

LETTER 26

Michael A. Cohen

5/18/2005 11:27 AM FROM: Fax 617-734-8828 Boston University TO: 1,301,480,8056 PAGE: 002 OF 003

Ms. Valarie Nottingham, Chief
Environmental Quality Branch
Division of Environmental Protection
Office of Research Facilities
National Institutes of Health
DHHS, B13/2W64
Bethesda, MD 20892

Re: Boston National Emerging Infectious Diseases Laboratories Facility—Scoping for
Supplimental Environmental Impact State

Dear Ms Nottingham:

Enclosed as an attachment to this letter is my comments to the NIH Supplemental Draft Environmental Impact Statement. My detailed comments are contained in the attachment. While this document provides a worse case scenario not only is it deeply flawed, it fails to give sufficient information to justify an opinion one way or another. For an example, it asserts that the sewage system in Boston is adequate to handle the waste of the Baobabs but fails to provide any information to support the claim. Similarly it fails to discuss failures of the HEPA filtration system. Neither of these claims are academic as Plum Island filtration system was secured by duct tape in 1992 and has been for years the first or second major polluter in Long Island Sound. Plum Island is one of the high security Biolabs in existence since the end of World War II and provides ample evidence of what a failure of security could bring to New England. There was no indication of the frequency of transportation of hazardous materials along with their sources and destinations so one could not even begin to assess risk. The documents assertion that the preparers Kevin Tuohey the chief safety officer of the project and Jack Murphy a manager of one of the core facilities have no financial or other interest in this project is about as likely a claim as an assertion that George Bush had no "financial or other interest in his reelection campaign".

I act as an action editor on a Scientific Journal and I would not even send this piece out to review if I had received it, it would be returned, rejected, with notes as to what an adequate piece would be. Finally, the issue of accountability, transparency and democracy never has been raised. Should there be a release and or a transmission of disease through the insects colonies contained in the BSL4 lab or through negligence or intent how will responsibility be established? Who will pay for any cleanups that might occur, bear in mind the anthrax cleanup of the Washington Post Offices cost several hundred millions of dollars, what would a mosquito release of Dengue Fever cost? Why aren't the citizens of the area involved given a chance to vote on this issue? We say we believe in democracy but of matters of great importance to the well being of the areas of citizens we don't even both to take a vote.

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I thank you for the opportunity to comment on this NIH draft and would in the future like to be put on any email or other distribution lists.

Respectfully yours,

Michael A. Cohen
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Brookline, Mass 02446
Sent via Email: nihnepa@mail.nih.gov
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**COMMENTS ON THE NIH
SUPPLEMENTAL DRAFT IMPACT
STATEMENT**

*Why this does not pass scientific muster as a serious justification for
BSL4 Lab in Boston.*

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ABSTRACT THE NIH SUPPLEMENTAL DRAFT ENVIRONMENTAL IMPACT STATEMENT

ABSTRACT

The draft environmental impact statement is flawed in many respects. The process conducted is virtually incapable of producing objective assessments of the lab costs and benefits. The NIH process for constructing the Impact Statements is almost virtually precludes an objective assessment. There is no attempt to deal seriously with the risk of many alternative scenarios. While one certain instance of a breach of security is analyzed, the analysis appears flawed. None of the other scenarios are seriously addressed. As for issues of the environmental justice, the BU treatment is a travesty since it does not seriously address the issues and gives no evidence that the low income residents of the area will benefit from this project in any significant

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SECTION I CREDIBILITY

The National Institute of Health wants us to believe that this lab is entirely safe even though in their memo written in December 2000, the NIAID notes that the "Rocky Mountain BSL4 Lab is located in Western Rural Montana, well removed from major population centers. The location reduces the possibility that a release of a BSL4 organism would lead to a public health disaster. Evidently, the NIH is aware of this risk in Boston. It is interesting that reportedly the NIH cannot operate the BSL4 laboratory on its own campus due to the opposition of the local residents of Bethesda. It was interesting that this very same memorandum spoke of joint operations of the Bethesda Lab on the NIH campus and the lab.

As a means of comparison of different Universities I take the number of papers in refereed Journals on microbiology, the subject which study of emerging infectious diseases as indexed in Pub Med the National Library of Medicine Database. Of course this is far from a perfect measure, but it correlates highly with the University activity and the distinctions drawn will not be fine.

Of course the premier new site for a BSL4 lab is the home of the NIH from the standpoint of availability of scientific talent interested in this endeavor. For example the last year the NIH wrote 113 papers in Microbiology many of which involve the agents to be studied under this program. Another wonderful site from this standpoint would be Harvard University which could upgrade the already existing unused biolab on the Cambridge, Alston border, saving a great deal of construction costs. The close proximity of the RCE at Harvard with National Center would be a clear plus. Furthermore the Distinguished Biology Departments at Harvard University and Harvard Medical School with 139 papers on the subject shows great scientific strength. In contrast all of BU has 17 papers published last year on Microbiology which includes the study of emerging infectious diseases (as measured by a Search in Pub Med). However, Harvard did not apply perhaps because it felt that the more stringent public control necessitated by Cambridge ordinance or they agreed with the NIH's earlier memo and its actions in Bethesda which suggests they are aware of the dangers of a site placed in a City. Its pretty clear that First Rate Biological // Medical Campuses like say Harvard, Berkeley, Stanford, Cornell, Johns Hopkins have stayed away from competitively applying for NCEID's. Second Tier schools looking to increase their medical research capacity have applied for this. While this may be laudable from their administration's desire to strengthen their research capacity, it is hardly a conducive arrangement for conducting the best research.

In short the NIH would have a lot more credibility in their claims if they operated and expanded the Bethesda BSL4 facility which is the most natural site for expansion, neglecting of course threats to an Urban population.

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SECTION II PROCESS

PROCESS

It is perhaps useful to have the primary preparers of this document be affiliated with Boston University. After all it is they have a strong financial interest and will naturally bias their account in favor of proceeding with the process. However, to have no outside competent review of the claims is irresponsible. To quote Page 171 of the SDEIS, "The following personnel provided technical assistance to the NIH. None of these persons have a financial or other interest in the outcome of this project". The list of names and associations are presented herein.

Table I

Name	Position	Place of Employment	Relationship with BU
Sara Arulanandam	Senior Technical Coordinator	RWDI	No Apparent Relationship
Ellen Berlin	Director Communications	Boston University Medical Center	Medical Center Employee
Paul Avery	President, P. E.	Oak Engineers, Newburyport Mass	No Apparent Relationship
Scott Butler, P.E.	Architect, Project Director	CUHZA, Princeton New Jersey	Scott is currently leading CUHZA's design team on the Boston University Medical Center's National Biocontainment Laboratory in Boston.
Jamie M. Fay	President, A.I.C.P	Fort Point Associates	BU's chief consultant for this and other projects
Cameo Flood	NEPA Specialist	Maxim Technologies, Missoula Montana	Prepared EIS for the NIH
Charles Haytner RLA	Senior Associate	Stubbins, Associates	Help design many buildings for Boston University including, Dental School Renovations and Biosquare Lab Buildings
Jane Howard	Transportation Engineer/Planner	Howard Stein Hudson	Routinely does transportation planning for Boston University.
Karyn Lincoln	EJ Justice Specialist	Maxim Technologies,	No direct connection

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		Helena Montana	to BU.
Jack Murphy, PhD	Professor of Medicine and Microbiology	BMC Employee	BSL4 Containment Core Director
Stephen Ransom	Environmental Engineer	Ransom Environmental Newburyport	No immediate connection
Carla Richards	Director, Community Relations	Boston University Medical Center	In charge of community relations for this BU project
Robert Rossi CCM	Senior Atmospheric Scientist	Tech Environmental, Inc.	No Apparent Relationship
Rebecca Ryan MPH	Biosafety Officer	BUMC	BU Medical Center Employee
Peter Schneider	Director of Environmental Safety	BUMC	BU Medical Center Employee
Felipe Schwartz	Planner, Architectural Associates	Fort Point Associates	BU's general City Planning and Consulting Firm
Susan St. Pierre	A.I.CP, Senior Associate	Fort Point Associate	Chief BU Consulting firm for the BSL4 Project
Kevin Tuohey, C.H.P.A. Executive Director Operations and Public Security	Executive Director, Operations and Public Safety, B.A. Criminal Justice	BUMC	Chief Security Officer, for BSL4 project, responsible for security Planning
Kara Wilber	Planner BA Environmental Studies	Fort Point Associates	Chief BSL4 lab consulting firm and planner for Boston University.

Out of the 19 acknowledged preparers for this project 13 out of the 19 are either personnel employed by BU or its consultants or have a substantial stake or play an integral part in the project. Individuals which the NIH claimed had no stake in the project include one of its chief scientists and its director of security. The more **accurate statement is that key personnel with a substantial interest in the granting of this project prepared this document. Such transparent and blatant falsehoods** about lack of interest in this project further undermine any confidence one has in this report.

While of course the best advocates and often the individuals who know the project best including its warts are the developers, it is a great deal to ask given the substantial financial stake that this group has in the project that to expect any form of objectivity. A much better approach would have all NIH extramural projects of this size reviewed by an outside authority, one unrelated to the project. A suitable blue ribbon panel of people are not hard to find. "The committee on research standards and practices to prevent the Destructive Application of Biology" of the National Research Council should be reactivated to see if security concerns, regulation and location of this BSL4 project are adequately addressed. **Voluntary review by outsider observers and revisions if necessary of the entire project is necessary if security concerns are to be met.**

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26.1 The list of preparers indicates those who participated in the preparation of the EIS. The statement that none of these persons have a financial interest in the outcome of the project is accurate, even though some of those persons may be employed by BUMC. The NIH will make an independent, objective decision on whether to proceed with the Proposed Action in the NIH's ROD.

26.2 The DEIS, SDEIS, and FEIS for the proposed Boston-NBL have been made available to the public for comment. The distribution list may be found prior to the Appendices in the FEIS. Moreover, the document has been reviewed by the NIH's Division of Physical Security Management.

26.1

26.2

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SECTION III ALTERNATIVE LOCATION FOR THE BIOLABS

While there is extreme fear of nuclear weapons due to their ability to incinerate large numbers of people instantaneously infectious agents during pandemics have killed huge numbers of people with much suffering in short periods of time. The bubonic plague has killed 30 to 35% of the population in Europe over a period as short as five years. Smallpox eradicated some American Indian and Latin Indian populations with no immunity with up to 90% mortality. The influenza epidemic of 1918-1919 killed from 20 to 40 million people worldwide and 500,000 people in the US within a year. In contrast the death toll from Hiroshima and Nagasaki combined is approximately 340,000 considerably less than by these infectious disease pandemics. Not to minimize the dangers due to nuclear weapons, infectious diseases under the right circumstances can be both highly lethal and lead to painful and unpleasant death. For this reason serious infectious agents should be treated with the utmost caution and their engineering while studying cures or defending against attacks should be done conservatively.

On the other hand, the threat of emerging infectious diseases is real. 250 people just died of the Marburg virus and all experts believe that a serious flu epidemic is a disaster waiting to happen. In fact, it is not clear why a major pandemic due to flu virus mutation hasn't happened already. The Asian Avian flu with a 60% mortality is already jumping from chickens to people in Vietnam but so far we have been spared human to human transition. The aids pandemic is devastating Africa and killing very substantial portions of their population. It is not human nature to wait for diseases to kill off substantial parts of the population, its important to act now.

The compromise of the last generation was instructive, rather than attempt to build nuclear facilities for testing and wait till the Nazi's built them first, the Manhattan project under General Leslie Groves was set up in Los Alamos New Mexico an unpopulated area and a nuclear weapon was eventually detonated. One did not set up the facility in New York, Boston, San Francisco, Princeton where most of the scientific talent was and build nuclear devices because of "the natural synergy that existed between scientists". No doubt given the level of risk if the scientists were asked whether they wanted to do this experimentation in the middle of cities they would be horrified. However, these are different times and the Government understandably wants to get the most bang for the least capital, since there is not uniform agreement as to the risk from not acting. Moving the New England Center and the Regional Center for Excellence to a lightly populated area would indeed be more costly in the short term. This is not certain however, because construction costs could possibly be less in a low demand isolated area. If on the other hand there is a "public-health" disaster as the NIH puts it in their own memo, the cost would be astronomical and this approach would look exceedingly short sighted a textbook case an example of externalizing risk. Thus the intuitive approach is to move the Center to a geographically stable site in an unpopulated area. The NIH argues that the risk of one of these BSL4 labs is negligible and thus it doesn't matter from the standpoint of public safety where the labs are put. The argument is first that the safety record of the BSL4 labs in existence is exemplary and second that a calculation of risk under the worst case is so negligible to be unimportant. It's the evaluation of these two arguments which we now turn. Then we will turn to discuss the public health value of the New Research.

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Section IV The History of Safety in Biological Laboratories

The NIH study of intramural BSL4 labs suffers from at least three types of sampling bias. The first has to do with underreporting of incidents within these facilities itself. Every external incentive for these labs is to keep all health incidents unreported. Any report of an incident leads to unwanted outside scrutiny and possible disciplinary action. For example the recent Tularemia incident at BUMC was not reported to the public until an anonymous whistleblower leaked the information to the press. OSHA has found the BU system during this incident to be so deficient that it felt compelled to levy a \$8100 fine. Neither the Boston Public Health Commission, nor BU felt the need to publicly report this incident. Indeed current CDC regulations suggest that such incidents be kept secret. Hidden key records establishing culpability may be destroyed by the offending institution itself as these institutions have control of this information.

Secondly, the NIH has studied the published and internal safety record at its elite facilities in which career officials have devoted their life and careers to establish safety. The performance of these institutions represents a best case of what might occur and may not be typical. Even here we will see some lapses. Performance at other laboratories at Universities, abroad and other government labs are not surveyed, is often far less rosy. Since the NIH claims not to be running this new Lab as a BSL4 Intramural Lab, and there is no reason to believe that they can magically transfer the performance at the best labs to these new University Labs. A blanket assertion that this is the case is unsubstantiated hubris.

Finally, no review of cases where the evidence is speculative but suggestive is discussed. It is noteworthy that we are certain of the origins of **none** of the emerging infectious diseases. Table II discusses some of this more speculative but suggestive evidence which at least raises the possibility that some of the spread of is caused by humans. In some cases, these claims cannot be evaluated largely because of the destruction of records at of the lapse of time.

**TABLE II
EMERGING INFECTIOUS DISEASES WHOSE ORIGINS MIGHT BE CAUSED BY HUMAN
INTERVENTION**

Disease	Social Cost	Suggested Human Facilitation	Source
HIV/Aids	20 million dead since 1981, 40 million living with aids	The testing of oral polio vaccine in Africa using monkey sera contaminated with SIV occurred at 75% of the locations where the earliest cases of aids occurred.	Edward Hooper, London Review of Books
SARS	600+ individuals dead	The origin and cause of the current SARS outbreak was caused by the contamination of food related to the feeding, processing and slaughter of animals, meat products, and other elements in the surrounding environment. This was directly caused by a location where food products and people are	www.trv.com/news/ts_L_051303.htm

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		contained and working. There is contamination by a liquid containing microorganisms, animal fluids, and feces. The location is a rural farm-like operation in China that could possibly be a forced labor camp similar to the Shayang Farm in the Hubei province.	
		Over two month period, two graduate students working BL 3 laboratory acquired SARS, leading to transmission to seven other people outside the lab, one death, and quarantining of over 200 people in two province	www.gene-watch.org
Lyme Disease	142,000 cases total 24,000, originally observed in Lyme Connecticut 1975	There were large-scale tick experiments conducted on Plum Island contemporaneously with the initial outbreak of Lyme Disease in 1975, on the heels of a proven virus outbreak that occurred on Plum Island in 1978. Lyme disease	Lab 257, Michael Carroll and others
West Nile Virus	12300 Cases for last two years	West Nile Virus first appears in horses close to Plum Island	Circumstantial evidence that virus stored at Plum Island two years earlier. See Lab 257

These inconclusive but suggestive accounts suggest that some of the most recent and deadly diseases resulted from human action and were not man made. The suggestion that these and other emerging infectious diseases results from the human actions most commonly in biolabs need to be taken seriously. **It is the height of arrogance to assume that the future will not bring surprises like the past and the Boston lab unlike earlier labs will be immune from consequential human error.** Table III taken from www.gene-watch.org below shows recorded well documented cases of recent accidents and there are documented earlier cases. We will see that the NIH accounts suffer from heavy selection bias.

**Table III a more complete account of
Accidents and Problems at US and other Biolabs**

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Mistakes Happen: Accidents and Security Breaches at Biocontainment Facilities last updated on 1/27/2005

Category	Date	Location	Accident Type	Agent	Description	Reference
Environmental Safety	01/01/02	USAMRIID Fort Detrick, MD	Accidental Release, Exposure of Personnel	Anthrax (Bioaerol Level 2, 3 and 4)	Releases of actual spores for exposure to anthrax spores, which were also released into airport highway and office.	Drew Lehman, "First Overexposure Tests Positive for Anthrax Exposure," Associated Press, 4/19/2002
	04/03/03	USAMRIID Fort Detrick, MD	Accidental Release, Exposure of Personnel	Anthrax (Bioaerol Level 3, 3 and 4)	One worker tests positive for anthrax exposure after several tests at USAMRIID.	Rex White & David Snyder, "Anthrax Leaks a 2nd Time at Army Lab," Washington Post, 4/24/2003, B1.
	02/01/03	Federal Express Columbus, OH	Environmental Release	West Nile Virus (Bioaerol Level 2 and 3)	A package containing the West Nile Virus spilled in Federal Express building, exposing workers to possible infection & creating others to be exposed.	"Package Carrying West Nile Virus Spilled at Columbus Depot," Associated Press, 2/20/2003
Accidental Release	06/01/03	USAMRIID Fort Detrick, MD	Environmental Release	Breathable (Bioaerol Level 2 and 3), Anthrax (Bioaerol Level 2, 3, and 4), and Stds (Bioaerol Level 19 2B, 4) and others.	U.S. Army scientist 1 to bacteria-containing vial during an operation to sterilize task, creates a 4-inches wide hole, including the vial, without end-to-end burial between 1998 and 1999.	Lisa Egan, "Fort Detrick Turns Up 'Chemical A Ringhead News,' 8/8/2003, p. 12
	11/26/03	(suspected) U.S. Army Institute of Biomedical Research Institute (Columbus, OH)	Intentional Release	Anthrax (Bioaerol Level 2, 3 and 4)	Anthrax spores used in 2001 mail attacks, using five people, contained properties that could only be manufactured in one of a small number of specialized government or corporate laboratories.	Gary Meisner, "Anthrax Powder: Make of the Art," Science, Vol. 302, November 28, 2003, p. 1492-97
	05/11/01	USAMRIID Fort Detrick, MD	Intentional Release	Anthrax (Bioaerol Level 3, 3 and 4)	Dry anthrax spores derived from USAMRIID were used in the Top 2001 mail attacks that resulted in 8 deaths.	Stanley D. Seal, et al, "Comparative Genomic Sequencing for Discovery of Novel Polymorphisms in Bacillus Anthracis," Science, 4/14/2004, Vol. 304, pp. 2519-23
Containment and Security Failure	12/29/03	Ram Mandi Animal Quarantine Laboratory, USDA (Plain Island, NY)	Containment / Security Failure	None Reported	3-hour power failure compromised containment systems, leading workers to seal windows & doors with duct tape, or co-sprayers failed.	Mark Sankara, "Power Falls for Three Hours at Plain Island Infectious Disease Lab," New York Times, December 29, 2003, p. B1
	06/18/01	National Institute of Infectious Diseases (NIH), Troy, NY	Facility deemed at risk to public health and safety	Varicella, at a Biosafety Level 3 facility	A 1997 inspection of the Biosafety Level 3 facility at NIH conducted by a biosafety consultant to the World Health Organization concluded that there was a "strong probability" that the facility could be an unacceptable risk to public health and safety.	Dr. Christopher DeWitt and Dr. David Fennelly, "Report of an Inspection Conducted at the National Institute of Infectious Diseases, Troy, NY, 1-23-97," Washington, D.C., on 10/10/2001." http://www.niaid.nih.gov/ohrt/inspectr/inspectr.htm
Misuse Sample	05/07/02	U.S. Department of Agriculture (Columbus, OH)	Containment / Security Failure	None Reported	FB Investigation finds many USDA laboratories were being used by individuals to work, pursue unauthorized visitors, and circumvent, completely account for their petting holdings.	"Report Finds Deep Lab Access to Deadly Pathogens," Reuters, May 7, 2002
	01/10/05	Texas Tech University (Lubbock, TX)	Misuse Samples	Fluora (Bioaerol Level 2 and 3)	Scientist Thomas Huber reports the loss of several vials containing fluora.	"Scientist Says: He Tricked His Charges Past Clear Report of Missing Fluora Bacteria," Washington Post, 10/10/2003, p.A13

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Category	Date	Location	Accident Type	Agents	Description	Reference
	Early 1990s	GIABSD (Fort Detrick, Mixing Samples NC)		Arbitraz, Ebola, and others not listed.	Over two dozen dangerous agents including anthrax and Ebola go missing in the early 1990s at GIABSD. Agents subject to removal without notification.	Reference: Peter Weiss and Judy Warden, "Army Leak Track of Anthrax Bacteria," Washington Post, 1/21/2002, p. A1
Exposure and Infection of Personnel	5/15/04-6/16/04	Boston University Medical Center, Clinical Microbiology and Molecular Diagnostics Laboratory (Boston, MA)	Infection of Personnel	Tubercula (Dispersal Level 2 and 3)	Three scientists infected with tubercula over two-month period, while working in biosafety cabinets. Infection not discovered or reported for over six months.	"Stephen Smith, '3rd Outbreak Reporting Potentially Lethal Exposure,' Boston Globe, January 20, 2006.
	06/7/04	Chatham-Heightland Research Center (Chatham, GA)	Exposure of Personnel	Arbitraz (Dispersal Level 2, 3 and 4)	Southern Research Institute inadvertently sends researchers in Chatham, resulting in exposure of seven scientists. Pathogen detected after 48 of 50 area guinea pigs and other inoculation with animal samples. No human infections reported.	John Buckley letter, "US Lab to Start Live the Greater than death and/or samples to improve," The Scientist, June 11, 2004.
	05/03/04	State Research Center of Virology and Biotechnology (Russia)	Infection of Personnel	Ebola virus (Dispersal Level 4)	Scientist researching Ebola vaccine at a US-funded facility is infected with Ebola and dies. Infection not reported for several weeks, preventing prompt and effective treatment.	John Miller, "Russian Scientist Dies in Ebola Accident at Former Weapons Lab," New York Times, May 25, 2004.
	03/28/04	National Institute of Biotechnology (Beijing, China)	Environmental Release, Infection of Personnel	SARS (Dispersal Levels 3 and 4)	Over two month period, two graduate students in concentration to leave other people outside the lab, one death, and quarantining of over 200 people in two provinces.	David Brown, "SARS Cases in Asia Show Lab's Risk," Washington Post, May 24, 2004.
	02/19/04	USAMRIID (Fort Detrick, Dupont of Personnel NC)		Ebola virus (Dispersal Level 4)	Chris Army researcher possibly exposed to Ebola virus after accidentally pricking himself with a needle that contained the virus while injecting mice with the virus as part of a research effort.	http://www.cdc.gov/2004/NEA102/10/04/04021904.html, Reference: "Researcher Injured After Possible Ebola Exposure," CNN, 2/19/2004
	12/01/03	Institute of Preventive Medicine, National Defense University (China)	Infection of Personnel	SARS (Dispersal Levels 3 and 4)	Military researcher in a Biosafety Level 4 lab was infected while studying the SARS virus, leading to the quarantining of 24 people with whom he came in contact. No additional cases of SARS were reported.	"SARS Alert Likely to be Issued in New Year," China Post, 12/01/2003; Center for Disease Control, Taiwan, "A Report on the Laboratory- Acquired SARS Case in Taiwan," 1/7/2004.
	06/01/03	Environmental Health Institute (Singapore)	Infection of Personnel	SARS (Dispersal Levels 3 and 4)	Doctoral student handling SARS-contaminated West Nile virus sample in B. 2 facility is infected with SARS and hospitalized. Laboratory was found to not meet B. 3 safety standards.	David Brown, "SARS Cases in Asia Show Lab's Risk," Washington Post, July 24, 2004.
	04/01/02	University of Texas Health Science Center (Houston, TX)	Infection of Personnel	Arbitraz (Dispersal Levels 2, 3 and 4)	Laboratory worker with primary responsibility of handling anthrax specimens was diagnosed with cutaneous anthrax.	"Suspected Outbreak: Anthrax in a Laboratory Handling Anthrax Specimens," Morbidity and Mortality Weekly Report, 4/3/2002, p. 279.
	12/20/02	Illness	Infection of Personnel	West Nile Virus (Dispersal Levels 2 and 3)	Microweighter in U.S. laboratory contracted West Nile after cutting finger with a scalpel used to perform a necropsy on lab animal.	G. Campbell, et al, "Laboratory-Acquired West Nile Virus Infections—United States, 2002," Morbidity and Mortality Weekly Report, 12/20/2002, p. 1133.

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Category	Date	Location	Accident Type Violation of Personnel	Agent West Nile Virus (Biosafety Levels 2 and 3)	Description Microbiologist in U.S. respiratory specimen (NIH) after purchasing skin with a contaminated needle.	Reference G. Campbell, et al. "Laboratory-Acquired West Nile Virus Infection—United States, 2002," Morbidity and Mortality Weekly Report, 11/20/2002, p. 1133.
	04/01/01	Rocky Mountain Laboratory (Hamilton, MT)	Infection of Personnel	Plague (Biosafety/ Levels 2 and 3)	Release number of researchers were infected with plague in during lab research.	Carlota Crowell, "Scientists' Health not 'Major' Concern," <i>Science's Independent</i> , Vol. 14, no. 46.
	05/10/00	USAMRIID (Washington, DC)	Infection of Personnel	Q-fever (Biosafety Levels 2 and 3)	Microbiologist contracted Q-fever in his office after inhaling spores.	John Neumann et al., "Cases in a Military Research Microbiologist," <i>BMJ New England Journal of Medicine</i> (Vol. 354 (2001)); Stone "Q-fever," <i>Emerging Infectious Diseases</i> at Fort Detrick Lyle S. Schuchman, "Contracted Forefront Field Disease at Biological Defense Center," <i>Microbiology Press</i> , 04/14/00, p.43.
	06/10/98	Yerkes Primate Center (Atlanta, GA)	Infection of Personnel	Simian Hepatitis (Biosafety Levels 3 and 4)	Research Assistant at the Yerkes Primate Center, part of NIH's primate research program, died 6 weeks after being exposed in lab.	"Fatal Cercarial Dermatitis (Swimmer's Itch) (MSK) Infection Following a Nonoccupational exposure, Zoonoses and Infectious Disease Report, 43:1075-6, 1998, 1998.
	06/10/98	Yerkes Primate Center (Atlanta, GA)	Exposure of Personnel	Simian Hepatitis (Biosafety Levels 3 and 4)	A second researcher was exposed to possible infection from virus after first case (see above) at Yerkes Primate Center.	"Second researcher may have been exposed to deadly hepatitis B virus," <i>Star Tribune</i> , Minneapolis, MN, 1/17/99, p.23A.
	08/10/94	Yale University (New Haven, CT)	Infection of Personnel	Sabin Virus (currently Biosafety Level 4, though not designated as such in 1994)	Yale's strongest contracted Sabin virus and subsequently exposed 71 colleagues in the laboratory.	Dr. Barry M. Reed, L. Armstrong, et al., "Brief report, outbreak of a laboratory-acquired Sabin virus infection," <i>New England Journal of Medicine</i> , 1995, 333:29-4.
	1966-87	Washington, DC	Infection of Personnel	any (currently Level 2 and 3)	Two researchers who contracted what is called laboratory hepatitis became infected after using contaminated gloves. Exposed through cuts on hands.	"New AIDS Infection in a Lab," <i>Chicago Tribune</i> , 10/10/1987, p. 3
	04/01/87	unknown	Infection of Personnel	HIV (currently Level 2 and 3)	A researcher became infected with HIV after exposure through "squeezed while in gloves" operation. He attributes cause into contamination.	Chen, Shunyu, "Earlier Date AIDS Virus from Lab Job," <i>Wall Street Journal</i> , 1/4/1998, p.1

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The selection bias in the NIH reports is evident. Notice the security breach at Fort Detrick, Maryland where anthrax responsible for 5 of the mail anthrax deaths may have come. Notice the exposure and death of a worker due to Monkey virus at the Yerkes Primate Center in Georgia. The primate center is at Emory University, very close to the CDC. In addition in 1978 there was a documented outbreak of Foot and Mouth Disease which caused the destruction of all the animals on the Island (Carroll p. 100). In short by casting a narrow net and only using "official reports" the NIH seriously underestimates the amount of accidents in these facilities. Since the NIH fails to report documented accidents at facilities throughout the US including its own, the Credibility of this report is further weakened. The lack of agreement between the broader set of data and the Official Records casts considerable doubt on the value of the NIH recording methods.

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Security at Universities is particularly suspect, there have been numerous report questioning the viability of University Security. the USDA inspector General found security lax at the 104 institutions with no standardized methodology. The Sunshine project in a recent executive report found Institutional Biosafety Committees (<http://www.sunshineproject.org/biodefense/tspbc.pdf>), the University Committees responsible for biosafety woefully inadequate with most of the committees entirely inactive with no public records. Boston University had substandard results consistent with the results at many other Universities. It appears that up until the present Universities have not taken security and biosafety very seriously. This is not a surprise, as is well known security impedes the free exchange of ideas characteristic of a University environment. Furthermore students, and postdoctoral fellows the largest source of Labor at a University have no permanent career ties to their institutions, the stress is on obtaining publishable results fast and Universities cut corners on "unnecessary expenses". These reasons together suggest the University is a poor institution for maintaining security unless extraordinary other measures are instituted such as requiring students who work at these labs to take a job at these institutions for a significant period after they graduate.

Section V | Category A, Diseases, what BU Proposes to Study

26.3



BU lab is called that National Emerging Infectious disease lab. Actually the program is interest in biodefense which is by most authorities think to be dual use for offense. The agents studied are health problems but generally fairly minor. Surprisingly, some of the most dangerous infectious diseases from a standpoint of spread, mortality, or severity of public problem are at lower priority for this group. Hence the official name of this program National Emerging Infectious Disease Lab is largely a misnomer. Category A agents (BSL4) are described in Table IV which concentrates on the public health value of the study.

Table IV: The Value of Public Health for Research on Category A Agents

Infectious Agent	First Discovered	Size of Public Health Problem	Reasons for Category A
Anthrax	First named in 1800's thought to be plague of boils of the old testament 200 BC	1950-1978 500 reported cases in US	Not Contagious but inhalation anthrax i.e. enough in lungs generally fatal. No cure.
Botulism	1793, Named for German Sausage, first	1950 - 1996 1056 Total exposures	Very small number of molecules necessary for fatal exposure
Tularemia	First described 90 years ago. In the Czech republic tularemia was first identified in 1936. north-west and east of Bohemia	Between 1985 and 1992, 1409 cases and 20 deaths were reported in the United States, for a	Very High Level of Infectivity, 10 Organisms or Less

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26.3 The purpose of the Boston-NBL is to provide a highly contained and secure laboratory dedicated to studying emerging and re-emerging infectious diseases, many of which have potential as bioterrorism agents. The laboratory would not develop offensive or defensive biological weapons, as this is forbidden by a national security directive and international law.

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		mean of 171 cases per year and a case-fatality rate of 1.4%.	
Smallpox	Very serious disease 100 years ago. Now eradicated a triumph of medicine and sanitation.	Entirely eradicated. Two stores exists one in the CDC, the other in Russia	Easily translated from person to person, no effective therapy, and people generally lack immunity
Plague	Known since the Middle ages when a form of the bacteria wiped out 30% of the population	10 to 20 cases in the US. Mostly eradicated 56 deaths in India 1994	Aerosolized bacteria or occasionally spread directly person to person. Effectively treated by antibiotics without antibiotics near 100% mortality
Viral Hemorrhagic Fever	Significant Public Health Problem, variants of VHF are highly debilitating or lethal and result in significant deaths which are quite unpleasant. Originally discovered in 1779	1800 cases of Ebola since 1992 and 1200 fetalities, in contrast Dengue Hemorrhagic Fever has about 100,000 cases a year with approximately 1% Mortality.	These viruses pose a risk from intentional exposure because, with very few exceptions, no vaccines or proven treatments exist, and many of the diseases are highly fatal. Natural infections occur when people come in contact with rodents or insects that are infected or act as vectors. After human infection occurs, some VhFs can be transmitted from person to person through close contact or contaminated objects, such as syringes and needles.

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The choice of priority one diseases (category A, BSL4) by the NIH to study is curious. It is clear that the diseases by and large are neither new, nor in general major public health problems (Aids, Malaria, and Tuberculosis and Potentially the Flu is far worse). Hemorrhagic Fever is a significant public health problem and highly lethal in strains. In particular Dengue fever is mosquito transmitted and inflicts approximately 100,000 people a year in South East Asia with 1% mortality. Anthrax is entirely non-communicable, and Tularemia is generally a relatively mild infection with a 20% mortality rate in severe cases if untreated. Botulism is a toxin and is also non-communicable. Smallpox has been eradicated which is a major triumph of modern public health.

Some of this surprise vanishes when we realize a blue ribbon panel of NIH experts was asked to label diseases at a meeting in terms of their potential for terrorism. In reading their published document (<http://www2.niaid.nih.gov/biodefense/research/biotresearchagenda.pdf>) no apparent pattern or reason for picking the various agents for this classification is apparent. Until one is published we can only speculate as to why certain diseases were labeled as potential terrorist threats and others were not. We can only conclude that this labeling was idiosyncratic in the absence of additional evidence. While there reasons for choosing particular diseases are given, the reasons for ranking others such as influenza lower is not apparent.

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- 26.4 The classification of agents was not decided by the NIH, but by the Centers for Disease Control and Prevention (CDC). The rationale of this classification can be found in a paper by Rotz, et al. (Rotz , et al. 2002). Category A agents are defined as being easily disseminated or transmitted from person to person; resulting in high mortality rates and having the potential for major public health impact; causing public panic and social disruption; and requiring special action for public health preparedness, thus giving them research priority.

26.4

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SECTION VI	THE NIH WORST CASE SCENARIO -- NOT EVEN WRONG
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First I would like to commend the NIH for taking my earlier comments to heart involving scientific rigor. However rigorous simulations and quantitative analysis are worse than useless if the measurements necessary to support the model are highly indeterminate. In this case the normal approach in science is do further experiments. However rather than do this the consultants hired by BU chose to argue by assertion.

At this juncture, it will be useful to sketch what a "worst--case scenario" would entail and second outline the deficiencies of the BU argument. It is of course hypothetically possible that the BU argument is correct. We will show that insufficient evidence is provided to evaluate this or any claim so that the BU/NIH argument is not even wrong i.e. we have learned little or nothing from it.

The idea behind a worst case scenario is that a particular event is chosen which the most detrimental process which could possible happening is. If the risk from such an event is small then this bounds the risk from any one event. That being said it itself dodges the critical issue which is over time whether the union of a multiple of unlikely but catastrophic events occur. If this likelihood is too high then the biolabs project needs to be reevaluated.

Even granting that we are considering "worst case", two things need to be done to establish this. The first is to argue that all the other misheps have lesser risk; the second is to argue that "worst case" has acceptably small risk. The way the argumentation needs to proceed is first justify all other intuitively probable events have lower risk second that the "worst case" has negligible risk. We will treat the NIH argued case first and then we will sketch argumentation for what is necessary for all the other cases.

Section VIIa - THE BU WORST CASE ARGUMENT

Its worthwhile citing the Guillenin of the worst case scenario prepared by RWDI.

"In discussing a "range of exposure," the authors of the report make reference to the US Army's conclusion from monkey studies in the 1950s that the lethal dose for half the exposed population was 8,000-10,000 spores.² This conclusion was never meant to suggest a threshold for anthrax infection, below which an exposed individual is safe. Half the animals in the study died of doses much less than 8,000-10,000 spores. The report's reference to a 2% fatality rate in the 1979 Sverdlovsk epidemic in the USSR also needs explanation. Sverdlovsk, a closed Soviet city 900 miles east of Moscow, had a military facility for testing and producing anthrax spores for aerosol dispersal. On April 2, an accidental release of spores blew over the city and killed around 70 people and sickened another 15 or so, of some 5000 people exposed. The spores also killed sheep and cattle as far as 30 miles from the source of the release. In a ceramics factory directly in the path of the plume, some 450 workers in a pipe shop were exposed and of these 10 died of inhalational anthrax. Again, a 2% fatality or, in military terms, "attack" rate was suggested. A single gram of anthrax (around a trillion spores) is reckoned to have caused the total number of Sverdlovsk fatalities.³ Two percent fatality may seem a low rate, but not when one considers the small amount of lethal material, about half of what was in any of the recovered anthrax letters of 2001.

Records from the Sverdlovsk outbreak also indicated that infection can be delayed for up to six weeks following inhalation of the spores. In some individuals, the lung can apparently maintain the spore in a dormant state for a protracted period. Based on this finding and animal studies, those at risk from the anthrax letters were advised to take

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antibiotics for as long as three months."

It seems that the number of spores necessary for release in an anthrax experiment is disputed to range from 10 billion to 1 trillion 3 orders of magnitude and the numbers for a fatal infection are estimated to be one (Guillemin to a few thousand RWDI) . Furthermore, Guillemin evaluates the risk over an integrated area (which can be quite large) which seems reasonable whereas RWDI chosen the risk at a single point. Since there is dispute over source and reception data, which ranges over orders of magnitude, scientific experiment needs to be conducted on a formal basis using animal models to resolve this and no conclusion can be drawn from the RWDI analysis. In short roughly 11 orders of magnitude of disagreement on the input and output characteristics of the data (3 for source, 2 for transmission, and 3 for surface area considered) and this renders the rather pretty simulation modeling and win tunnel analysis useless. It is interesting that in practice the NIH and the government seem to agree in practice with the Guillemin conclusions as:

"During the crisis surrounding the 2001 anthrax postal attacks, the Centers for Disease Control and the US Postal Service (USPS) underestimated the vulnerability of postal workers to low levels of exposure to anthrax spores and consequently failed to shut down postal facilities immediately on discovering evidence of anthrax dispersal. Most of the fatalities and illnesses resulting from the letters were among postal workers. The result has been a series of "criminal neglect" law suits against the USPS and the US and local Governments by postal employees in Washington, DC, New Jersey, and Florida. The clean-up of more than 20 postal facilities and offices, in addition to the Hart Senate Office Building and other federal buildings in Washington, turned out to be much more difficult and cost hundreds of millions of dollars. The Brentwood facility in Washington, for example, took two years to decontaminate and even then did not return to full operation."

Presumably if the dispersion was so great, this cleanup was an entire waste of the taxpayer's money and a total waste of time. Evidently the Government reacts to real evidence and acts conservatively to their credit when lives are directly at stake. The same standards need to be upheld for academic and research facilities when the risk is high.

Section VIIb – Establishing that the Anthrax is Worst Case

It is well known that anthrax is not an infectious agent in humans and death from anthrax exposure results from the intake of anthrax spores from the outstanding environment. Biological diseases are unique in that they can reproduce and spread between hosts. Some diseases like West Nile virus called zoonotics may commonly jump from animals to humans via some vector like a mosquito. To argue that passive transmission such as by anthrax is the worst case, one must rule out infections between animals and humans and between humans. Its not enough to state that the spill of a vial on a lab floor will not cause harm because of sensitivity to air and natural UV radiation other methods of transmission need to be carefully considered. First we will discuss rare events which could cause catastrophic problems. Next we discuss the agents studied and indicate problems which could result from this handling and show the risk is low. Without serious analysis the risk remains indeterminate.

Rare Events

Transportation

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- 26.5 There are regulations in place governing shipment of select agents. Transportation of select agents to and from the Boston-NBL would be managed in accordance with all applicable local, state and federal regulations and guidelines and BUMC policy. These regulations and policy address appropriate notification, packaging, routing and delivery protocols including delivery personnel screening, predetermination of routes, date/time of travel and delivery and GPS monitoring to allow for vehicle tracking and response to incidents during travel time. See Appendix 7, High Hazard Material Management Policy.
- 26.6 As noted in Section 2.2.3.9, the building is designed to meet the stringent seismic design criteria of the Massachusetts State Building Code, sixth edition.
- 26.7 As noted in Section 3.10.3, the project site is located outside the 100 year floodplain and thus is not subject to flooding. NIH cannot comment on issues such as global climate change and oil supply levels over the next 100 years. These issues are not reasonably foreseeable and are outside the scope of the EIS.
- 26.8 The systems being installed in the facility would be incorporated into the preventative maintenance program, which shall follow the manufacturers' recommended service requirements. The operation of the systems would be validated and re-validated periodically to test the efficacy of the process. All wastewater discharge from this facility ultimately is treated in the Massachusetts Water Resources Authority's treatment plant. The waste disposal system and procedures are fully described in Sections 2.2.3.2, 2.2.8, and 3.8. Discharges to the sewer system are regulated by the BWSC, DEP and MWRA, each of which has the authority to issue fines for violations of permits and regulations, and to shut down laboratory discharges, if required. The correlation of the buildings systems proposed for this facility to the failure of the Plum Island wastewater treatment system is inappropriate.

26.5

While as of 1997 the WHO reports no illnesses resulting from transport Gene-watch above reports exposure to Anthrax as a result of transport. The frequency of transport of infectious agents will doubtless increase as transport to the Proteomics Center at MIT, the BSL3 labs on the Harvard Medical School Campus, and the Blood Institute on Huntington Avenue as Part of the Regional Center of Excellence and the NEIDLB will without regulation become more frequent. The probability of within city and extra city release over a 20 year period needs to be estimated. **More importantly, the substances which can be shipped through the City need to be regulated so as to prevent potential catastrophe. The contents of transport need to be of public record and violations of shipping regulations be subject to substantial fines from \$50,000 to \$100,000 per incident so as to enforce utmost care in transport.**

Earthquake

26.6

Boston is in a moderate earthquake zone with a 5.2 Richter scale earthquake occurring on Cape Anne in 1775. One scenario which needs to be addressed is how this building would stand up during an intense earthquake which could in theory cause the collapse of the building.

Climate Change and Flooding and Oil Depletion

26.7

Climate change in the next 100 (<http://www.ipcc.ch>) is projected to raise the average temperature by 10 degrees Fahrenheit and melt the polar icecaps. Boston where the Biolabs is located is near Sea Level and subject to floods. How will this building handle floods? What effect does submerging this building have on release, these issues need to be addressed and are not? In addition oil is likely to deplete or at least become very costly as the Global supply of oil runs out. How will this effect the operation of this building? Even if the requirements satisfy the current law the document needs to explain why this is adequate.

Less Rare Events and Concerns

Waste Disposal

26.8

While we are assured that BU is installing a state of the art waste disposal systems there is no assessment of the breakdown rate of such facilities and with the care that they will be maintained not in the short term but over time. For example, the facilities at Plum Island used to be also state of the art but now from time to time its test with 60,000 gallons of fecal colonoform release making it the second largest water polluter in the New York area. These violations have gone for 10 years (Carroll, p. 226). Promises are made and routinely broken to improve the situation. **In order to preserve the offshore fishing industry, (New Yorks Lobster industry was decimated by Plum Island Pollution). Water pollution violations need to be punished if above the EPA standard at a price not to be less than \$100,000 per incident. In this way, the taxpayer might be compensated for the horrible degradation of the environment and the severe threat to the fishing industry which can result from improper disposal of sewage.**

Terrorism Overt and Covert

26.9

It is likely that the Biolabs will be guarded by state of the art systems as proposed in the DEIS and the SDEIS at least at the outset, although the militarization of both BU and Harvard Medical Schools as a partial result of these biodefense centers will hardly make the respective Universities a more attractive place to study. However, covert terrorism i.e. the obtaining of hazardous agents from these

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26.9 The Boston-NBL would be owned, operated and managed by BUMC and therefore BUMC is responsible for all operations. Staffing plans include 24 hour a day, seven day a week staffing of points of entry and building patrols. Individuals working in the Boston-NBL would undergo significant background checks and would be mandated to work with other approved individuals. Concerns over the staff with access to select agents have been addressed though careful screening, mandatory two-person rule protocols, layers of access that must be replicated for egress and surveillance by closed circuit television. This system of audits and check and balances on approved personnel is intended to mitigate risks associated with approved staff. Incidents of non-compliance or systems malfunctions would be reported immediately to responsible officials.

26.10 Insects would be housed in specialized insectarium rooms. There would be complete segregation of uninfected insects from those insects that contain vector borne pathogens. Different insect species would be kept segregated. See Section 4.2.1.1 "Community Safety and Risk – Other Potential Risk Scenarios (c)" in the FEIS.

26.11 There would be multiple barriers from the insectaria designed to prevent the escape of any insects. Primary containment in the room would include at least 3 barriers including filtered containers, screens and doors. Additional room barriers would depend on the types of insects. For example an oil filled moat would be installed in locations where non-flying insects would be contained since they move by crawling. Multiple additional barriers would be in place outside of the primary containment rooms including multiple additional doors, sealed windows, filtered air intakes and exhausts. In addition, all insects would be inventoried before and after each experiment to ensure that no insects are unaccounted for. See Section 4.2.1.1 "Community Safety and Risk – Other Potential Risk Scenarios (c)" in the FEIS.

26.9

labs to use elsewhere has not been treated. If Anthrax can be stolen from Fort Detrick and the Army Biolab in Columbus Ohio, our most highly secure biowarfare sites what is to prevent similar activities from happening in Boston? Simply asserting that BU has a state of the art security system is not sufficient, in all probability so does Fort Detrick. Furthermore, if Fort Detrick, and the recent Tularemia outbreak are any guide, the Regional Center of Excellence and the National Emerging Disease Lab in Boston will act to keep secret all security breaches. What's needed is a tested system or some rationale for believing that over the long haul BU's and Harvard's security will prove superior.

The Animal BSL4 Laboratory in Boston

The Plum Island Animal Biolab was interesting in becoming a animal BSL4 facility in 1994. However, the wealthy residents of nearby Connecticut and the Hamptons blocked this development. A account of this action on www.genewatch.org states.

"In stormy public hearings in Connecticut and on Long Island, citizens challenged both the safety and the purpose of the expanded laboratory. Many consider it an intolerable risk in a highly populated area. Though on an island, Plum Island's lab is not truly quarantined. Scientists and other laboratory workers commute to Connecticut and Long Island. At the public hearing in Waterbury, Connecticut, one Plum Island scientist told the audience "we hug our kids every night," so trying to persuade the audience that he considered the work safe and they should too. The audience was not reassured. In August 1994, a worker at Yale's Arbovirus Laboratory became infected with Sabia Virus but went home and then to Boston before realizing his symptoms were serious. The risk of accidental exposure would be greater on Plum Island, where instead of cultures in flasks (as at Yale), there are animal populations infected with zoonotic diseases (an illness communicable from animals to humans under natural conditions). Such diseases have incubation times of days: a worker could easily go home or travel without realizing that they had been infected."

While the Residents of the Hamptons and wealthy suburbs of New York and Bethesda Md. feel it intolerable that such a lab be placed in a highly populated area, the NIAID quietly certified the new Boston Facility to be a new **BSL4 animal insect lab**, thus bringing to a low income area of Boston a facility which the citizens of the Hamptons and Connecticut vigorously rejected. Very serious questions as to the alternative modes of transmission are critical.

26.10

- **What will prevent infected insects from mixing with uninfected insects over a 20 year period?**
- **What happens if infected insects escape to the external environment?**
- **What procedure is there if there is a short breach in the containment area and ticks escape to the external environment? How will such insects be detected? How will they be prevented from attaching themselves to birds migratory or otherwise?**
- **What will prevent ticks carrying various forms of encephalitis from exiting the lab?**
- **What experience does the PI from Tufts in Veterinary Medicine with maintaining longstanding insect colonies with safety? Does he have any experience with a BSL4 insect lab? If not, how will he be properly trained?**
- **Will animals other than primates, rodents and insects be studied at the Boston Lab? If so what will prevent animal, to tick, to bird transmission which was the vector for West Nile Virus?**

26.11

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Section VIIc Specific Comments About Various Diseases and Human Transmission

Table V : Noteworthy Specific Diseases to Be Studied

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- 26.12 Monitoring systems accounting for each insect would be in place. The barriers to escape are discussed in Section 4.2.1.1 "Community Safety and Risk – Other Potential Risk Scenarios (c)" in the FEIS.
- 26.13 See Response to Comment 26.11.
- 26.14 All personnel would be required to demonstrate proficiency in the operating procedures of the BSL-4 laboratory prior to working in the BSL-4 laboratory.
- 26.15 Animal models would be developed to meet the research needs of the proposed experiments. Rodents and non-human primates would be the principal animal species housed in the Boston-NBL. Housing is separate for insects and mammalian species. The building would include design features to preclude the escape of animals from the laboratory.

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Disease	Transmission	Reason For Study	Significant Public Health Problem Mortality	Carrier
Glanders	Aerosol, horse secretions	Few organisms for transmission	No, usually fatal if blood infection	No
Smallpox	Body fluids, sneezing etc	High mortality	No eradicated except for Russian and American stores	No, yes?
Hendra Virus	Exposure to Horse Fluids infected. As no natural transmission can be weaponized	High Mortality > 40%	Extremely sparse cases. One outbreak of related NIPAH virus in 1994	Unknon
Rift Valley Fever	Mosquito bites	1997 Large Loss of Cattle 300 Human deaths. A Hemorrhagic fever in severe cases. Permanent loss of central vision is suffered by some 50 per cent of those affected; there may be permanent unilateral or bilateral blindness	Recurring endemic problem in Middle East. Studied as Germ Warfare agent at Plum Island	No
Q Fever	Airborne dust containing organisms from animals	Initially debilitating 1 % mortality	Highly resistant to drying or heating. Highly Infectious	No
Rocky Mountain Spotted Fever	Ticks	approximately 3% to 5% of individuals who become ill with Rocky Mountain spotted fever still die from the infection. 30% w.o. antibiotics	Still debilitating disease with no vaccine. Can be used in Germ warfare.	No
Viral Hemmorrhagic Fevers	Ticks, Contact with Human Blood and Secretions	Mortality can be as high as 80% or more, complications commonly include blindness	Lethality and extreme unpleasantness of symptoms make for good weapon. Very high mortality but not high incidence with the exception of Dengue fever which has low mortality	No carrier state.

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Herpes B Virus	Monkey Bite	100% Morality if cone down with disease	Not yet, but if mutates to be a pure human virus a total disaster	Not to anyones knoledge
Various Tick Borne Encephalitis	Tick Bite	Little death but 20% permanent neurospsychological effects	No cure	No

The various tick borne diseases if disease ticks ever escape to be carried by birds could lead to chronic endemic disease in the Boston area, and similarly for mosquitoes. Thus the ticks and the mosquitoes which breed rapidly and are very small require perfect filtration system with no gaps in the biocontainment system. Herpes B if it is engineered to be transmitted between people could be a weapon as lethal as any nuclear device and could easily become the "Andromeda Strain".

In short, doing this work with this combination of diseases in the middle of Boston is terrifying. The number of places this work should be done is minimal and preferably in a lifeless desert, far from a habitat which any of these insects can naturally breed. That being said, it is clear that at least some diseases, especially those like avian Flu, some variants of Hemorrhagic fever or perhaps Herpes B need to be studied somewhere if for no other reasons to prevent disasters in the rest of the world. A significant number of these diseases if spread could be the next AIDS only worse.

We now turn to the compensation offered to the lower income communities of color for placing the study of the most incurable infectious agents in the world in their community. Compensation to this community needs be substantial whatever the NIH's thought about the risk as comparable communities in Bethesda Md., the Hamptons, and Davis California who evaluated the risk differently than the NIH chose by protest to keep the NIH from doing BSL4 construction.

CHAPTER VIII	Environmental Justice
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The EPA defines environmental justice through the attainment of the following two goals.

1. EPA's first goal is to ensure that no segment of the population, regardless of race, color, national origin, or income, suffers disproportionately from **adverse human health or environmental effects** [emphasis added] as a result of EPA's policies, programs and activities.
2. EPA's second goal is to ensure that those who must live with environmental decision must have every opportunity for public participation in the making of those decisions.

Table VI below describes the specific contributions to environmental justice made by Boston University in their current proposal.

Table VI, BU's Contribution to the Minority Community for This Project

Contributed	Program	Requirement for Project	Beneficiaries
\$920,000	Cities Neighborhood Housing Trust, for affordable housing	Yes	Low cost Housing fund Boston Housing Authority

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26.16 There is no need to compensate "lower income communities of color" specifically. BUMC would contribute to jobs and housing creation trust funds as described in Section 4.3.1.1.

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\$185,000	Neighborhood Job Trust Program	Not mentioned	Job training for residents to participate in the program
\$1,000,000	Training in Biomedical and Biotechnology Fields	No	107 Residents who are trained for the job.
...	Additional Emergency Phones	No	Residents
	Sundry Traffic Improvements including, turn signs, traffic signal upgrades	Required by the Boston Transportation Department	Workers at the Project.

Aside from the \$2,000,000 offered by BU of which \$1,000,000 is required by Law. There is virtually no contribution to the lower income residents of Boston. The contribution appears generous but compared to the approximately \$1.5bn which is anticipated will flow to BU for various services over 20 years the amount is a paltry .13% of the entire project. **A more serious commitment to environmental justice would be to hire a fixed percentage of the low income residents to jobs at average biolab pay, training them to assume jobs for the project. In this reviewers view a commitment to lower income housing and job training an order of magnitude larger would start to look less like a pittance.**

The no action alternative is not likely to occur simply because the property on which the Biolabs exist is valuable commercial property. The no action alternative needs to be replaced by a standard commercial development say a hotel and the benefits to the lower income residents need to be compared **with this alternative.**

Finally we turn to the second point of made by the EPA. If participation in decisions intimately affecting people's life means that the color of traffic sign posts is chosen to respect local wishes or transport is by BU chosen drivers rather than by UPS then the bar is meant. If participation means the community has the ability to control decisions which might intimately impinge on their own lives then these "concessions" are woefully inadequate. It's worthwhile at this point to state that the process by which the NEIDL was placed in Boston was entirely bureaucratic and authoritarian. First the president and his advisors met with HHS advisors to discuss the bioterrorism threat. Next a blue ribbon panel got together and decided what diseases need to be given priority. Then a competition was held the winners of which were chosen by another bureaucracy. In no part of this process did the residents have any say in its outcome. **The natural method to chose the placement of this lab should be largely the choice of the people who live in the area. A referendum should be held which asks the people of the towns within a 10 mile radius of the site whether they want this built in the area. The willingness to abide by the will of the people on an important matter such as this will do as much to fight terrorist attacks on the US in this reviewers opinion as the entire bioterrorism program.**

Summary of Recommendations and Further Recommendations.

- 26.17 1. That this lab be set up in an area with very low population density
- 26.18 2. That major potential public health problems like avian flu, aids, and SARS be given priority with hemorrhagic fever be given lower priority.
- 26.19 3. All experimentation carried out at such a lab and reviews by the Institutional Review Boards be made public and posted on the BU Website for all to see.
- 26.20 4. That Both an independent team of scientific experts, and a committee of laypeople have the power to shut the lab down be chosen by an outside authority to prevent potential problems from occurring.

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26.17 See Response to Comment 19.2.

26.18 See Response to Comment 26.4.

26.19 All research protocols involving biohazardous agents would be reviewed by the Institutional Biosafety Committee (IBC). Minutes of the meetings of the IBC are available for public review.

26.20 The facility would be owned and operated by Boston University. Oversight of facility operations is discussed in Table 1-4 and Sections 2.2.5 and 2.2.7.

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- 26.21 A number of the NIAID priority category A, B and C infectious diseases are vector born diseases. Animal models for these infectious diseases are currently being developed and are possible research projects that may be conducted in the Boston-NBL. See Response to Comment 26.19.
- 26.22 The public has been given full opportunity to be involved in the environmental review of the proposed action. Whether the citizens of Boston should vote on the proposed action is outside the scope of NEPA and of this EIS.
- 26.23 BUMC is the designated clinical care facility for individuals that might be exposed to potentially serious infectious diseases. Plans are in place for the care of such individuals. Part of the care plan involves keeping exposed individuals in isolation for the duration of the incubation period following exposure. The Boston-NBL is not designed as a clinical care facility.
- 26.24 See Response to Comment 26.16.
- 26.25 The Occupational Health Department will be responsible for the testing of employees as it relates to ability to perform functions of their job and in response to potential exposures. Occupational Health and the Office of Environmental Health and Safety will manage employee orientation and education programs, will institute scheduled and unscheduled inspections of areas including reviews of protocols and will expand protocols involving medical surveillance of employees. The Office of Public Safety will manage access and audit control systems to assist in the management of protocols and the security of materials and individuals. Incidents involving contamination or exposure will involve a coordinated response by these three departments to isolate and contain the incident, to appropriately treat the employee, to notify appropriate agencies and to close the laboratory if necessary. See Section 4.2.1.1 "Community Safety and Risk – Other Potential Risk Scenarios (a)" in the FEIS.

- 26.21
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5. A clear statement be made as what animal research is to be done at these labs, which ticks, mosquito's and other insects are to be bred there.
6. Since the risk of these labs over the long term is both uncertain, potentially large and the benefits are unclear, that the people of the city decide democratically by referendum whether to place this lab in the city.
7. An isolation wing be built at the lab to isolate individuals exposed to potential serious diseases
8. That the low income communities surrounding the lab be more highly compensated for the risk they are assuming
9. That lab workers be tested on a frequent basis in all the labs for exposure to the agents with which they are working. A detection of organisms either on the bodies of these individuals or new antibodies to the ailment lead to a shutdown of the lab until the source of contamination be identified.
10. That a serious estimate of the number of times per period of time the lab will be transporting dangerous materials be given and made public. Also the density of traffic to and from the city and within city needs to be estimated.
11. That a list of high mortality organisms be given to the MWRA and waste disposal tests be developed for their presence in the labs sewage, any presence of such agents should lead to a stiff fine and the shutting down of these labs until the source of the pollution be identified.
12. That challenge experiments for Marburg, Anthrax, and Ebola as proposed in the grant application be explicitly banned in humans even with attenuated organisms and that explicit fines and penalty shutdown of the lab be exacted for such experiments. The grant application mentions challenge experiments for these agents but no explicit description of what is meant for these cases.

LETTER 26

Michael A. Cohen

- 26.26 Approximately 1-2 deliveries per month of pathogenic microorganisms are anticipated for the laboratory. All such deliveries would be pre-scheduled and meet all local, state and federal guidelines pertaining to registration, packaging and transportation. As discussed in Section 4.11.2, there would be no unacceptable adverse impacts on existing traffic conditions caused by the proposed facility.
- 26.27 All wastewater from the BSL-4 area (including water from showers, floor drains, autoclaves and sinks) would be chemically decontaminated prior to reaching the BSL-4 drain. Chemically disinfected wastewater would be plumbed directly into large cook tanks for thermal disinfection. The cook tanks are designed to pressurize and superheat the BSL-4 wastewater to ensure complete destruction of any organism that might be present. BUMC is in discussions with MWRA to determine exactly how they would like to see the Boston-NBL wastewater plumbed, tested and discharged. MWRA would need to be satisfied that the wastewater decontamination process is thorough, failsafe, and redundant. See Section 4.8.1.1 of the FEIS.
- 26.28 Studies of this nature will not be allowed in this facility. The facility design does not support these studies. The proposed BSL-3 clinic was not approved and is no longer part of this design.



CONSERVATION LAW FOUNDATION

May 18, 2005

By Email and First Class Mail

Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892
nihnepa@mail.nih.gov

RE: Supplemental Draft Environmental Impact Statement for the proposed National Biocontainment Laboratory at the Boston University Medical Center

Dear Ms. Nottingham:

By this letter, the Conservation Law Foundation ("CLF") submits comments on the Supplemental Draft Environmental Impact Statement ("SDEIS") for the proposed National Biocontainment Laboratory at the Boston University Medical Center.

The SDEIS prepared by the National Institutes of Health ("NIH") fails to consider alternative sites and therefore violates the National Environmental Policy Act ("NEPA"). NEPA requires that NIH "rigorously explore and objectively evaluate all reasonable alternatives" to a proposed action. 40 C.F.R. §1502.14 (a). The SDEIS continues to fail to comply with NEPA in that respect. In our comment letter on the Draft Environmental Impact Statement ("DEIS"), sent January 3, 2005, we urged NIH to comply with the mandate of NEPA and provide a full analysis of feasible alternatives. CLF now, once again, urges NIH to provide the necessary analysis to comply with NEPA and fully evaluate the proposed action.

The legal shortcomings of the analysis in the SDEIS stem from several NEPA violations. First, the NEPA process should have been carried out before NIH made a decision to fund a biocontainment laboratory at Boston University Medical Center. Second, NIH delegated the responsibility for NEPA compliance without maintaining the proper oversight and as a result the DEIS and SDEIS represent Boston University's advocacy for its chosen laboratory site, rather than the NEPA-required analysis of NIH's entire siting selection process, i.e. the mechanisms by which NIH undertook an objective assessment of the Boston University site vis-à-vis other feasible sites for biocontainment laboratories. Third, as a result of this flawed delegation and NIH's adoption of Boston University's analysis, NIH has failed to analyze feasible alternatives in derogation of its legal obligation to assume ultimate responsibility for NEPA processes and EIS outcomes.

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27.1 See Section 2.3, where alternative sites are considered and rationale provided.

27.2 Any decision by NIH to partially fund the proposed Boston-NBL remains subject to the completion of the NIH's NEPA review for the project and the selection of a course of action in the NIH's ROD. In accordance with the CEQ regulations implementing NEPA, the NIH has not taken any action during the preparation of the environmental review that would either "have an adverse environmental impact" or that would "limit the choice of reasonable alternatives" to the proposed action. See 40 C.F.R. § 1506.1(a).

27.3 The NIH did not delegate the authority for the NEPA process to Boston University. The Council on Environmental Quality's regulations implementing the National Environmental Policy Act permit the preparation of EISs by contractors selected by the agency responsible for the EIS. 40 C.F.R. § 1506.5(c). NIH is the responsible agency for ensuring NEPA compliance for the proposed project. The SDEIS contains an objective analysis of the potential environmental impacts that could occur under the proposed action and the no action alternative. Furthermore, any decision by NIH to partially fund the proposed Boston-NBL remains subject to the completion of the NIH's NEPA review for the project and the selection of a course of action in the NIH's ROD.

27.4 The FEIS contains an analysis of all reasonable alternatives identified and, in Section 2.3, the rationale for the elimination from further study of other alternatives that were considered. The NIH did not delegate the authority for the NEPA process to Boston University, and NIH is the responsible agency for ensuring NEPA compliance for the proposed project. The NIH will make an independent, objective decision on whether to proceed with the Proposed Action in the NIH's ROD.

27.1

27.2

27.3

27.4

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- 27.5 See Response to Comment 27.2. Additionally, the reasons for eliminating other alternatives from detailed analysis were not “non-environmental”, as characterized in the comment. These reasons are related to the purpose and need for the proposed action and careful analysis of the reasonableness of alternatives.
- 27.6 The NIH recognizes its responsibility to comply with NEPA and to provide a full and objective review of the potential environmental impacts of the proposed action, as well as to examine reasonable alternatives to the proposed action and reasonable mitigation measures to any potentially significant impacts. The NIH has fulfilled this responsibility. The comment offers no evidence of how NIH allegedly “failed to properly oversee NEPA compliance in the environmental process.”

27.5



- I. NIH must stay its decision to fund a biocontainment laboratory at Boston University until it has complied with NEPA and assessed the Boston University proposal in light of the ROD of that analysis.

NIH failed to prepare an EIS early enough to inform its decision to fund the Boston University biocontainment laboratory and thereby violated the fundamental legal requirement that NEPA analysis and its EIS outcome must be completed early enough to inform and contribute to the decision-making process and must not be used to rationalize or justify decisions already made. See *Metcalf v. Daley*, 214 F.3d 1135, 1142 (9th Cir. 2000). NEPA analysis must be pursued “at the earliest possible time to insure that planning and decisions reflect environmental values.” *Andrus v. Sierra Club*, 442 U.S. 347, 351 (1979).

Environmental review pursuant to NEPA should have been prepared well in advance of the decision to fund a biocontainment laboratory at Boston University. NIH prepared its DEIS and SDEIS after making its decision to fund a biocontainment laboratory at the Boston University site. Even where it purports to discuss alternative sites in the SDEIS, NIH fails to evaluate these sites with respect to the environmental factors at issue and instead puts forth non-environmental reasons for rejecting alternative options and defending its prior decision to fund the Boston University project. This *ex post facto* and self-serving rejection of any alternative sites follows from NIH’s failure to undertake any environmental review of its program prior to approving the Boston project. NIH cannot evade its statutory responsibilities by hiding behind the interests and justifications of a particular program contractor. Such an approach would obviate the decision-forcing aspects of NEPA that courts have long and widely recognized.

27.6



- II. NIH failed to oversee delegated NEPA responsibility to ensure good faith and objective analysis.

NIH also violated NEPA because it failed to properly oversee NEPA compliance in the environmental review process. The lead agency on a proposal for federal action may delegate the preparation of environmental impact statements but retains responsibility for its scope and contents. 40 C.F.R. § 1506.5. Responsibility for environmental impact statements includes the requirement to ensure good faith and objectivity. *Isle of Hope Historical Ass’n v. U. S. Army*, 646 F.2d 215, 220 (5th Cir. 1981); *Brooks v. Volpe*, 380 F.2d 1287, 1291 (W.D. Wash. 1974). Oversight by the responsible agency is essential because, where an agency delegates a significant part of its responsibility by substituting statements and perspectives of a private applicant for its own, there is a danger that the applicant’s environmental review analysis will be based on self-serving assumptions. See *Greene County Planning Board v. Federal Power Commission*, 455 F.2d 412, 420 (2nd Cir. 1972).

That danger has been realized in the DEIS and SDEIS for the biocontainment laboratory. Due to NIH’s failure to properly oversee the NEPA process, the DEIS and SDEIS have adopted and limited the scope of their environmental review to the narrow bounds of Boston University’s project justification. NIH, however, has a broader responsibility to the public under NEPA law to oversee preparation of environmental impact statements to ensure a good faith objective analysis. The environmental review here fails to meet that responsibility with the result that no objective analysis of the proposed action and alternatives has been undertaken.

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27.7 The NIH has considered and examined fully the range of reasonable alternatives to the proposed action. In the FEIS, the NIH explains the reasons for eliminating other possible alternatives from further study. A primary reason for rejecting other alternatives is that they failed to enable the NIH to satisfy the purpose and need of the proposed action. Alternatives considered in an EIS must satisfy the needs of the proposed Federal action. *Environmental Defense Fund v. Corps of Engineers*, 492 F.2d 1123 (5th Cir. 1974). It is unclear from the comment how many alternatives the commenter would have the NIH consider. As noted by the Supreme Court, a “detailed statement of alternatives’ cannot be found wanting simply because the agency failed to include every alternative device and thought conceivable by the mind of man. Time and resources are simply too limited to hold that an impact statement fails because the agency failed to ferret out every possible alternative . . . ” *Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc.*, 435 U.S. 519, 551 (1978).

27.8 The NIH has fully considered and examined the range of reasonable alternatives to the proposed action. Additionally, NEPA does not require that an agency select the “most beneficial alternative”. The EIS demonstrates that the “lack of risk from the proposed action” is not merely “perceived”, as noted in the comment. The NIH has thoroughly assessed the potential risk to the public posed by the proposed action and determined that the risk is so negligible as to be nonexistent. Additionally, the NIH’s analysis of the potential environmental impacts of the proposed action, as well as all comments from the public, in the EIS would enable the agency to make an informed decision in the ROD.

27.7

III. NIH failed to analyze feasible alternatives and the justifications they provide for failing to do so are all flawed.

The requirement to analyze alternatives is the “heart of the environmental impact statement” required by NEPA. 40 C.F.R. § 1502.14. As stated in our letter of January 3, 2005 on the DEIS, agencies are required to “rigorously explore and objectively evaluate all reasonable alternatives” and “devote substantial treatment to each alternative in detail.” 40 C.F.R. § 1502.14 (a)-(b). “The requirement for a thorough study and detailed description of alternatives... is the linchpin of the entire impact statement.” *Monroe County Conservation Council v. Volpe*, 472 F.2d 693, 697-98 (2nd Cir. 1972). Until the analysis of alternatives mandated by NEPA is completed, NIH cannot make a decision to fund a biocontainment laboratory at Boston University or at any other alternative site or setting.

Several feasible alternatives were mentioned in the scoping process on the EIS. The DEIS and SDEIS, however, both rely on flawed arguments to dismiss the feasible alternatives identified. In our letter of January 3, 2005, CLF refuted the flawed argumentation. We were disappointed to see the same arguments in the SDEIS against analyzing alternatives rather than the necessary analysis itself. The failure to evaluate alternatives is inexcusable given both the mandate of NEPA and the potential environmental impacts of significant federal investment in a level four biocontainment laboratory in the heart of Boston.

While our letter of January 3, 2005 discusses the significant flaws in the justifications for failing to analyze alternatives, we summarize that discussion below.

27.8

a. The alternatives may provide an environmental advantage over the proposed action.

The SDEIS claims that alternative locations would not “alter, reduce, or mitigate the environmental impacts.” However, risk to the public and the surrounding community may be decreased if the biocontainment laboratory were located in lower density areas outside of Boston. Because alternatives may provide environmental advantages, they must be analyzed in the SDEIS.

NIH cannot make a legally-defensible finding that alternatives to the proposed action provide no environmental benefit when the alternatives themselves have not been analyzed. Indeed, an agency cannot avoid the NEPA mandate to analyze alternatives even if a proposal is environmentally beneficial. *U.S. Army v. Environmental Defense Fund*, 492 F.2d 1123, 1135 (5th Cir. 1974) (“The congressional mandate to develop alternatives would be thwarted by ending the search for other possibilities at the first proposal which establishes an ecological plus, even if such a positive value could be demonstrated with some certainty”). It is wholly inappropriate to refuse to analyze feasible alternatives on the basis of the perceived lack of risk from the proposed action. Alternatives must be analyzed to inform decision-making about the most beneficial alternative and that decision-making must follow, not precede, full environmental review.

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27.9 Alternatives considered in an EIS must satisfy the needs of the proposed federal action. *Environmental Defense Fund v. Corps of Engineers*, 492 F.2d 1123 (5th Cir. 1974). An agency's decision on the range of alternatives considered needs to be reasonable. As one court explained, "No purpose would be served by requiring [an agency] to study exhaustively all environmental impacts at each alternative site considered once it has reasonably concluded that none of the alternatives would be substantially preferable to the proposed site." *Roosevelt Campobello International Park Comm'n v. Environmental Protection Agency*, 684 F.2d 1041 (1st Cir. 1982). The range of alternatives addressed in the SDEIS is justified by reasonable analysis of the scientific, security, and other factors related to the proposed action and its potential impacts. Additionally, this comment misrepresents the NIH's explanation of the purpose and need for the proposed action and why the proposed location for the NBL was analyzed. Contrary to an assertion in this comment, the NIH does not state that any legal authority restricts the construction of the proposed Boston-NBL to the Biosquare Research Park.

27.10 The NIH recognizes its responsibility to comply with NEPA and to provide a full and objective review of the potential environmental impacts of the proposed action, as well as to examine reasonable alternatives to the proposed action and reasonable mitigation measures to any potentially significant impacts. The NIH has fulfilled this responsibility. The comment offers no evidence of how NIH allegedly "failed to properly oversee NEPA compliance in the environmental process."

27.9

b. The alternatives meet the project purpose and need.

The scope of feasible alternatives that must be analyzed in an environmental impact statement may not be limited by the goals of a particular applicant. *Van Ebbema v. Fornell*, 807 F.2d 633, 638 (1986); *Sierra Club v. Marsh*, 714 F.Supp. 539, 573-79 (D. Maine 1989) (holding that "[a] project's principal goals must override the stated preferences of the applicant for purposes of NEPA's 'reasonable alternatives' analysis" and rejecting the argument that "federal decisionmakers need only examine alternatives tailored to the applicant's proposal").

The purpose of the proposed action as identified in the Broad Agency Announcement for this project is "to provide a highly contained and secure laboratory dedicated to studying emerging and infectious diseases, many of which have potential as bioterrorism agents." ES-2. The SDEIS makes the incorrect claim that the purpose of the proposed action is "to partially fund the construction of the Boston-NBL facility at the BioSquare Research Park in Boston, Massachusetts" and "contribute to the overall National Institute of Allergy and Infectious Diseases (NIAID) biodefense research agenda." The project purpose set forth in the SDEIS imposes a false requirement that the lab be built at the Biosquare Research Park. Nothing in federal law compels NIH to such a conclusion. This self-serving, non-objective statement of the purpose wrongly precludes analysis of feasible alternatives that would meet the true project purpose and need that has not been analyzed. NIH should correct this false statement of the project purpose and undertake an unbiased public review of the siting options. NIH should not allow this manipulation of the NEPA process to undermine the essential procedural requirement to analyze alternatives.

The failure of the environmental analysis here to properly review alternatives is clearly highlighted by the "No Action" alternatives analysis. In the SDEIS "No Action" section, the document states only "Under the No Action Alternative, the Boston-NBL would not be built." EIS 2-35. Based on this summary of the No Action Alternative, the SDEIS concludes that while the No Action Alternative would result in the non-occurrence of mitigated impacts, only through the proposed action would the purpose and need of NIH biodefense research be fulfilled. EIS 2-45. Yet clearly, it does not necessarily or logically follow that the program purpose and need cannot be fully satisfied at existing facilities, with no expansion of the program to de-centralized laboratories such as the Boston University facility. Nothing in the environmental review allows a member of the public or the agency itself to understand the environmental consequences of the different execution options that NIH actually faces in meeting its purpose of "provid[ing] a highly contained and secure laboratory dedicated to studying emerging and infectious diseases, many of which have potential as bioterrorism agents." EIS-2. While it may be that a de-centralized approach offers the greatest combinations of benefits, it certainly is not the only strategy that is viable and the SDEIS wholly ignores the possibility of continuing research efforts at current facilities under a "no action" option.

27.10

c. The programmatic and siting criteria inappropriately restrict analysis of alternative sites.

The SDEIS assumes the objective validity of programmatic and siting criteria that have never received environmental review; these criteria themselves are the heart of the NEPA review that NIH must do before they are used to choose between feasible alternatives such as the Boston

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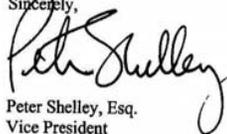
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University proposal. The programmatic and siting criteria relied on in the DEIS and SDEIS as the basis for dismissing the feasibility of alternatives include highly restrictive, location specific requirements such as mandatory proximity to Harvard University Medical School's Regional Center for Excellence and the existing Boston University Medical Center facilities and programs. Proximity to these institutions may provide benefits and should appropriately be considered in the discussion of the proposed action. Alternatives to that proposal, however, must be also considered. Analysis of these criteria and alternatives to these criteria should have preceded selection of Boston University for this program and Boston University's site selection criteria may not be used by NIH to avoid the NEPA requirement to analyze feasible alternatives.

V. Conclusion

We are disappointed that the SDEIS utterly fails again to correct the earlier review's failures to analyze alternative locations in violation of NEPA. In order to comply with the mandate of NEPA, the Final Environmental Impact Statement must include a full analysis of all feasible alternative locations. When adhered to, the NEPA process ensures that the public and decision-makers are informed about all options so that environmentally sound decisions can be made. Here, where the siting of a laboratory to study diseases for which there is no known cure is being considered and a very large governmental investment is being made, all of the siting options should be on the environmental review table. There is no reason or authority to bypass the NEPA process. Indeed, there is every reason to take the time and fully analyze all of the options—to comply with NEPA, to foster an educated dialogue about risks and benefits, and to inform this important decision about public health and safety.

Sincerely,



Peter Shelley, Esq.
Vice President



Carrie Schneider, Esq.
Staff Attorney

CLF: "Defending the Law of the Land"

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Conservation Law Foundation

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Cc:

Senator Edward M. Kennedy
Senator John F. Kerry
Congressman Michael E. Capuano
Congressman Stephen Lynch
Governor Mitt Romney
Speaker Salvatore DiMasi
State Senator Diane Wilkerson
State Representative Byron Rushing
State Representative Gloria Fox
Douglas I. Foy, Chief, Office for Commonwealth Development
Ellen Roy Herzfelder, Secretary, Executive Office of Environmental Affairs
The Honorable Thomas M. Menino, Mayor of Boston
Boston City Councilor Chuck Turner
Mark Maloney, Boston Redevelopment Authority
Richard J. Towle, Senior Vice President, Boston University
Mark S. Klempner, M.D., Associate Provost for Research, BUMC
Jamie Fay, Fort Point Associates
Alternatives for Community and Environment

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Message

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Bayha, Ryan (NIH/OD/ORS)

From: Nottingham, Valerie (NIH/OD/ORF)
Sent: Tuesday, May 24, 2005 10:59 AM
To: Bayha, Ryan (NIH/OD/ORS)
Subject: FW: National Emerging Infectious Diseases Laboratories

From: rbcorley@bu.edu [mailto:rbcorley@bu.edu]
Sent: Wednesday, May 18, 2005 10:40 AM
To: NIH NEPA Comments
Cc: klemprer@bu.edu
Subject: National Emerging Infectious Diseases Laboratories

May 18, 2005
Ms Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892
Re: Supplemental Draft Environmental Impact Statement-
National Emerging Infectious Diseases Laboratories (NEIDL)

Dear Ms Nottingham:

I am writing to you in support of the Biosafety Lab also known as the National Emerging Infectious Diseases Laboratory (NEIDL) proposed at Boston University Medical Center (BUMC).

As you are aware, biomedical research laboratories operate under strict procedures and protocols at BUMC and at other academic and private laboratories throughout the Greater Boston region. This research is done safely and makes important medical contributions to the nation and the world.

I believe that the NEIDL at BUMC will be one of the safest laboratories in the world. I have been briefed on the systems and the design and am familiar with operations in biomedical research laboratories. I am impressed by the building's safety and security features and by the team BUMC has assembled to build this important project. While I understand that there are some who have incorrectly raised the city of Boston's rDNA regulations as a reason the laboratory should not be built, this is simply misinformation. rDNA research is conducted in Boston under the Boston Public Health Commission's regulations. On numerous occasions, BUMC authorities have stated that they will do all research in compliance with the Health Commission's guidelines.

As a scientist working on developing new strategies for enhancing immunity to pathogens, I strongly support the proposed laboratory. Obviously, the federal government has recognized that there is a critical need for such facilities. There is

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Ronald B. Corley, Ph.D.

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not enough biosafety Level 3 or Level 4 laboratory space to accommodate the work that needs to be performed if we are to understand the pathogens that cause new emerging infectious diseases and develop treatments and vaccines to deal with them.

Our public health system is continually being challenged as new diseases emerge. Some examples from our recent history include West Nile virus, SARS, and the annual outbreaks of influenza with the real fear of a global pandemic in the near future. This laboratory will be an important project for the research community and those interested in finding cures for emerging infectious diseases, and I fully support it.

Yours sincerely,

Ronald B. Corley, Ph.D.

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LETTER 28

Ronald B. Corley, Ph.D.

5/24/2005

Message

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Bayha, Ryan (NIH/OD/ORS)

From: Nottingham, Valerie (NIH/OD/ORF)
Sent: Tuesday, May 24, 2005 11:00 AM
To: Bayha, Ryan (NIH/OD/ORS)
Subject: FW: Fnal Comments to NIH concerning the proposed Boston University BSL-4 Laboratory in Boston
Importance: High

From: Mary Crotty [mailto:mcrotty@mnarn.org]
Sent: Wednesday, May 18, 2005 2:42 PM
To: NIH NEPA Comments
Cc: Julie Pinkham; David Schildmeier; Karen Higgins; Dorothy McCabe; Charles Stefanini; Sandy Eaton
Subject: Fnal Comments to NIH concerning the proposed Boston University BSL-4 Laboratory in Boston
Importance: High

To: Valerie Nottingham, Division of Environmental Protection

The National Institutes of Health, B13 Rm. 2W64

900 Rockville Pike, Bethesda, MD 20892

I am writing on behalf of the Massachusetts Nurses Association, which opposes the proposed citing of a Biosafety level-4 laboratory in the heart of Boston, next to Boston Medical Center.

I have attached both the formal position statement of the Massachusetts Nurses Association and a copy of the testimony I delivered to the NIH hearing at Faneuil Hall in Boston on April 25, 2005. Both documents are also pasted below.

Thank you.

Mary Crotty, RN, MBA, JD
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5/24/2005

LETTER 29

Mary Crotty, RN, MBA, JD

NIH Supplemental Review
Faneuil Hall
Boston, MA

April 25, 2005

**Massachusetts Nurses Association
Position Statement
On the Proposed BU Biosafety Level 4 Lab**

CANTON, Mass. -- The Massachusetts Nurses Association is the professional association for registered nurses in the Commonwealth and is committed under our professional ethics to advance public policy that protects the health and safety of all residents of our communities. It is with this mission in mind that we register our opposition to the placement of any Biosafety Level 4 laboratory (BSL-4 lab) in an urban, densely populated area, where the accidental or deliberate release of a deadly biological agent could have a devastating impact on a large population of residents.

Therefore, we believe the BSL-4 lab proposed for a site located very near and directly between Boston Medical Center and the I-93 on-ramp should not be built in inner-city Boston.

While the stated purpose of enhancing public health is commendable, a number of questions arise concerning the decision to build this facility in this place at this time. Among the areas of concern are the following:

Safety

While it is true that those working within the facility will be at the greatest risk of exposure, any breach would potentially infect those living and working nearby, as well as those at some distance, through known or unknown human vectors.

Are nearby hospital emergency departments prepared to contain, and treat victims of, such an outbreak? Indications are that they are not. Congressman Barney Frank testified last year that Massachusetts hospitals are not prepared for the "average Friday night," referring to overcrowding and frequent diversion of emergency patients.

Is evacuation of the community possible? Massachusetts was recently ranked as one of the states least prepared to respond to a disaster in the entire country. While this proposed laboratory is cited as a means of enabling the country to better respond to terrorist threats, the threat posed by the laboratory does not appear designed to resolve Massachusetts' disaster preparedness deficiencies.

What will be done with the waste products of this laboratory? Will waste be adequately processed prior to disposal? Will adequate care be taken to maintain the efficiency of this equipment? It takes 48 hours to verify these tests. Will waste products be held long enough for the completion of tests to confirm decontamination of the load? Where? Will any organisms or parts of organisms be chemically disinfected and poured down the drain? Is incineration or transportation to another site the last stage in decontamination of waste products? What is the environmental impact of the total disposal process?

LETTER 29

Mary Crotty, RN, MBA, JD

29.1 See Response to Comment 19.2.

29.2 Boston Medical Center has a robust emergency response plan as part in anticipation of its role in responding to emergency situations. This response plan was in place prior to any consideration being given to the construction of a biosafety lab. The Boston-NBL would provide more expertise to issues of emerging and re-emerging infectious diseases and the construction of the building would not increase the level of risk that these diseases present. Massachusetts has the intellectual and scientific infrastructure to do the research necessary to create vaccines, therapeutics and treatments for these diseases. Boston has the emergency response skills to respond to issues throughout the city. BUMC has the facilities and utilities infrastructure to operate the Boston-NBL without failure. The Boston-NBL does not create a risk; rather it addresses a need to deal with an existing risk that is prevalent in urban environments.

29.3 See Response to Comment 22.3.

29.4 As described in Section 2.2.8.2, the use, storage, and disposal of all solid and special waste would be performed in accordance with state and local regulations. All contaminated solid wastes would be treated prior to disposal. Pre-disposal treatment would include alkaline hydrolysis. Multi sterilization systems (autoclaves) would be used for biological wastes and tissue digesters would be used for animal wastes. A dedicated liquid effluent decontamination system would treat all liquid wastewater including autoclave drains and chemical disinfectants wash waste.

LETTER 29

Mary Crotty, RN, MBA, JD

- 29.5 BUMC has addressed risks identified by NIH and BUMC staff as well as the community. These risks, including a complete mechanical failure and subsequent release, an attack on the facility, the removal of agents from the building, employee injuries and transportation related risks have been addressed at a variety of meetings and are included in public documents. An attack on the facility from the air would result in damage that would primarily impact the BioSquare Research Park, and would result in no release as the agents in the building are destroyed by fire. The location of the Boston-NBL is in an area that provides response infrastructure for major incidents and creates no more or less risk than it would in a rural area. See Section 4.2.2.1 “Community Safety and Risk”, and also Appendices 11 and 12.
- 29.6 Individuals working in the Boston-NBL would undergo significant background checks and would be mandated to work with other approved individuals as a safety and security risk mitigation measure. Concerns over the staff with access to select agents have been addressed through careful screening, mandatory two-person rule protocols, layers of access that must be replicated for egress and surveillance by closed circuit television. This system of audits and check and balances on approved personnel is intended to mitigate risks associated with approved staff. BUMC would institute protocols to minimize the opportunity for the removal of unauthorized materials from the Boston-NBL. See Section 4.2.1.1 “Community Safety and Risk – Other Potential Risk Scenarios (e)” in the FEIS.
- 29.7 BUMC will promote and hire appropriate in-house personnel to manage and maintain systems within the Boston-NBL. The selection of personnel will include appropriate background screening, relevant education and experience and willingness to work in a complex environment. BUMC will include specialized in-house employees in the commissioning process and will minimize reliance on external

Security

29.5 The assertion that there have been no reported breaches at existing Level 4 laboratories is of little predictive value. Most of these laboratories are described as “urban,” but none are in as congested a neighborhood or with such a narrow buffer. Despite increasingly tight rings of internal security and a nearly impenetrable ground perimeter, has there been any thought of attack from the air or from surface-launched projectiles? The proposed laboratory is within two air-miles of Logan Airport and traffic helicopters regularly fly over this area near the heart of Boston. The only way to avoid harm from an accidental or intentional plane crash into the facility is to remove it to a location where this occurrence would present a lesser threat.

In July 2004, I-93, the major transportation thoroughfare across Boston, was closed during the Democratic National Convention out of just such a concern. Moreover, indications are that the anthrax attack on this country in 2001 was birthed using anthrax specimens originating in a U.S. government facility.

Competent Staff/Maintenance

29.6 In support of maximum safety and security, all individuals entering this facility in whatever capacity need to pass muster both with government agencies and with appropriate credentialing bodies. While those using and maintaining this laboratory need to be assessed to be of the highest caliber, history shows that there is still no guarantee that mistakes and security breaches will never occur.

29.7 The fact that this laboratory will be used as a teaching facility and the fact that cost-containing impulses may lead to the employment, even on an ad hoc basis, of service and support personnel less than fully competent raise long-term concerns. As doors, units and biosafety cabinets are opened and closed, the airflow system must remain balanced to ensure that the potentially contaminated air not enter open areas. All contaminated air is to exit through hepa filters. Failure to maintain such filters has had disastrous effects in the past. Preventative maintenance with on-board skilled staff is necessary to ensure all equipment is serviced and operating appropriately.

Transparency

29.8 Will the exact nature of the organisms being studied or developed be open knowledge? With international cooperation at an all-time low and with long-standing treaties and covenants being abrogated, any military or proprietary secrecy would help create a climate of suspicion, possibly fostering a germ-warfare arms race.

29.9 The Ontario nursing community in the spring and summer of 2003 found official denial by both provincial and municipal officials to be prolonging and exacerbating the SARS outbreak it was mobilized to defeat. It is particularly alarming that Boston University failed to meet its legal requirements to disclose recent safety lapses and resulting harm to workers, and that subsequently, other regulatory agencies and public officials also failed to publicly disclose the potentially lethal outbreaks.

LETTER 29

Mary Crotty, RN, MBA, JD

contracted services to address concerns over inappropriate personnel being provided access to the Boston-NBL.

29.8 A list of agents that may potentially be studied by BUMC at the laboratory appears in Appendix 2. The purpose of the Boston-NBL is to provide a highly contained and secure laboratory dedicated to studying emerging and re-emerging infectious diseases, many of which have potential as bioterrorism agents. The laboratory would not develop offensive or defensive biological weapons, as this is forbidden by a national security directive and international law.

29.9 As soon as confirmed cases of tularemia were identified BUMC officials notified all appropriate authorities as required including the Boston Public Health Commission (BPHC), the Massachusetts Department of Public Health and the CDC. The BPHC's report on these exposures recommended that stronger procedures be put in place to monitor lab personnel and report suspected cases. BUMC concurred with these recommendations in its public Statement of Responsibility. BUMC has already implemented procedures including a mandatory notice to the Occupational Medicine Department after missing one day with any sickness and a medical alert card carried by all tularemia lab workers. BUMC has begun to implement the following procedures: increased safety training and procedures for lab workers; strengthened laboratory safety procedures; unannounced safety inspections of BUMC laboratories; applying additional tests and safeguards to infectious material sent to BUMC for research purposes; outside, expert review of BUMC research controls and procedures; and, working with the Boston Public Health Commission to improve the notification process. See Section 4.2.1.1 "Community Safety and Risk – Other Potential Risk Scenarios (a)".

Oversight

In a democracy, those affected by such a project have a right to know and object to potential threats to their well-being. The professional, technical and residential communities, and organs of government at all levels, need ongoing representation on all oversight committees. Private-citizen appointments to such bodies should be made from a list of nominees submitted by long-standing groups which are independent of Boston University and the federal government.

Accountability

Boston University's spokespeople have asserted that there will be a "number" of oversight committees, but the MNA's concern is that there also be a single, ultimately accountable entity charged with the responsibility for planning and responding to an emergency or unexpected attack from or on the laboratory. Moreover, Massachusetts currently has no regulatory program for BSL-4 laboratories.

Massachusetts does have standards for other inherently dangerous facilities such as landfills and power plants as to where they might be sited, how the location decision is to be made, operations and maintenance requirements and other appropriate standards to protect the public health and environment. Similar requirements are equally relevant and important for BSL-4 laboratories. The recent multiple failures to protect workers, to report incidents appropriately, and to provide accurate information in legal filings for the proposed laboratory have underscored the need for legislation to provide the accountability, and to protect the public health and common good.

Notwithstanding our strong opposition to this project, if policymakers ultimately decide to support construction of this facility at this site, it is imperative that a single responsible entity be identified and be required to develop and communicate to the community a *safety plan* that outlines community response, protection and evacuation in the event of the accidental or deliberate release of any infectious organism or infectious substance and/or potentially infectious RNA or DNA material considered a biohazard. We would further request that members of the community participate in the development of that *safety plan*, and that there be quarterly review of both the plan and the status of the project.

Any risk/benefit analysis of this Level 4 laboratory-construction proposal must take into account the criteria associated with these principles. In situations such as these, it is prudent to err on the side of caution.

Submitted by
Mary Crotty, RN, MBA, JD
Associate Director, Nursing
Massachusetts Nurses Association
340 Turnpike Street
Canton, MA 02021-2711
mcrotty@mnam.org
www.massnurses.org
Tel: 781 821-4625 x743

LETTER 29

Mary Crotty, RN, MBA, JD

29.10 BUMC would have several measures in place to ensure oversight of laboratory operations. See Response to Comment 4.28. While BUMC would be involved in emergency response planning, the ultimate authority for response lies with public emergency response agencies. See Response to Comment 29.2. The siting of the proposed laboratory has been reviewed and approved by many local, state and federal agencies and thus there is no need for additional regulation of the siting process.

29.11 The Boston-NBL would be owned, operated, and managed by BUMC and therefore BUMC is responsible for all operations. In addition to other agencies that regulate the operations of the Boston-NBL, the Boston Public Health Commission would be involved in all aspects of safety within the building and would be represented on oversight committees set up by BUMC. These oversight committees would include an executive committee with representatives of the public, a community oversight committee and both internal and external scientific committees. The oversight committees would have access to all research being performed in the building and all safety protocols in place.

29.10

29.11

Testimony of Massachusetts Nurses Association
April 25, 2005
NIH Supplemental Review

Good evening. My name is Mary Crotty. I am a Registered Nurse, attorney, and Associate Director of Nursing for the Massachusetts Nurses Association. I am testifying this evening on behalf of the nearly 24,000 nurses in Massachusetts whom we represent, as well as the patients and members of the public for whom our nurses care.

Our primary concerns are as follows:

➤ **Safety**

Massachusetts was recently ranked as one of the states least prepared to respond to a disaster in the entire country. While plans may be underway to improve national preparedness, a dangerous lab should not be located in a state ill prepared to prevent human error or ANOTHER 9/11 terrorist act.

29.12

➤ **Boston hospitals have no ability to respond if there is an incident.**

Hospital emergency departments have no extra capacity to handle an average days' visits, let alone respond to the surge from a real or imagined incident at the lab. Diversion statistics for the month of March were up in every region of the state by as much as 40 percent over just the prior month. And, there are NO surge plans for handling a disaster and there is no Diversion planning by the state underway.

29.13

➤ **Equity issues: Disparate treatment of racial and ethnic minorities.**

Boston University is planning to site this extremely dangerous laboratory facility next to Boston Medical Center, which primarily serves an underserved community in Roxbury, Dorchester and Boston. The opinions and rights of the largely minority community concerning the lab that will be in their backyard are being trampled. **While research dollars and jobs** will pour into Boston University, community members gain nothing. Instead they are being placed at risk of enormous bodily harm and subjected to the psychological terror that there will be another breach at a BU lab, with the possibility of a horrendous death from Ebola, tularemia, anthrax or unknown biologically altered organisms

29.14

At the Boston City Council hearing on tularemia in the laboratory a few weeks ago, BU officials were unable to explain how the lab accident occurred and they now admit they may NEVER know why.

LETTER 29

Mary Crotty, RN, MBA, JD

29.12 BUMC is prepared to respond to any and all city, state or national emergency situations and provide assistance as a Level 1 trauma center and as an academic medical center with multiple areas of clinical expertise. The City of Boston and the Commonwealth of Massachusetts have hospital surge plans, evacuation plans and disaster plans. These plans are tested regularly.

29.13 Boston hospitals have a surge plan developed by the Public Health Commission, The Conference of Boston Teaching Hospitals, Boston Emergency Medical Services and the Boston Emergency Management Agency. This surge plan has been tested, works and resulted in the freeing up of 1,000 hospital beds in Boston on September 11, 2001.

29.14 The federal Centers for Disease Control and Prevention is currently making efforts to determine the sources of the contaminated culture.

LETTER 29

Mary Crotty, RN, MBA, JD

29.15 See Response to Comment 19.5.

29.16 The comment does not provide a citation to any Department of Homeland Security regulation that would prohibit either NIH or BUMC from notifying the public of a release of infectious agents from the proposed NBL or other accident. Nothing in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Bioterrorism Act") prohibits a facility from voluntarily releasing information to the public about any accident, release, theft, or infection involving select agents. Further, the Bioterrorism Act requires that a facility that handles select agents must notify the Secretary of the Department of Health and Human Services about any release so that the Centers for Disease Control and Prevention (CDC), acting on the Secretary's behalf, can take appropriate action to notify the public and local authorities. CDC's notification is in addition to any actions the facility may take. The facility is not prevented from directly notifying the public about any accident, release, theft, or infection.

29.15

Although tularemia is one of the most frequently researched biological weapons, BU public relations people likened tularemia to having the flu and Council President James Kelly responded that having the flu wasn't so bad—several of his colleagues had it last year.

29.16

➤ **BU may not be permitted to give notice to the community.**
While BU has been busy telling us about the oversight and accountability mechanisms that will now be put into place, **Department of Homeland Security provisions** may prevent BU from providing notice of an accident or incident even if they would wish to share that news with the community.

For that reason alone, the only sane thing to do is not to site the lab where deadly consequences could have an enormous impact of a major population center.

Thank you.

Mary Crotty, RN, MBA, JD
Associate Director of Nursing
Massachusetts Nurses Association
340 Turnpike Street
Canton, MA 02021
Tel 781 830-5743

Valerie Nottingham
NIHB13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham,

As a resident of the Greater Boston community, I do not believe that the supplemental environmental impact statement (SDEIS) concerning Boston University's proposed biolab seriously addresses my concerns. It was not prepared by an organization independent of Boston University, which renders it irretrievably flawed. It correctly states that the area surrounding this lab faces a "growing challenge of housing affordability," but nowhere does it give a hint as to how such a lab would do other than exacerbate this problem by taking up valuable space. In addition, it gives precious little reassurance to those who DO live in the area that a realistic worst case scenario has been imagined or dealt with in any serious fashion.

It would, of course, be impossible to guarantee immunity to human error in such a project. Human error is inevitable (check out the news on the Big Dig), but when the consequences include possible exposure to deadly, incurable pathogens (e.g., Ebola, anthrax, hemorrhagic fever, plague) any risk is unacceptable.

It is now time to Just Say No.

Sincerely,

Marge Dieter
Marge Dieter
10 Claflin Rd.
Brookline, Ma 02445

LETTER 30

Marge Dieter

30.1 See Response to Comment 1.1.

30.2 See Response to Comment 1.2.

30.3 See Response to Comment 1.3.

30.4 See Response to Comment 1.4.



Division of Endocrinology, Diabetes & Hypertension
221 Longwood Avenue
Boston, MA 02115
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Email: rdluhy@partners.org



Robert G. Dluhy, M.D.
Professor of Medicine
Program Director, Fellowship in Endocrinology

May 12, 2005

Ms. Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab also known as the National Emerging Infectious Diseases Laboratory (NEIDL) proposed at Boston University Medical Center (BUMC).

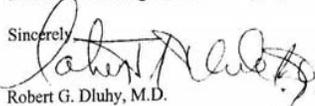
As you are aware, biomedical research laboratories operate under strict procedures and protocols at BUMC and at other academic and private laboratories throughout the Greater Boston region. This research is done safely and makes important medical contributions to the nation and the world.

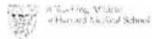
I believe that the NEIDL at BUMC will be one of the safest laboratories in the world. I have been briefed on the systems and the design and am familiar with operations in biomedical research laboratories. I am impressed by the building's safety and security features and by the team BUMC has assembled to build this important project.

I should also note that there are some who have incorrectly raised the city of Boston's rDNA regulations, as a reason the laboratory should not be built. This is simply misinformation. rDNA research is conducted in Boston under the Boston Public Health Commission's regulations. On numerous occasions, BUMC authorities have stated that they will do all research in compliance with the Health Commission's guidelines.

This laboratory will be an important project for the research community and those interested in finding cures for emerging infectious diseases and I fully support it.

Sincerely,


Robert G. Dluhy, M.D.



LETTER 31

Robert G. Dluhy, M.D.

Nottingham, Valerie (NIH/OD/ORF)

From: Drapkin, Mark S.,M.D. [MDRAPKIN@PARTNERS.ORG]
Sent: Tuesday, May 03, 2005 12:12 PM
To: NIH NEPA Comments

Mark S. Drapkin MD
(Residence) 129 Clark Road
Brookline, MA 02445

Ms. Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

As a physician in infectious diseases practice in the Boston area for 30 years and as a resident of Brookline, MA, I am writing to express support for the National Emerging Infectious Diseases Laboratories at Boston University Medical Center (BUMC). There is an urgent need in this country to create facilities to conduct research aimed at finding causes, diagnoses and therapeutics for the alarming number of recently emerging and re-emerging infectious diseases.

I would like to comment on two very important issues raised in the document - the appropriateness of the proposed location of the facility and the safety of the proposed Biosafety Level 4 laboratory.

As discussed in the document, prior to making a determination to site the proposed NEIDL facility at the BioSquare Research Park, Boston University undertook an alternatives siting analysis that evaluated existing sites under its control to determine the best location for the facility. The study concluded, and I agree, that the best location for this facility is exactly where it is proposed in the BioSquare Research Park in the City of Boston, MA. BioSquare Research Park is a state of the art medical research park which contains medical research facilities including Biosafety Level 1, 2 and 3 laboratories that the proposed facility will be able to take advantage of. BioSquare Research Park is also located directly across the street from the Boston University Medical Center campus which also houses hospital and medical research facilities and is the largest Level 1 Trauma Center in New England.

I understand that some community members feel that such a facility

LETTER 32

Mark S. Drapkin, M.D.

should be located in a more rural location. As one who lives within three miles of the proposed facility, I feel strongly that the facility should be located in an urban area which functions as a hub for medical research activities and which has a significant base of resident medical research scientists. Siting the facility in this manner assures that efficiencies are reached in terms in the ability to share research facilities and knowledge through direct collaboration among the various institutions located in the greater Boston area.

In regards to concerns regarding the safety of the proposed facility and in particular, the Biosafety Level 4 laboratory, I have no question that the facility will be safe. There are several federal and state programs which require the facility to be constructed and operated at extremely high safety standards. Similar laboratories throughout the United States have operated safely for decades.

In closing, as one who lives and works close to the proposed facility, I urge you to proceed with the funding to construct this much needed national resource at the BioSquare Research Park in Boston.

Sincerely,

Mark S. Drapkin, M.D.
Associate Chief, Infectious Diseases Service, Newton-Wellesley Hospital
Professor of Medicine, Tufts University School of Medicine
2000 Washington Street Suite 122
Newton, MA 02462

Note: The information contained in this message may be proprietary, privileged, or confidential. If you are not the intended recipient, you are hereby notified that any disclosure, copying, distribution, or the taking of any action in reliance on the contents of this message is strictly prohibited. If you have received this in error, please contact Dr. Drapkin or his staff at 617-243-5436 or by return e-mail immediately. Thank you.

LETTER 32

Mark S. Drapkin, M.D.

Valerie Nottingham
NIHB13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham,

33.1

33.2

33.3

33.4

As a resident of the Greater Boston community, I do not believe that the supplemental environmental impact statement (SDEIS) concerning Boston University's proposed biolab seriously addresses my concerns. It was not prepared by an organization independent of Boston University, which renders it irretrievably flawed. It correctly states that the area surrounding this lab faces a "growing challenge of housing affordability," but nowhere does it give a hint as to how such a lab would do other than exacerbate this problem by taking up valuable space. In addition, it gives precious little reassurance to those who DO live in the area that a realistic worst case scenario has been imagined or dealt with in any serious fashion.

It would, of course, be impossible to guarantee immunity to human error in such a project. Human error is inevitable (check out the news on the Big Dig), but when the consequences include possible exposure to deadly, incurable pathogens (e.g., Ebola, anthrax, hemorrhagic fever, plague) any risk is unacceptable.

It is now time to Just Say No.

Sincerely,

Joan Eckler - Prof. of Sociology (retired) 11/13/00
14 Sterling St
Newton, MA 02465

LETTER 33

Joan Eckler

33.1 See Response to Comment 1.1.

33.2 See Response to Comment 1.2.

33.3 See Response to Comment 1.3.

33.4 See Response to Comment 1.4.

Valerie Nottingham
NIHB13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham,

As a resident of the Greater Boston community, I do not believe that the supplemental environmental impact statement (SDEIS) concerning Boston University's proposed biolab seriously addresses my concerns. It was not prepared by an organization independent of Boston University, which renders it irretrievably flawed. It correctly states that the area surrounding this lab faces a "growing challenge of housing affordability," but nowhere does it give a hint as to how such a lab would do other than exacerbate this problem by taking up valuable space. In addition, it gives precious little reassurance to those who DO live in the area that a realistic worst case scenario has been imagined or dealt with in any serious fashion.

It would, of course, be impossible to guarantee immunity to human error in such a project. Human error is inevitable (check out the news on the Big Dig), but when the consequences include possible exposure to deadly, incurable pathogens (e.g., Ebola, anthrax, hemorrhagic fever, plague) any risk is unacceptable.

It is now time to Just Say No.

Sincerely,

Reita G. Ennis
3 Lepland Road
Brookline, MA 02445

LETTER 34

Reita G. Ennis

- 34.1 See Response to Comment 1.1.
- 34.2 See Response to Comment 1.2.
- 34.3 See Response to Comment 1.3.
- 34.4 See Response to Comment 1.4.

MAY-18-2005 08:58

P.02



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 1
1 CONGRESS STREET, SUITE 1100
BOSTON, MASSACHUSETTS 02114-2023

OFFICE OF THE
REGIONAL ADMINISTRATOR

May 17, 2005

Valerie Nottingham
National Institutes of Health
NIH B13/2W64
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Supplemental Draft Environmental Impact Statement for National Emerging Infectious
Diseases Laboratories Boston, Massachusetts, CEQ # 20050138

Dear Ms. Nottingham:

In accordance with our responsibilities under the National Environmental Policy Act (NEPA) and
Section 309 of the Clean Air Act, we have reviewed the National Institutes of Health's (NIH)
Supplemental Draft Environmental Impact Statement (SDEIS) for the National Emerging
Infectious Diseases Laboratory (NEIDL) at the Boston University Medical Center Campus in
Boston, Massachusetts.

The SDEIS describes the same proposed action detailed in the October 2004 DEIS. The
proposed action includes the construction of a 194,000 square foot biosafety lab facility at the
BioSquare Research Park in Boston. EPA commented on the DEIS for this project in January
2005. At that time we identified concerns related to air quality, cumulative impacts and
environmental justice. A copy of our comments are provided again for your reference.

While the SDEIS was responsive to many of the comments and concerns we raised on the DEIS,
the attachment to this letter describes issues and questions that we believe need to be addressed
in the FEIS. We have rated the SDEIS "EC-2-Environmental Concerns-Insufficient
Information" in accordance with EPA's national rating system, a description of which is attached
to this letter. Please contact Timothy Timmermann (617-918-1025) of EPA's Office of
Environmental Review with any questions.

Sincerely,

Robert W. Varney
Regional Administrator

attachment

617-918-1010

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LETTER 35

U.S. Environmental Protection Agency

MAY-18-2025 08:58

P.03

Additional Detailed Comments on the SDEIS for the National Emerging Infectious Diseases Laboratories (NEIDL), Boston, Massachusetts

General Comment

It would have been helpful for all readers if new information and analysis provided in response to comments on the DEIS were specifically highlighted in the SDEIS through marginal notes, bolded text or in some other manner. Without such notations, it is more difficult to identify changes that were made to the DEIS. We recommend that the FEIS highlight or otherwise make known the changes between the DEIS, the SDEIS and the FEIS.

Air Quality

Construction Management Plan (SDEIS section 2.2.10)

Given the public health concerns about diesel exhaust, EPA continues to strongly recommend that measures be implemented to reduce fine particle emissions associated with the construction of this facility. The SDEIS indicates that the project will comply with the Massachusetts DEP's Diesel Retrofit Program for Construction Vehicles. Currently, both the Massachusetts Highway Department (MHD) and the Massachusetts Bay Transportation Authority (MBTA) are requiring advanced pollution controls on vehicles used in construction projects. We support this approach.

35.1

However, the requirements adopted by the MHD and MBTA do not apply to the NEIDL. EPA recommends that all construction vehicles associated with this project be equipped with diesel oxidation catalysts, and/or use cleaner diesel fuel such as low sulfur diesel (highway diesel fuel) to reduce fine particle emissions, and we request that the FEIS clarify the specific commitment to the use of retrofitted equipment and/or cleaner diesel fuel in the construction of this facility. Please refer to the language of our Construction Impacts comments on the DEIS (as attached for reference on page ADC-4) for the specific recommendations that we support for this project.

Building Design

The additional information provided in response to EPA comments on the use of HEPA filters remains incomplete and should be expanded. The SDEIS states (page 2-10) that the HEPA filters are designed to resist moisture and low level solvents. Therefore, it is assumed that the actual body of the filter as well as the holders are resistant to moisture. There is no mention of pre-filters. The statement that HEPA filters are effective since they are used in respirators is not a complete response or analysis of this issue. For example, HEPA filters are required in asbestos abatement workers' respirators. Unfortunately workers' behavior as well as working conditions frequently defeat the protective feature of the HEPA filtered respirators. Therefore, it is essential to have supervision and outside inspection as well as multiple levels of training and protective devices to ensure that workers are protected and that HEPA respirators do not represent the only significant source of protection.

35.2

ADC-1

LETTER 35

U.S. Environmental Protection Agency

35.1 As noted in Section 2.2.10 of the FEIS, the project is committed to the DEP Diesel Retrofit Program for Construction Vehicles, which would include the use of retrofitted equipment and/or cleaner diesel fuel. Electric welders would be used and no diesel powered generators would be used unless for emergency reasons. The exhaust system of all heavy equipment including excavators and cranes would be modified with scrubbers if they were to remain on site for more than two months. All diesel equipment would utilize low sulfur fuel. All diesel equipment would be equipped with a mufflers and sound shrouds / shields.

35.2 With regard to building design, pre-filters are used in-line prior to supply HEPA filters to prevent premature loading of the supply HEPA filters. Laboratory air exhausted through HEPA filters is not subjected to pre-filtration because laboratory environments do not generate large numbers of particulates which may prematurely load filters. Additionally, static pressure drops are measured across HEPA filter installations as a real time measurement of filter efficiency and operation. These installations are tested and certified by National Sanitation Foundation (NSF) certified technicians against NSF Standard 49 requirements. HEPA filter installations are re-certified annually and are provided with full redundancy. See Section 2.2.3.4 of the FEIS.

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The SDEIS also states that the HVAC system will provide 100% outdoor air and that the air exchange rate will be between 8-12 air changes per hour so that laboratory agents or chemicals will not build up in concentration. Although the BSL-4 is HEPA filtered, there is no information provided regarding the general laboratory air exhaust (BSL-3 and lower) as to its filtration. This exhaust could be passed through controls to contain chemicals (such as general laboratory solvents) and particulate matter, thereby reducing cumulative exposures to the neighborhood.

Fault-Tree Analysis

35.3

A fault-tree analysis was requested in our comments on the DEIS to evaluate health and safety features. The SDEIS (page 2-8) states that a graphical technique, similar to a fault-tree analysis was used, but the SDEIS does not contain this evaluation. We recommend that the graphical analysis of normal lapses in laboratory safety and health procedures coupled with equipment failure and aging of the building be provided for review.

Risk Assessment

The worst case quantitative risk assessment used many assumptions that were not appropriate for a worst case quantitative risk assessment. On this issue, the SDEIS did not provide information EPA requested in comments on the DEIS. We offer the following observations:

35.4

- Only inhalation exposure for a person standing at the location of predicted maximum exposure was used; all routes of exposure, such as dermal and ingestion, should be evaluated and population exposure estimates used along with the maximally exposed individual.

35.5

- Even though the SDEIS (page 4-4) states that anthrax spores are highly resistant to adverse environmental conditions, there is no discussion of the fate of the spores after the estimated 30 minute release.

35.6

- The results section does not provide the health benchmark that was used. Page 4-4 of the SDEIS presents an argument for 9 spores as an infectious dose but it is unclear if this infectious dose is the comparison dose used in the quantitative risk assessment. Because other infectious dose estimates are provided in the published literature, it is recommended that a range of these doses be used to provide comparisons as health benchmarks.

35.7

In addition, our review of the revised risk assessment prompts the following two concerns. First, anthrax spores were modeled as a heavy dense gas that produces fractions of spores. Since spore fractions are not possible, wherever there is a fraction, the fraction should be rounded up to one intact spore as an assumption protective of public health. Second, a potential scenario that should be evaluated is the potential of release of one of the insect vectors of the BSL-4 organisms in addition to the escape of an infected traditional laboratory animal.

ADC-2

LETTER 35

U.S. Environmental Protection Agency

35.3 The design of the facility has been reviewed multiple times throughout the design development. These reviews would continue throughout the design and construction process. The operation of the facility would only occur after the formal commissioning process is successfully completed; with failure mode tests have been performed based on the review of the final as built design of the facility. The operation of the BSL-4 laboratory with select agents can only be authorized upon submission review and approval of the standard operating procedures for laboratory protocols by the CDC (the authority approving the use of Select Agents). See Section 2.2.4 for information on commissioning.

35.4 Inhalation exposures to anthrax spores represent the worst case exposure scenario in terms of public health impact (See Rotz, 2002). Cutaneous anthrax is easily treated with antibiotics and is not considered an outcome of accidental release from this building. Gastrointestinal (G.I.) anthrax outbreaks do occur but are related to handling and consuming meat from infected cattle in African, Asia and the former Soviet Union where anthrax is an endemic disease. Gastrointestinal anthrax would not be the most likely outcome of an accidental release of the agent from a BSL-4 facility and therefore is inappropriate for the inclusion in worst case scenario modeling.

35.5 Spores released in the modeling scenarios (1-10 μ in size) will remain in the air for extended periods of time. After the 30 minute release the small numbers of spores released will further dissipate with regard to concentration.

35.6 In the appended Maximum Possible Risk model (see Appendix 12), 500 spores over an 8 hour period was used as the pathogenic benchmark (Brachman 1966).

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U.S. Environmental Protection Agency

- 35.7 In Section 4.2.1.1 “Community Safety and Risk – Worst-Case Release Scenario Risk Assessment”, the summary of results for the worst case examined (i.e., no HEPA filter case), the calculated maximum number of spores that may be inhaled is 0.2925 spores. Instead of expressing the maximum number of spores as a spore fraction, the above results are equivalent to an estimate of a single spore in a volume of 3.4 m³ of air. Assuming a breathing rate of 30 litres per minute, it would take approximately 1.9 hours to inhale this volume of air.

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Appendix 9 of the SDEIS includes a modeling study of an accidental release of anthrax spores. We offer the following comments and observations about that modeling study.

- The use of the ISC-Prime model is appropriate for this exercise. The maximum concentrations resulting from the model are several orders of magnitude higher than those calculated by the SLAB model used in the DEIS.
- 35.8 • The meteorological data used is not specified in the analysis. The report describes the meteorological data as "...a range of weather conditions that may be encountered, based on historical meteorological data for the Boston area." We believe a specific station and timeframe of data should be specified.
- 35.9 • The receptor grid is not specified, so we cannot say whether it is sufficiently dense enough to see small scale variances in the concentration of spores.
- 35.10 • As we mentioned in our comments on the DEIS, the report assumes that 400,000 of the 10 billion anthrax spores will become airborne, but does not explain what will happen to the remaining spores.

Other Comments

- 35.11 • EPA believes that the analysis of alternative locations should be expanded to provide more detail about the benefits and disadvantages of physical isolation of the BSL-4 from the Boston BioSquare Research Park. The purpose of the BU NEIDL is to provide a highly contained and secure laboratory dedicated to studying emerging and re-emerging infectious diseases. The SDEIS states that the proposed project location would enable collaborations among investigators in 11 listed laboratories, at least half of which are located outside of Boston. The Executive Summary states that alternative locations were not analyzed in detail as they were technically infeasible, provide no environmental advantage, or do not meet the purpose and need for the project. The alternative locations with a lower density of human occupation area were dismissed because they were outside Boston and "location in lower density areas would not ...reduce the risk to the public." (SDEIS page 2-43) EPA questions the assumptions in the worst case analysis leading to this conclusion (see discussion later in this attachment) and believes the FEIS should provide additional information to justify why physical isolation for a laboratory studying emerging and re-emerging infectious diseases in humans and other animals is not desirable. We also note NIAID correspondence regarding the Rocky Mountain Laboratory BSL-4 laboratory which lists the advantages and disadvantages of construction of BSL-4 laboratory space in Hamilton, Montana. The letter indicates that the Rocky Mountain Laboratory is located in rural western Montana well removed from population centers thereby reducing "the possibility that an accidental release of a

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35.8 In Section 4.2.2.1 "Community Safety and Risk – Worst-Case Release Scenario Risk Assessment", modeling was completed using two computer models (SLAB and ISC PRIME) and using wind tunnel tests. For the SLAB and wind tunnel results, the meteorological conditions used were screening-level conditions that were compared to actual Boston area data to confirm that the conditions modeled are conditions that may occur in the Boston area. The ISC PRIME modeling was completed using long-term hourly surface data from Logan (Boston) International Airport.

35.9 As explained in Appendix 9 "Risk Assessment Report March 23, 2005 – Appendix A", for the wind tunnel assessment of the Boston-NBL, a model was built to a scale of 1:200. The model consisted of the Boston-NBL and any surroundings within an 800 foot radius. This included many Boston University Medical Campus (BUMC) buildings (existing and future), and the surrounding commercial and residential areas. Because of the height of the penitentiary south of the Boston-NBL, an extension was also added to include this in the model. Receptor locations in the wind tunnel were connected to tracer gas meters and are tested for multiple wind speeds and wind directions for each source in order to capture the worst-case impact.

Receptor locations included Boston-NBL air intakes and pedestrian locations, BUMC building air intakes and pedestrian locations, and off-site locations such as commercial buildings and residential areas. They were chosen based on RWDI's experience and input from Boston University, CUH2A, and Hemisphere Engineering. They include locations where the highest exhaust concentrations are expected to occur.

35.10 The remaining anthrax in the scenario that is not released into the environment remains in the laboratory. The sample either remains in the sample tube, or spills over on to the laboratory floor. In either case the spill is cleaned under laboratory standard procedures and the surfaces are decontaminated.

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U.S. Environmental Protection Agency

- 35.11 NIH analyzed the alternatives determined to be feasible. One of the main considerations in determining whether an alternative is reasonable is its ability to meet the purpose and need of the project in its entirety. There is no benefit to locating the facility elsewhere to reduce risk because the risk is negligible. The Rocky Mountain Laboratory memo referred to in the comment was never officially signed or sent, and its author is unknown. NIH does not support the content of the memo as rationale for the location of any laboratory. NIH would have to believe that the proposed facility was unsafe, which it does not. Where the staff lives is not as important as where they work to facilitate collaboration. All the facilities listed are within a close distance, and not far removed from the city.
- 35.12 Separation refers to a great physical distance between laboratories. Isolation means barriers to entry and exit, and does not refer to the distance from one another. In this way, laboratories can be isolated and safe, while being close enough to create efficiencies due to co-location.
- 35.13 The use of any radioactive isotope in research at the Boston-NBL would first need to be reviewed and approved by BUMC's Radioisotope Committee. Part of the approval process would be a review of the disposal requirements. Any radioactive wastes would be deactivated biologically (through the process described in Section 2.2.8.2 – Biological Waste) prior to treatment as a radioactive waste. Short-lived radioactive wastes would be held in the laboratory until complete decay of the isotope. Long-lived radioactive wastes would require disposal off-site. For further information on biological and radioactive waste, see Section 2.2.8.2 of the FEIS.
- 35.14 The air quality analysis in Appendix 10 of the SDEIS was performed to predict the cumulative effects of the proposed Boston-NBL and other nearby proposed and existing air pollutant sources in Boston. Besides the proposed Boston-NBL, other modeled laboratory sources

- 35.11 biosafety level-4 organism would lead to a major public health disaster.¹¹ We note that while the SDEIS explains that the BSL-4 lab needs to be in Boston due to needs for collaboration discounts, the majority of the laboratories listed are located outside of Boston and over half (63%) of the new 660 person workforce are expected to live outside of Boston.
- 35.12 The SDEIS (page 2-44) states that separating the BSL-4 facilities from the other laboratories would result in inefficiencies of capital expenditures and labor. Throughout the safety section, the isolation of the BSL-4 from the general laboratories is underscored. The SDEIS does not evaluate the benefits of physical isolation of the BSL-4 since actual site isolation emphasizes the need for enhanced laboratory safety procedures to personnel entering the BSL-4 area.
- 35.13 With respect to waste disposal in the BSL-4, the description of disposal of radioactive waste doesn't take into account that the radioactive waste might be from the BSL-4 area; therefore, the process of decontaminating biological BSL-4 waste must be done prior to the procedures for disposal of radioactive waste. We recommend that the NIH and NEIDL incorporate this decontamination into the radioactive material disposal protocols.
- 35.14 EPA requested an analysis of the cumulative effect of the laboratory along with others in the area, not just a reference to information on file. The cumulative exposure analysis in the SDEIS states that the NEIDL VOC emissions were assumed to be below 2,000 lbs. The cumulative analysis used the estimated emissions of 2,000 lbs for the surrounding laboratories. Please provide the stack testing information or calculations of usage to verify the estimated VOC emissions for the proposed laboratory as well as the operating laboratories.
- 35.15 Appendix 10 (page 18) states "none of the extremely low air concentrations of particulate matter or VOC compounds...would aggravate asthma in persons living near the site." We question the rationale for this conclusion as individuals exhibit a broad range of responses to pollutants. Also, please check footnote 11 since there is no EPA statement on the FAQ page referenced that viral infections are the leading cause of acute asthma attacks.
- 35.16 The listing of the 21 members of the Biosafety Laboratory Advisory Group requested in our comments on the DEIS was not provided in the SDEIS. We recommend that the FEIS include it.
- 35.17 Key project documents, including the SDEIS were stated on p.1-17 to be made available for download electronically at www.bostonbiosafety.com. When the website was

¹¹January 9, 2003 letter from Paul A. Marshall, Freedom of Information Coordinator, NIAID, to James Miller, President, Friends of the Bitterroot.

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included the existing Evans Research Building and the proposed BioSquare Buildings E and G. Boston University performed a study of the emissions from its wet chemistry laboratory on the Charles River Campus, which would have higher VOC emissions than a biological laboratory such as the proposed Boston-NBL. Estimated annual VOC emissions from the Charles River Campus laboratory were less than 1,000 pounds of VOC per year, as most of the chemicals are either used in reactions or disposed of. Therefore, the assumption that the Boston-NBL, the Evans Research Building, and the other two proposed laboratories at the BioSquare facility will have emissions of 2,000 pounds of each VOC per year is a very conservative approach. Nevertheless, the maximum predicted cumulative VOC impacts are safely in compliance with the Massachusetts DEP air toxics TEL and AALs and show that the Boston-NBL will not have an adverse health effect on the community.

- 35.15 The results of the air quality analysis showed maximum predicted cumulative concentrations of particulate matter (PM10 and PM2.5) that are safely in compliance with the NAAQS, and cumulative VOC concentration safely in compliance with Massachusetts DEP 24-hour average Threshold Exposure Limits (TELs) and annual average Allowable Ambient Limits (AALs) for air toxics. The NAAQS were designed to protect the most sensitive members of the population from adverse health effects, with a margin for safety. The NAAQS for particulates were designed to include protection from increased respiratory symptoms for persons with asthma. Similarly, the Massachusetts DEP TEL and AAL criteria are health-based standards established by the DEP to protect all individuals from adverse health effects, including asthma, with a margin for safety. Footnote 11 on page 18 of Appendix 10 of the SDEIS should read as: <http://env1.kangwon.ac.kr/project/sdwr2004/litsurv/intwebsites/epa-ost/www.epa.gov/asthma/introduction.html>. This reference clearly states that "Viral infections are the leading cause of acute asthma attacks."

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35.16 Membership of community advisory groups can be obtained from the BUMC Office of Community Relations.

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LETTER 35

U.S. Environmental Protection Agency

35.17 Due to technical issues, the SDEIS was not available on the web for download. However, the document was made available for review in a timely and public manner. Copies of the SDEIS were placed at the Boston, South End, Dorchester and Roxbury branches of the Boston Public Library. In addition, paper and/or electronic copies of the SDEIS were mailed to nearly 100 individuals who either provided public comment on the DEIS or requested a copy. See Distribution List prior to Appendices.

35.18 NIH believes that the EPA's National Ambient Air Quality Standards (NAAQS) are sufficient to protect human health and therefore, further mitigation is not necessary. In most cases, the emissions would be well below the standards. There is a commitment to reduce construction vehicle emissions as well. See Responses to Comments 35.1 and 35.14.

35.17

searched using the wording "Draft Environmental Impact Statement" on April 19 and May 6, the only item that was available was a press release on NIH's decision to provide a supplemental statement. On April 25, the day of the public meeting on the Supplemental Statement, the website was not accessible. No copies of comments on the DEIS were posted on the website or provided to the public and to other commentors. We encourage the NIH to strengthen public outreach efforts by providing access to comments and reports on the project at the project website in a timely manner.

Environmental Justice

35.18

The SDEIS notes "some of the communities located in the Environmental Justice study area, including the South End, Roxbury and Dorchester are neighborhoods with high rates of asthma morbidity" (Section 3.4, 3-22). Although the SDEIS notes that modeled impacts from significant emissions sources associated with the project do not exceed the NAAQS, we continue to believe that action is necessary to mitigate for air quality impacts from diesel emissions to at-risk populations in the surrounding communities from construction and operation of the facility. We recommend that construction vehicles associated with this project be equipped with diesel oxidation catalysts, and/or use cleaner diesel fuel such as low sulfur diesel (highway diesel fuel) to reduce fine particle emissions (see construction management plan comments above). EPA recommends these measures to address the potential cumulative health effects from preexisting health conditions (e.g., asthma) and to ensure that an increased or disproportionate burden is not placed on members of the surrounding communities.

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Summary of Rating Definitions and Follow-up Action

Environmental Impact of the Action

LO--Lack of Objections

The EPA review has not identified any potential environmental impacts requiring substantive changes to the proposal. The review may have disclosed opportunities for application of mitigation measures that could be accomplished with no more than minor changes to the proposal.

EC--Environmental Concerns

The EPA review has identified environmental impacts that should be avoided in order to fully protect the environment. Corrective measures may require changes to the preferred alternative or application of mitigation measures that can reduce the environmental impact. EPA would like to work with the lead agency to reduce these impacts.

EO--Environmental Objections

The EPA review has identified significant environmental impacts that must be avoided in order to provide adequate protection for the environment. Corrective measures may require substantial changes to the preferred alternative or consideration of some other project alternative (including the no action alternative or a new alternative). EPA intends to work with the lead agency to reduce these impacts.

EU--Environmentally Unsatisfactory

The EPA review has identified adverse environmental impacts that are of sufficient magnitude that they are unsatisfactory from the standpoint of public health or welfare or environmental quality. EPA intends to work with the lead agency to reduce these impacts. If the potentially unsatisfactory impacts are not corrected at the final EIS stage, this proposal will be recommended for referral to the CEQ.

Adequacy of the Impact Statement

Category 1--Adequate

EPA believes the draft EIS adequately sets forth the environmental impact(s) of the preferred alternative and those of the alternatives reasonably available to the project or action. No further analysis or data collection is necessary, but the reviewer may suggest the addition of clarifying language or information.

Category 2--Insufficient Information

The draft EIS does not contain sufficient information for EPA to fully assess environmental impacts that should be avoided in order to fully protect the environment, or the EPA reviewer has identified new reasonably available alternatives that are within the spectrum of alternatives analyzed in the draft EIS, which could reduce the environmental impacts of the action. The identified additional information, data, analyses, or discussion should be included in the final EIS.

Category 3--Inadequate

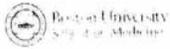
EPA does not believe that the draft EIS adequately assesses potentially significant environmental impacts of the action, or the EPA reviewer has identified new, reasonably available alternatives that are outside of the spectrum of alternatives analyzed in the draft EIS, which should be analyzed in order to reduce the potentially significant environmental impacts. EPA believes that the identified additional information, data, analyses, or discussions are of such a magnitude that they should have full public review at a draft stage. EPA does not believe that the draft EIS is adequate for the purposes of the NEPA and/or Section 309 review, and thus should be formally revised and made available for public comment in a supplemental or revised draft EIS. On the basis of the potential significant impacts involved, this proposal could be a candidate for referral to the CEQ.

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U.S. Environmental Protection Agency

B O S T O N U N I V E R S I T Y M E D I C A L C E N T E R



Cancer Research
Center

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Douglas V. Faller, Ph.D., M.D.
Director

Faculty Development
Professor of Cancer Research

Professor of Medicine

Vice Chairman,
Department of Medicine

Professor of
Biotechnology, Microbiology,
Pediatrics and Pathology
and Laboratory Medicine

May 3, 2005

Ms. Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious
Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

The Boston University Cancer Research Center is writing to express support for the
National Emerging Infectious Diseases Laboratories at Boston University Medical Center
(BUMC). There is an urgent need in this country to create facilities to conduct research
aimed at finding causes, diagnoses and therapeutics for the alarming number of recently
emerging and re-emerging infectious diseases.

Our organization would like to comment on two very important issues raised in the
document - the appropriateness of the proposed location of the facility and the safety of
the proposed Biosafety Level 4 laboratory.

As discussed in the document, prior to making a determination to site the proposed
NEIDL facility at the BioSquare Research Park, Boston University undertook an
alternatives siting analysis that evaluated existing sites under its control to determine the
best location for the facility. The study concluded, and our organization agrees, that the
best location for this facility is exactly where it is proposed in the BioSquare Research
Park in the City of Boston, MA. BioSquare Research Park is a state of the art medical
research park which contains medical research facilities including Biosafety Level 1, 2
and 3 laboratories that the proposed facility will be able to take advantage of. BioSquare
Research Park is also located directly across the street from the Boston University
Medical Center campus which also houses hospital and medical research facilities and is
the largest Level 1 Trauma Center in New England.

We understand that some community members feel that such a facility should be located
in a more rural location. We feel strongly that the facility should be located in an urban
area which functions as a hub for medical research activities and which has a significant
base of resident medical research scientists. Siting the facility in this manner assures that
efficiencies are reached in terms of the ability to share research facilities and knowledge
through direct collaboration among the various institutions located in the greater Boston
area.

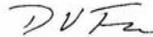
LETTER 36

Douglas V. Faller, Ph.D., M.D.

In regards to concerns regarding the safety of the proposed facility and in particular, the Biosafety Level 4 laboratory, our organization has no question that the facility will be safe. There are several federal and state programs which require the facility to be constructed and operated at extremely high safety standards. Similar laboratories throughout the United States have operated safely for decades.

In closing, we urge you to proceed with the funding to construct this much needed national resource at the BioSquare Research Park in Boston.

Sincerely,



Douglas V. Faller, Ph.D., M.D.
Director, Cancer Research Center

LETTER 36

Douglas V. Faller, Ph.D., M.D.

Valerie Nottingham
NIHB13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Dear Ms. Nottingham,

As a resident of the Greater Boston community, I do not believe that the supplemental environmental impact statement (SDEIS) concerning Boston University's proposed biolab seriously addresses my concerns. It was not prepared by an organization independent of Boston University, which renders it irretrievably flawed. It correctly states that the area surrounding this lab faces a "growing challenge of housing affordability," but nowhere does it give a hint as to how such a lab would do other than exacerbate this problem by taking up valuable space. In addition, it gives precious little reassurance to those who DO live in the area that a realistic worst case scenario has been imagined or dealt with in any serious fashion.

It would, of course, be impossible to guarantee immunity to human error in such a project. Human error is inevitable (check out the news on the Big Dig), but when the consequences include possible exposure to deadly, incurable pathogens (e.g., Ebola, anthrax, hemorrhagic fever, plague) any risk is unacceptable.

It is now time to Just Say No.

Sincerely,


The Rev. Dr. Norman Farranelli
28 Harris St.
Waltham, MA 02452

LETTER 37

Norman Farranelli

37.1 See Response to Comment 1.1.

37.2 See Response to Comment 1.2.

37.3 See Response to Comment 1.3.

37.4 See Response to Comment 1.4.

Robina E. Folland
9 Perry Street
Brookline, Massachusetts 02445

May 18, 2005

Valerie Nottingham
Division of Environmental Protection
The National Institutes of Health
B13, 2W64
9000 Rockville Pike
Bethesda, Maryland 20892

Re: Boston University National Emerging Infectious Diseases Laboratory
UC6 AI058618

Dear Ms. Nottingham,

Once again, I am writing in support of Boston University Medical Center's National Emerging Infectious Diseases Laboratory project.

It is my understanding that project opponents felt that alternative laboratory sites were not sufficiently described in the original Environmental Impact Statement and that a less densely populated site should have been chosen for safety reasons. Although Boston University does own land in more rural areas, Tyngsborough, Massachusetts and Peterborough, New Hampshire, neither of these sites offers the proximity to the resources and infrastructure of the greater Boston scientific community or easy access to public transportation. Locating the Laboratory in Biosquare, the BU Medical Center Research Park solves both the infrastructure and transportation problem.

Boston University has made every effort to address community safety and environmental issue in its environmental impact statement documents. As part of its commitment to the local community, Boston University is providing one million dollars in scholarship aid for local residents to attend its CitiLab program to retrain for a research career. Many inner city residents who will avail themselves of this educational opportunity do not own an automobile and rely on public transportation.

Infectious Disease research is of vital importance for all of us and I continue to support Boston University Medical Center and its efforts to make this laboratory a reality.

Sincerely,


Robina E. Folland

LETTER 38

Robina E. Folland

9 Clinton Path Apt 1
Brookline MA 024445-4207
May 1, 2005

Valerie Nottingham
NIHB13/2W64
9000 Rockville Pike
Bethesda MD 20892

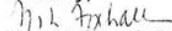
Dear Ms. Nottingham:

As a resident of the Greater Boston community, I do not believe that the Supplemental Environmental Impact Statement (SDEIS) concerning Boston University's proposed biolab seriously addresses my concerns. It was not prepared by an organization independent of Boston University, which renders it irretrievably flawed. It correctly states that the area surrounding this lab faces a "growing challenge of housing affordability," but nowhere else does it give a hint as to what such a lab would do other than to exacerbate this problem by taking up valuable space. In addition, it gives precious little reassurance to those who now live in the area that a realistic worst case scenario has been imagined or dealt with in any serious fashion.

It would, of course, be impossible to guarantee immunity to human error in such a project. Human error is inevitable (check out the news on the Big Dig), but when the consequences include possible exposure to deadly pathogens (e.g., ebola, anthrax, hemorrhagic fever, plague) any risk is unacceptable.

It is time to Just Say No.

Sincerely,


Mary Linda Foxhall

CC:

Senator Ted Kennedy
Senator John Kerry
Congressman Barney Frank
Representative Frank Smizik
Senator Cynthia Creem

LETTER 39

Mary Linda Foxhall

- 39.1 See Response to Comment 1.1.
- 39.2 See Response to Comment 1.2.
- 39.3 See Response to Comment 1.3.
- 39.4 See Response to Comment 1.4.

B O S T O N U N I V E R S I T Y M E D I C A L C E N T E R
100 EAST NEWTON STREET BOSTON, MASSACHUSETTS 02118-3008 TEL: 617-638-4780 FAX: 617-638-4490



Boston University
Goldman School of
Dental Medicine

Office of the Dean

100 East Newton Street
Boston, Massachusetts 02118-3008
617-638-4780 Tel
617-638-4490 Fax

May 3, 2005

Ms. Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

As Dean of the Boston University School of Dental Medicine, I am writing to express support for the National Emerging Infectious Diseases Laboratories at Boston University Medical Center (BUMC). There is an urgent need in this country to create facilities to conduct research aimed at finding causes, diagnoses and therapeutics for the alarming number of recently emerging and re-emerging infectious diseases.

Our organization would like to comment on two very important issues raised in the document - the appropriateness of the proposed location of the facility and the safety of the proposed Biosafety Level 4 laboratory.

As discussed in the document, prior to making a determination to site the proposed NEIDL facility at the BioSquare Research Park, Boston University undertook an alternatives siting analysis that evaluated existing sites under its control to determine the best location for the facility. The study concluded, and our organization agrees, that the best location for this facility is exactly where it is proposed in the BioSquare Research Park in the City of Boston, MA. BioSquare Research Park is a state of the art medical research park which contains medical research facilities including Biosafety Level 1, 2 and 3 laboratories that the proposed facility will be able to take advantage of. BioSquare Research Park is also located directly across the street from the Boston University Medical Center campus which also houses hospital and medical research facilities and is the largest Level 1 Trauma Center in New England.

We understand that some community members feel that such a facility should be located in a more rural location. We feel strongly that the facility should be located in an urban area which functions as a hub for medical research activities and which has a significant

LETTER 40

Spencer N. Frankl, D.D.S., M.S.D

Page 2

base of resident medical research scientists. Siting the facility in this manner assures that efficiencies are reached in terms in the ability to share research facilities and knowledge through direct collaboration among the various institutions located in the greater Boston area.

In regards to concerns regarding the safety of the proposed facility and in particular, the Biosafety Level 4 laboratory, our organization has no question that the facility will be safe. There are several federal and state programs which require the facility to be constructed and operated at extremely high safety standards. Similar laboratories throughout the United States have operated safely for decades.

In closing, we urge you to proceed with the funding to construct this much needed national resource at the BioSquare Research Park in Boston.

Sincerely,



Spencer N. Frankl, D.D.S., M.S.D.
Professor and Dean

LETTER 40

Spencer N. Frankl, D.D.S., M.S.D



Boston University
School of Medicine

Doctors Office Building, Suite 1107
720 Harrison Avenue
Boston, MA 02118-2903
Tel: 617 638 7580
Fax: 617 638 8858

Ms. Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)

Medical Information
Systems Unit

Dear Ms. Nottingham:

ROBERT H. FRIEDMAN, MD
Chief

This letter is in support of the Biosafety Lab also known as the National Emerging Infectious Diseases Laboratory (NEIDL) proposed at Boston University Medical Center (BUMC).

Boston Medical Center

Professor of Medicine
and Public Health
Boston University School of Medicine

I am a senior faculty member at BUMC whose research is unrelated to NEIDL. Nonetheless, I am someone who would be adversely affected by an accident of the type that has been raised by some people. Yet I am not concerned about this risks because I consider them non-existent. I believe that the NEIDL will be an extremely safe laboratory. I am familiar enough with the design of the laboratory and its planned operations to be impressed by the building's safety and security features and by the team BUMC has assembled to build and operate this important laboratory.

TIMOTHY DICKMORRIS, PhD
Assistant Professor of Medicine
Boston University School of Medicine

I strongly feel that the facility should be located in an urban area like BUMC which functions as a center for medical research and training. Siting the facility in the heart of Boston facilitates collaboration among scientists at our many universities and research laboratories.

RAMESH FARZANFAR, PhD
Assistant Professor of Medicine
Boston University School of Medicine

This laboratory will be an important project for the Boston research community and beyond. There is an urgent need in this country to create facilities to conduct research aimed at finding causes, diagnoses and therapeutics for the alarming number of recently emerging and re-emerging infectious diseases. And this is a matter I am concerned about.

JEFFREY MIGNI-SH I, PhD
Assistant Professor of Medicine
Boston University School of Medicine

Sincerely,


Robert H. Friedman, MD

LETTER 41

Robert H. Friedman, MD

Nottingham, Valerie (NIH/OD/ORF)

From: G Gallagher [ggalla@bu.edu]
Sent: Monday, May 02, 2005 4:14 PM
To: NIH NEPA Comments
Cc: Klempner@bu.edu
Subject: NEIDLsupport

Ms. Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab also known as the National Emerging Infectious Diseases Laboratory (NEIDL) proposed at Boston University Medical Center (BUMC).

As you are aware, biomedical research laboratories operate under strict procedures and protocols at BUMC and at other academic and private laboratories throughout the Greater Boston region. This research is done safely and makes important medical contributions to the nation and the world.

I believe that the NEIDL at BUMC will be one of the safest laboratories in the world. I have been briefed on the systems and the design and am familiar with operations in biomedical research laboratories. I am impressed by the building's safety and security features and by the team BUMC has assembled to build this important project.

I should also note that there are some who have incorrectly raised the city of Boston's rDNA regulations, as a reason the laboratory should not be built. This is simply misinformation. rDNA research is conducted in Boston under the Boston Public Health Commission's regulations. On numerous occasions, BUMC authorities have stated that they will do all research in compliance with the Health Commission's guidelines.

This laboratory will be an important project for the research community and those interested in finding cures for emerging infectious diseases and I fully support it.

Sincerely,

George T. Gallagher, D.M.D., D.M.Sc.
Professor of Oral and Maxillofacial Pathology
Department of Oral Diagnostic Sciences and Patient Services
Boston University Goldman School of Dental Medicine
100 East Newton Street, Rm. G-04
Boston, MA 02118-2392

LETTER 42

George T. Gallagher, D.M.D., D.M.Sc.

BUEngineering

Boston University
Biomedical Engineering
44 Cummington St
Boston, MA 02215

Ms. Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Supplemental Draft Environmental Impact Statement-National Emerging Infectious Diseases Laboratories (NEIDL)

Dear Ms. Nottingham:

I am writing to express support for the National Emerging Infectious Diseases Laboratories at Boston University Medical Center (BUMC). There is an urgent need in this country to create facilities to conduct research aimed at finding causes, diagnoses and therapeutics for the alarming number of recently emerging and re-emerging infectious diseases.

Our organization would like to comment on two very important issues raised in the document - the appropriateness of the proposed location of the facility and the safety of the proposed Biosafety Level 4 laboratory.

As discussed in the document, prior to making a determination to site the proposed NEIDL facility at the BioSquare Research Park, Boston University undertook an alternatives siting analysis that evaluated existing sites under its control to determine the best location for the facility. The study concluded, and our organization agrees, that the best location for this facility is exactly where it is proposed in the BioSquare Research Park in the City of Boston, MA. BioSquare Research Park is a state of the art medical research park which contains medical research facilities including Biosafety Level 1, 2 and 3 laboratories that the proposed facility will be able to take advantage of. BioSquare Research Park is also located directly across the street from the Boston University Medical Center campus which also houses hospital and medical research facilities and is the largest Level 1 Trauma Center in New England.

We understand that some community members feel that such a facility should be located in a more rural location. We feel strongly that the facility should be located in an urban area which functions as a hub for medical research activities and which has a significant base of resident medical research scientists. Siting the facility in this manner assures that efficiencies are reached in terms in the ability to share research facilities and knowledge through direct collaboration among the various institutions located in the greater Boston area.

In regards to concerns regarding the safety of the proposed facility and in particular, the Biosafety Level 4 laboratory, our organization has no question that the facility will be safe. There are several federal and state programs which require the facility to be

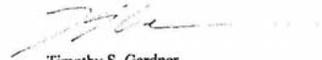
LETTER 43

Timothy S. Gardner

constructed and operated at extremely high safety standards. Similar laboratories throughout the United States have operated safely for decades.

In closing, we urge you to proceed with the funding to construct this much needed national resource at the BioSquare Research Park in Boston.

Sincerely,



Timothy S. Gardner
Assistant Professor
tgardner@bu.edu
Ph: 617-358-0745

LETTER 43

Timothy S. Gardner

Valerie Nottingham
NIHB13/2W64
9000 Rockville Pike
Bethesda, MD 20892

April 25, 2005

Dear Ms. Nottingham,

44.1

As a resident of the Greater Boston community, I do not believe that the supplemental environmental impact statement (SDEIS) concerning Boston University's proposed biolab seriously addresses my concerns. It was not prepared by an organization independent of Boston University, which renders it irretrievably flawed. It correctly states that the area surrounding this lab faces a "growing challenge of housing affordability," but nowhere does it give a hint as to how such a lab would do other than exacerbate this problem by taking up valuable space. In addition, it gives precious little reassurance to those who DO live in the area that a realistic worst case scenario has been imagined or dealt with in any serious fashion.

44.2

44.3

44.4

It would, of course, be impossible to guarantee immunity to human error in such a project. Human error is inevitable (check out the news on the Big Dig), but when the consequences include possible exposure to deadly, incurable pathogens (e.g., Ebola, anthrax, hemorrhagic fever, plague) any risk is unacceptable.

It is now time to Just Say No.

Sincerely,

Elizabeth B. Gealach, M.Ed., BU SED 1976
10 Manchester Rd.
Newton MA 02461

LETTER 44

Elizabeth G. B. Gealach

44.1 See Response to Comment 1.1.

44.2 See Response to Comment 1.2.

44.3 See Response to Comment 1.3.

44.4 See Response to Comment 1.4.

LETTER 45

Barbara A. Gilchrest, M.D.

Nottingham, Valerie (NIH/OD/ORF)

From: Barbara A. Gilchrest, M.D. [bgilchre@bu.edu]
Sent: Wednesday, May 04, 2005 11:50 AM
To: NIH NEPA Comments
Subject: BU National Emerging Infectious Diseases Laboratory

5/4/05

To: Ms. Valerie Nottingham

Dear Ms. Nottingham:

I was unable to attend the April 25 public hearing to obtain further input regarding the above from the Boston community. At this time, however, as a department chair and senior member of the Boston University School of Medicine faculty, as well as immediate neighbor to the intended new Laboratory, I wish to offer my strongest support for this project. I believe there is an urgent need to create facilities to conduct research aimed at understanding, diagnosing and treating the alarming number of emerging and re-emerging infectious diseases in the world, including in the United States.

I would like to comment on two important issues raised in the Supplemental Draft Environmental Impact Statement: the appropriateness and safety of the facility.

As a researcher who is very familiar with laboratory procedures generally and those at BU particularly, I believe the potential for good far far outweighs any conceivable risk of having this facility on the BU Medical Center's urban campus. Federal and state standards will require the facility to be constructed and operated at extremely high safety standards. The comparable laboratories already operating throughout the United States have a superb safety record. Moreover, there is an enormous need to study emerging infectious diseases. The proposed Laboratory will benefit not only the Boston research community, but the Boston and American populations at large.

In conclusion, I strongly urge that the proposed construction of the National Emerging Infectious Disease Laboratories be allowed to continue as planned.

Sincerely yours,

Barbara A. Gilchrest, M.D.

Department of Dermatology
609 Albany Street - J507
Boston, MA 02118
Tel: 617-638-5538
Fax: 617-638-5550

May 17, 2005

Valerie Nottingham
NIH B13/2W64
9000 Rockville Pike
Bethesda MD 20892

Re: Supplemental Draft Environmental Impact Statement
National Emerging Infectious Diseases Laboratories
Boston, Massachusetts

Dear Ms. Nottingham,

Reading the Supplemental Draft Environmental Impact Statement for the National Emerging Infectious Diseases Lab in Boston I was struck by the tone of the writing. The message voiced over and again is that the risk to our community by having this Lab in our midst is minimal. Nowhere in the SDEIS do I hear a healthy respect for the unexpected. My experience in life has trained me to look for the weakest link in the chain as the source of all boondoggles. It is the attitude that "We have it all covered" that I find the most disturbing in the SDEIS.

I find the worst case scenario, an anthrax spill, offered in the SDEIS unimaginative. I would look for a tragedy to come from the transportation of deadly pathogens to the Lab. In Appendix 2, Table 3, Page 2-13, the reservoir for Congo-Crimean hemorrhagic fever is "Hares, birds and Hyalomma ticks. Domestic animals may serve as hosts...". This disease is transmitted by the bite of an infected adult tick. Suppose a Fedex truck delivering the pathogens and/or ticks carrying the disease is held hostage by a terrorist or other nut. The attention this draws from passers-by causes a severe traffic jam like the one experienced in Boston February 1, 2005. (See Boston Globe article enclosed.) In the commotion the deadly package is damaged and chaos reigns. Who is to say neighborhood cats, dogs, birds or insects may not inadvertently become contaminated?

Suppose that the Fedex or UPS truck is involved in a traffic accident. The traffic jam of February 1, 2005 demonstrated the extent of gridlock possible in this area of Boston. "I would like to think it's a fluke," said Tom Tinlin, deputy commissioner of the Boston Transportation Department. Tinlin said agencies did not tell one another quickly enough about problems such as traffic signal malfunctions and backups on feeder roads leading to Interstate 93. No agency, however, accepted blame yesterday, and no one apologized to commuters." (Boston Globe 2/3/05 Page A1 Metro Section.) This traffic jam is a clear case of human nature at work.

I would anticipate that tragedies involving the Level-4 Biolab in Boston would be the result of human error. Section 4.7.1 regarding air quality states that "Valves, fittings, and

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Patricia Glynn

- 46.1 In the evaluation of potential scenarios, the agent, its quantity, form and dissemination potential are all considered. The worst case scenario was chosen as it presented a culmination of these factors. Removing or limiting any of these factors reduces the impacts of potential scenarios. In the event of a vehicular accident, the quantity and dissemination potential are extremely limited. BUMC will manage all transportation related issues to minimize risk as described in Appendix 7, High Hazard Material Management Policy. Scenarios involving transportation do not disseminate materials with the type of risk potential presented in the worst case scenario.
- 46.2 BUMC, as evidenced in Appendix 7, High Hazard Material Management Policy, has plans in place to address risk associated with the transportation of materials. While these plans do not specifically address traffic accidents or traffic jams, they do address the ability to track, the ability to communicate and the ability to respond to such incidents as necessary. Packaging requirements will be in place as required by law and there have been no known environmental releases when the proper shipping procedures have been followed.
- 46.3 The reference is to the maintenance and operational protocols that would be incorporated into this facility, in regard to periodic visual inspection of trained maintenance personnel. The overall program to be implemented in the facility would be a comprehensive system of inspections and planned preventative maintenance. The operational effort would be centered on identifying potential issues prior to component failures.

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- 46.4 As noted throughout the FEIS, the project is being designed and constructed with redundant utility and mechanical systems to avoid system failure. The effluent decontamination system is operated by an active control system. The operational parameters required to maintain efficacy would be continuously monitored. The variation of any of these parameters outside of tolerances would cause the system to restart the entire cycle. That being stated, the system would be validated through thermal means only. In actual operations, the decontamination system would be operationally a secondary process. The primary decontamination would occur at the laboratory level. Any agent being disposed of through the system would first be exposed to chemical disinfection. An aqueous based chemical disinfection would be used for inactivation of agent prior to disposal, and similarly the facility and APR suits would be cleansed with an aqueous disinfection agent.
- 46.5 The Director of Operations and Public Safety at Boston University Medical Center would be responsible for coordination with local, state, and federal law enforcement agencies

46.3

tubing for any gaseous chemicals would be checked for leaks periodically." There is margin for error here.

46.4

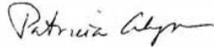
Section 4.8.1.1 regarding waster water states that the building would "feature a sterilization system designed to use heat sterilization to kill and biological agents..." What if the heat system fails? What if it is not discovered until contaminated wastewater is discharged into the sewer system? I want this system explained further and I want to be convinced that it is failure-proof.

46.5

Appendix 5: Boston -NBL Security Program and Emergency Response is so general that it is obvious it has not been thoroughly thought-through. It is frightening. "The BUMC Public Safety Staff is supported by the Boston University Police Department's fifty-five sworn police officers. Within these two operations there is ongoing coordination related to technology by systems experts, investigations by trained and experienced investigators and *joint coordination with local, state and federal law enforcement agencies.*" **Who is in charge?** Is there going to be finger-pointing for blame here too? The Perimeter Vehicular entry/exit point and the Loading Dock will be staffed only 12 hours a day during the business week and monitored by closed circuit television over the weekend. That is horrifying! This facility should be completely patrolled 24 hours a day 7 days a week. This is a weak link in the chain!

I am convinced that this facility should not be sited in such a densely populated area.

Sincerely,



Patricia Glynn
6 Fort Ave. Terr.
Roxbury MA 02119

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TAKING DETOUR THROUGH FRUSTRATION

Author: By Mac Daniel, Globe Staff

Date: 02/02/2005 Page: B1 Section: Metro/Region

Globe correspondent Emma Stickgold contributed to this report. Thousands of motorists spent hours in *traffic* in and around Boston yesterday, some crawling barely 15 feet a minute for much of the afternoon. Hospitals, especially Massachusetts General Hospital, dealt with delayed ambulances, and doctors and nurses worked hours into extra shifts until co-workers arrived. Parents picked up their children late from school.

"It's hell," Ryan McManus, 32, of Hingham, said as he waited at a stoplight just past Boston Medical Center, with only 15 minutes to get to his child's day-care center in Braintree.

While there was no single reason for the gridlock, one apparent trigger was a Massachusetts Highway Department crew patching potholes along the Southeast Expressway. The crew worked from about 10 a.m. to 2 p.m. in the left southbound lane in spots between Dorchester and Braintree.

Even after city transportation officials ordered the crew off the highway, *traffic* snarled throughout the city, resulting in what *traffic* watchers say was one of the worst commutes in recent memory.

To escape the gridlock, drivers clogged city streets, Storrow Drive, and the Leverett Connector, said Tom Tinlin, deputy commissioner of the Boston Transportation Department.

The tie-ups were compounded by another work crew filling potholes on the Longfellow Bridge, combined with construction around Charles Circle. The recent closure of an onramp to Interstate 93 south from the Massachusetts Avenue connector and a new and often clogged merge to I-93 south in front of the South Bay Shopping Center also worsened congestion.

"Volumes were so huge that surface streets quickly got mired," Tinlin said.

State, city, MBTA, and Massachusetts Turnpike officials plan an emergency meeting today to discuss what went wrong.

The situation clearly frustrated commuters. Lines of cars stretched 5 miles in

April 28, 2006

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*
This article is
about human
nature and the very
real potential for
disaster from
unexpected traffic
congestion in
the neighborhood
of the Lab.

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and out of the city, largely along I-93 and nearby feeder roads. Drivers reported that trips from Cambridge to Dorchester took two hours. Jamaica Plain to Dorchester was an hour.

Cars snaked down Melnea Cass Boulevard in Roxbury on a one-hour drive to the Southeast Expressway that normally would take 10 minutes. Along Massachusetts Avenue, fed-up motorists made sudden U-turns or darted down side streets.

It got so bad late yesterday afternoon on I-93 south that State Police closed Exit 15 (Columbia Road/JFK-UMass) as a safety precaution as frustrated drivers sought shortcuts wherever they could. Cars on the exit ramp were backing up into the highway. Problems persisted for southbound cars into the night.

Jon Carlisle, spokesman for the Massachusetts Highway Department, denied that the pothole crew created the jam and instead blamed other agencies and problems with *traffic* signals.

"We talked to a member of the crew on the ground who told us there weren't any backups behind them," he said. "The issues were associated with *traffic*-signal timing on local roadways and the [Massachusetts] Turnpike funneling *traffic* onto Frontage Road. There were no backups behind our pothole crews."

But Tinlin said the MassHighway crew started the jam, saying he based that conclusion on his review of video feeds of city streets and the I-93 corridor and reports from Boston police.

"What we're focused on right now is not who is at fault, but how to fix it," he said.

Jeff Larson, general manager of SmartRoutes, which monitors *traffic*, said there is probably no one to blame. More drivers returned to the roads yesterday after a week of bad weather and frigid temperatures, he said.

"Whenever you get into a situation where you have this much volume, *traffic* signals don't matter that much," he said.

"All the time I was on the road, there was no police officer, no sign of response," he said. "It was beyond frustrating. It all stopped and fell apart."

Mac Daniel can be reached at mdaniel@globe.com.

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Patricia Glynn

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April 26, 2005

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WORDS OF BLAME AND RESOLVE AFTER GRIDLOCK

Author: By Mac Daniel, Globe Staff Date: 02/03/2005
Page: A1 Section: Metro/Region

After an emergency meeting about Tuesday's massive gridlock in Boston, state and local officials said yesterday they will keep using daytime pothole crews, despite the problems and public anger they generated, and went as far as to blame drivers for helping cause the mess.

Transportation officials pledged to prevent a repeat of the worst congestion in recent memory by starting hourly communication between agencies, closely monitoring six trouble spots, and stationing more police officers at those choke points.

They said Tuesday's jams, which stranded thousands of commuters for hours on local roads, resulted from a number of factors.

The causes included more cars returning to the roads with better weather, a midday pothole crew on the Southeast Expressway, the tedious merge of four lanes into one from Frontage Road to the expressway, roads narrowed by snowbanks, and a key *traffic* light malfunction. The problems rippled across much of South Boston and Dorchester.

"I would like to think it's a fluke," said Tom Tinlin, deputy commissioner of the Boston Transportation Department.

Tinlin said agencies did not tell one another quickly enough about problems such as *traffic* signal malfunctions and backups on feeder roads leading to Interstate 93. No agency, however, accepted blame yesterday, and no one apologized to commuters.

"We had a great meeting with these folks," said Tinlin, who 12 hours prior was blaming a Massachusetts Highway Department pothole crew for triggering the gridlock. "It was . . . about teamwork, moving forward, and making sure that this doesn't happen again." for the predicted *traffic* nightmare surrounding last summer's Democratic National Convention, a weeklong jam that never materialized.

The hourly communication between agencies during commuting hours will enable them to spot problems quicker and dispatch police to try to fix them, officials said.

<http://register.bostonglobe.com/archives2/cgi-bin/archives.cgi?DBLIST=bg05&DOCNUM...> 4/26/2005

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Patricia Glynn

Despite the promises of stricter *traffic* management and better communication, problems continued on the Mass. Pike yesterday morning, as a bridge-inspection crew set up east of the Prudential Tunnel around 9:30, closing the eastbound left lane and backing up *traffic*.

"Turnpike policy is to not do *traffic* setups earlier than 9:30 a.m., and we don't do them if there is existing *traffic* [congestion] on the roadway," Doug Hanchett, spokesman for the Turnpike Authority, wrote in an e-mail. "While we are not aware of any *traffic* problems associated with this morning's setup, we apologize for any inconvenience it may have caused."

Tinlin said city, state, and Turnpike Authority crews would continue to repair potholes during the day.

"If folks are out there repairing potholes, they're doing so because that is also a public safety issue," Tinlin said. "Frankly, if somebody had been hurt or injured, or a car crashed because they hit a pothole, some folks out there would have been saying that people should have been doing more."

MassHighway spokesman Jon Carlisle said pothole repairs at night are less safe and more complicated because the rolling crews have more difficulty spotting the cracks. He said daytime work doesn't cause problems if crews watch for backups.

"If you do it responsibly, you shouldn't have significant impacts on *traffic*," he said.

Carlisle denied that the MassHighway paving crew played any role in the backups.

He said that the crew members never saw any backup behind them as they worked on both sides of Interstate 93 yesterday from 10 a.m. to 2 p.m. between Dorchester and Braintree.

Officials said some drivers, including many using unfamiliar roads to escape the gridlock, worsened the situation by blocking intersections, making U-turns, jumping curbs, and violating other *traffic* rules.

"But in fairness to the drivers . . . they had every right to be frustrated," Tinlin said.

While officials said they were satisfied with yesterday's meeting and solutions, some drivers were not.

"Oh, that really makes it better," Anne Novak, 52, of East Bridgewater, said sarcastically. "More police? Every time people see a flashing light, they stop." between garage levels. She and her carpool mate gave up, called home, left the car, and went to get a bowl of soup.

Tinlin said six trouble spots largely caused Tuesday's gridlock, and police monitored yesterday afternoon's commute at those locations:

The Columbia Road- Interstate 93 interchange (Exit 15) where faulty *traffic* lights caused backups on to I-93 south. The exit was eventually closed for several hours Tuesday afternoon.

The intersection of Dorchester Avenue and Columbia Road, where leftover snow and an NSTAR crew caused further standstills.

The intersection of Melnea Cass Boulevard and Massachusetts Avenue,

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where **traffic** jammed Tuesday night headed to I-93 south.

The Frontage Road-I-93 southbound merge at the South Bay Shopping Center, where four lanes now merge to one rather than two after a month-old Big Dig change.

The Frontage Road-Southampton Street merge, which was affected in part by the I-93 merge at South Bay.

Another probable factor in the jam, though Turnpike officials dispute it, was the new interchange near the Massachusetts Avenue exit (Exit 18).

"We didn't overnight reconfigure the geometry of Exit 18," said Michael Swanson, chief operating officer for the Big Dig who attended the meeting, "and we haven't had gridlock.

"Clearly something happened south of Interchange 18 that caused it to gridlock," Swanson said.

South of that interchange, officials blamed the failure of **traffic** signals at the Columbia Road-I-93 interchange and a pothole crew, both controlled by MassHighway.

Snow removal on city streets, more than a week after the record-setting blizzard, was also a factor.

SIDEBAR:
ANATOMY OF GRIDLOCK
PLEASE REFER TO MICROFILM FOR CHART DATA.

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Patricia Glynn

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