of (off
14 mike) health burden is required by
15 Presidential Executive Order 12898, which
16 mandates consideration of environmental
17 justice concerns for federal decisions which
18 affect minority and low-income populations.

19 As an aside, Executive Orders are
20 mentioned in this document, one on wetlands
21 and one on flood plains. But the one
22 Executive Order that governs and requires the

1 production of this report in consideration of
2 environmental justice is not cited at all.
3 If you look in the NEPA guidance on
4 environmental justice, you will find that
5 agencies, federal agencies, are directed to
6 consider relevant public health data
7 concerning the potential for multiple or
8 cumulative exposure to human health or
9 environmental hazards in the infected
10 population and to consider historical
11 patterns of exposure to environmental
12 hazards. Agencies have to do this even if
13 those matters are not within their control or
14 subject to their discretion. None of this is
15 done in this document, although it's required
16 in an environmental justice evaluation.

17 Just two more matters. One of them
18 is the acknowledgement in this document that
19 Boston is an environmental justice community
20 whereas the other are not, although the
21 distress of this community is somewhat
22 downplayed by saying that there are some

1 high-income people also in the community. It
2 has undergone gentrification in the last few
3 decades. It is still over 50 percent
4 minority, many living in public housing. The
5 closest residents to the proposed facility
6 are 452 units in the Cathedral Housing
7 Project.

8 And even worse, there are
9 communities that are not considered at all in
10 this document. Not 100 meters from the
11 facility, across the freeway, are 2
12 distressed communities: South Boston and
13 North Dorchester. And there's no mention of
14 the extremely large correctional facility,
15 that is the big jail, that is directly within
16 eyesight of this laboratory and is literally
17 (off mike) population.

18 The assessors conclude that since
19 there will be no -- and I'm quoting now,
20 "Since there will be no impact on the local
21 population at the BUMC site, there can be no
22 disproportionate impact on environmental

1 justice communities." This sort of takes my
2 breath away, I must admit. The assertion
3 that there will be no impacts on the local
4 population may be one of the most startling
5 and revealing statements in the whole
6 document. We've just gone through six pages
7 in the original document discussing and, in
8 my view, minimizing those impacts, and now in
9 the space of one sentence those impacts have
10 disappeared altogether.

11 There are manifestly foreseeable
12 impacts in all of the communities, impacts
13 that in this comparison, however, fall on an
14 environmental justice community that's
15 already been beset by many other burdens.
16 The idea that this somehow makes them less
17 sensitive as a community than other areas not
18 so burdened to this facility is pervasive
19 throughout this whole document.

20 Health care facilities are
21 mentioned. This is supposedly a big plus of
22 the Boston area because it's well-endowed

1 with high technology and very good health
2 care facilities. It does, however, compared
3 to the other communities, assume that
4 residents in the area have the same access to
5 health care as those in alternate sites.
6 They don't. They're underinsured, they're
7 under cared for, and they are much sicker.

8 Finally, let me just summarize by
9 saying that there are other things I could
10 discuss, but I think what I've discussed so
11 far has conveyed the essence of my problem
12 with the analysis. It is seriously
13 incomplete. It's contrived. It's not
14 serious in intent and it is dismissive. And
15 I think in many particulars it is wrong.

16 I have to conclude that this is an
17 elaborate exercise in decision justification
18 buried under an almost stupefying level of
19 detail. The gerrymandering of the agents
20 that are used in the analysis would be enough
21 to disqualify it in my view, but the
22 additional distorted analysis, the

1 environmental justice component, which is at
2 the heart of the assessment, is egregious and
3 shows a lack of respect for the community.

4 I'd be glad to answer any questions
5 if you have them. And I hope that you're
6 still on the other line of this line.

7 DR. AHEARNE: Any questions from
8 the committee? Paul, speak in the
9 microphone.

10 DR. LOCKE: Yes. Yes, Dr. Ozonoff,
11 this is Paul Locke and I want to ask you a
12 question I think we've managed to asked every
13 other person who's come before us. Could you
14 talk a little bit about what you would define
15 as a "worst-case scenario" for purposes of
16 analysis and a risk assessment like this?

17 DR. OZONOFF: I don't know what
18 other people have said. I heard what Marc
19 just said and I'm going to have the same
20 difficulty that they have. And I'll throw in
21 another one because I do a lot of
22 mathematics. This is not a linear order.

1 It's what we would call a partial order. So
2 not all of the scenarios are directly
3 comparable to each other. Some of them are
4 bad in different ways, which makes it -- you
5 know, makes all the other difficulties and
6 makes it even more difficult.

7 I think along with Marc I would say
8 that one takes the reasonably foreseeable
9 cases, and I would confine myself to the ones
10 that are reasonably foreseeable and not ones
11 that are outlandishly possible, and use them
12 as one end of the continuum, and ask what if
13 they happened. And that doesn't answer your
14 question specifically because it depends on
15 the particulars of the agents that are being
16 concerned, the environment, the host, and so
17 on. In fact, we haven't talked very much
18 about hosts here.

19 We've talked a lot about the
20 agents, but as I pointed out, the South End
21 has twice as many immunosuppressed people as
22 any other neighborhood in the city of Boston

1 much less the two areas that we're talking
2 about. It's stratospherically high. I think
3 there's 2,700 active HIV cases in the South
4 End neighborhood alone. And the next
5 nearest, which is Roxbury, something like
6 1,400.

7 So all of those things make a
8 difference. And there's so many different
9 dimensions under which things can be bad that
10 it's hard to answer your question.

11 DR. AHEARNE: Any other questions?

12 DR. JOHNSON: May I ask a question?

13 DR. AHEARNE: Please.

14 DR. JOHNSON: Hi. This is Barbara
15 Johnson. I just want to ask for a little
16 clarification and perhaps a specific
17 reference. In the text that you prepared for
18 us you reference a high prevalence of
19 immunosuppressed people in the South End
20 that's four times that of the Boston rate,
21 but you've just said it's twice that of the
22 Boston rate. Is there an exact -- can you

1 give us an epidemiological or a published
2 quote on that statistic?

3 DR. OZONOFF: Yes. I think what I
4 said, or at least what I meant to say, is
5 that it's twice the prevalence of the next
6 nearest neighborhood, which is Roxbury, and
7 four times the prevalence of Boston overall.
8 The reference for this, you can find it
9 actually online in the news hour -- the noon
10 hour, if you want to. It's the Boston Public
11 Health Commission, which is the city of
12 Boston's health department. You'll see on
13 the left sidebar I think there's something
14 called Neighborhood Health. If you click on
15 that, you'll see all the neighborhoods of
16 Boston. The South End neighborhood is
17 included along with the Fenway, but they're
18 broken out separately. And if you look under
19 I think there's something like 50, you know,
20 slides or, you know, presentations of the
21 health status, you'll find that figure in it.
22 The number's 2,700. Roxbury, I think, is

1 somewhere around 1,400 and the city of Boston
2 overall was 700 prevalent per X- thousand.

3 DR. JOHNSON: Thank you.

4 DR. AHEARNE: Other questions?

5 Well, thank you, Dr. Ozonoff, for sticking
6 with us.

7 DR. OZONOFF: My pleasure.

8 MS. SHELTON-DAVENPORT: Maybe you
9 could just stay on the phone. Do you want to
10 have more time for questions, Dr. Ahearne?

11 DR. AHEARNE: Well, (off mike) on
12 it for a minute. Anybody out in the Boston
13 University collection, do you have any
14 questions?

15 MR. NICKSA: Yes, we're here. I'm
16 sorry.

17 DR. AHEARNE: Do you have any
18 questions?

19 MR. NICKSA: No, I don't believe
20 so. Thank you.

21 DR. AHEARNE: This vast array of
22 people on the back wall, anybody there want

1 to ask a question?

2 Well, I guess not. So I --

3 MS. SHARPLES: Perhaps the people
4 who are with Dr. Ozonoff had a question.

5 MS. SHELTON-DAVENPORT: Yes. The
6 attorneys that are with Dr. Ozonoff at the
7 Harvard facility.

8 MS. SHARPLES: Dr. Ozonoff?

9 DR. OZONOFF: Yes.

10 MS. SHARPLES: Are your companions
11 there still there and do they have any
12 questions?

13 DR. OZONOFF: I'm sorry, you're
14 breaking up on me, so I didn't hear the
15 question.

16 DR. AHEARNE: The question is there
17 were two lawyers with you. Are they still
18 there and do they have any questions?

19 DR. OZONOFF: Yes, they are here
20 and I will turn the microphone over to them.

21 SPEAKER: Questions for Dr. Ozonoff
22 or questions for the committee?

1 DR. AHEARNE: Questions of the
2 presenters.

3 SPEAKER: I guess the NIH will they
4 be providing answers to the public, to all of
5 us, or just to the committee that you asked
6 today?

7 MR. LANKFORD: This is David
8 Lankford. Any answers that are provided to
9 committee will also be made public and part
10 of the administrative record.

11 SPEAKER: Thank you.

12 MS. SHARPLES: And they're also
13 going to the Academy's public access file.

14 DR. AHEARNE: All right. Well, I
15 thank you all. And with that, I -- Marilee,
16 anything else?

17 MS. SHELTON-DAVENPORT: I just want
18 to double-check because we're finishing
19 early, an hour early, if any -- do -- all the
20 committee members have had a chance to ask
21 all the questions for any of the speakers
22 that we have had?

1 SPEAKER: We can't hear you.

2 DR. AHEARNE: We're talking to the
3 committee.

4 MS. SHELTON-DAVENPORT: I'm just
5 asking if any committee members have any more
6 questions for any of the speakers that are
7 here, other than NIH which we will type those
8 questions up.

9 SPEAKER: Thank you.

10 DR. AHEARNE: Tom?

11 DR. ARMSTRONG: This is Tom
12 Armstrong. I have one possible follow-up
13 question in the design of the NEIDL
14 Laboratory and intended experts. Will much
15 aerosol route transmission research be done
16 either in the BSL-4 or elsewhere in the
17 facility?

18 DR. KLEMPNER: Like any other high
19 containment BSL-4 laboratories there are
20 specially designed aerobiology suites. They
21 include special design facilities such that
22 it is a Class 3 cabinet in which the

1 experiments are done. And that is then
2 attached within the Level 4 laboratory. So
3 all the work is done within a cabinet that is
4 within the aerobiology suite specially
5 designed. That's similar to both the
6 existing ones, although with much -- I think
7 more sophisticated design than some of the
8 ones that have been out there in the past.
9 And we have so far planned principally on
10 nose-only exposures.

11 DR. AHEARNE: All right. With
12 that, I think the open session has ended. I
13 thank all of you who stayed with us through
14 the various telecommunication problems and
15 thank the presenters and the array of
16 back-benchers. We will now take a 10-minute
17 break and go to closed session.

18 (Whereupon, at 11:52 a.m., the
19 PROCEEDINGS were adjourned.)

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