

Nottingham, Valerie (NIH/OD/ORF)

From: Alexandra Gorman [alex@womenandenvironment.org]
Sent: Friday, May 13, 2005 12:17 PM
To: NIH NEPA Comments
Subject: Comments on SDEIS, Boston University Laboratory

May 13, 2005

Valerie Nottingham
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B13/2W64
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Dear Ms. Nottingham,

Thank you for the opportunity to comment on the Supplemental Draft EIS for the proposed National Emerging Infectious Diseases Laboratory at the Boston University Medical Center.

As you may remember, I was integrally involved in the EIS process for the Integrated Research Facility at Rocky Mountain Laboratories (RML) in Hamilton, MT. To no surprise, I found several sections of this SDEIS very similar to the EIS written for RML.

It appears that several of the same concerns and problems with the RML EIS exist with this SDEIS. Specifically this SDEIS omits any true risk assessment to the community of a laboratory-acquired infection. And similar to the RML EIS, this document relies entirely on the assumption of an 'excellent' safety record of three BL-4s around the world as compiled by Karl Johnson, MD. I have met Dr. Johnson, and while I hold his life's work on infectious disease in very high regard, I am not especially assured by his report. It should be made very clear in this EIS, that Dr. Johnson's research for his report is anecdotal, rather than data-based - relying on interviews with several key staff at these facilities. It was not in fact a detailed review

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47.1 The portion of Dr. Johnson's report that addresses the exposure and clinical infection record of those three laboratories during the past 20 years is not anecdotal; it represents the facts, and particularly in the case of USAMRIID, it is based on written records from that Institute supplied to Dr. Johnson by Dr. Peter Jahrling, Principal Scientific Advisor to USAMRIID. Nobody working in the BSL-4 at USAMRIID suffered a clinical infection. The statement in Section 4.2.1.1 "Community Safety and Risk - Other Potential Risk Scenarios (a)" of the FEIS is correct with just one caveat. BSL-4 containment did not exist as such until 1984 when the first edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL) came out. That is why Dr. Johnson covered a 20 year period through most of 2003. No clinical infections occurred in BSL-4 work at USAMRIID in that 20 year interval.

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47.2 All the agents listed in the published article referenced in the comment are either BSL-2 organisms or BSL-3 agents. No clinical infections occurred in BSL-4 work at USAMRIID during the period of time in Dr. Johnson's study.

47.1 of all laboratory exposure events at these three facilities, and should not be relied upon to make claims about the safety of BL-4 facilities.

Most troubling is a statement on p 4-10 of the SDEIS which states:

"With the longest running experience with a BSL-4 (33 years) Ft Detrick Maryland has an outstanding safety record. Previous documents exposures at Fort Detrick in their original lab facilities mention one laboratory-acquired infection between 1959-1969 and no clinical or other infections in the more recently constructed USAMRIID facility."

47.2

This is, unfortunately, incorrect - and must be revised in the next version of this EIS to reflect the true safety record of this facility. USAMRIID has had an extensive history of both exposures and laboratory-acquired infections over the last two decades. According to a study by USAMRIID researchers, published in the Journal of Occupational and Environmental Medicine in August 2004, 234 employees at USAMRIID were evaluated for exposure to 289 biological agents classified as "bioterrorist agents", resulting in 5 confirmed clinical infections between 1989-2002. The recorded infections were from exposures to glanders, Q fever, vaccinia, chikungunya, and Venezuelan equine encephalitis. There were also numerous exposures to anthrax, plague, Western and Eastern equine encephalitis, orthopoxviruses, yellow fever virus, and Rift Valley fever virus which did not lead to infections, but for which postexposure antibiotic prophylaxis was administered (when available). For some of these diseases, of course, there is no available treatment.

This report, (Rusnak, et al. 2004, which is attached to this message) did thoroughly review all exposure records, and paints a significantly different picture of the safety record at USAMRIID than Dr. Johnson's report which implies that accidents are extraordinarily rare. In contrast this data shows that there were an average of 16.7 persons evaluated per year for accidental exposures to bioterrorist agents. In fact the authors of the study conclude:

"In summary, we reviewed available medical and safety records at USAMRIID from 1989 to 2002 and reported on 234 evaluations of potential exposures and illnesses to bacterial, rickettsial, and viral disease agents. During this period, there were five confirmed infections. The large number of exposure incidents reported in this time period serves as a reminder that work in a laboratory of this type is inherently hazardous." (emph. added)

This conclusion of this study must be included in this EIS in order to fully inform the public of the potential risks of such a facility. And, specifically, the incorrect claim in the SDEIS (p4-10) that no clinical or other infections were reported at USAMRIID must be deleted and replaced with the correct information that no less than 5 clinical infections were identified

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47.2  between 1989 and 2002.

Furthermore, The authors of Rusnak et 2004 also conclude :

"Therefore, it is imperative for laboratories that elect to work with highly hazardous agents to be fully cognizant of the risk of occupationally acquired illnesses and institute policies and proactive employee health procedures to evaluate potential exposures."

47.3  However, the SDEIS does not address Boston University's policies or proactive employee health procedures to evaluate potential exposures. **A section clearly explained these policies and procedures not only for preventing exposures, but for detecting and evaluating exposures are crucial to the health of both the employees and the surrounding community. This must be included in the EIS.**

Thank you for the opportunity to express my concerns about this project. I would appreciate a written response to these comments.

Sincerely,

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Enclosure: JOEM 804 2.doc (Rusnak, et al, 2004)

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47.3 See Response to Comment 4.47.

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Results: Journal of Occupational and Environmental Medicine
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Volume 46(8) August 2004 pp 801-811

Experience in the Medical Management of Potential Laboratory Exposures to Agents of
Bioterrorism on the Basis of Risk Assessment at the United States Army Medical Research
Institute of Infectious Diseases (USAMRIID)

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Abstract

Experience in managing laboratory exposures to potential agents of bioterrorism is limited. The United States Army Medical Research Institute of Infectious Diseases reviewed laboratory exposures involving these agents (1989 to 2002) to assess the effectiveness of medical management. The evaluation of 234 persons (78% vaccinated) for exposure to 289 infectious agents revealed 5 confirmed infections (glanders, Q fever, vaccinia, chikungunya, and Venezuelan equine encephalitis). Postexposure antibiotic prophylaxis was given for most moderate- or high-risk bacterial exposures (41/46; 89%); most unvaccinated minimal-risk (7/10; 70%), and subsets of vaccinated minimal-risk exposures (18/53; 34%) but generally not negligible-risk exposures (6/38; 16%). Vaccine "breakthroughs" were not unexpected (enzootic Venezuelan equine encephalitis, localized vaccinia) or presented with mild symptoms (Q fever). A multifaceted policy of personal protective measures, vaccination, early assessment, and postexposure antibiotic prophylaxis was effective in minimizing morbidity and mortality in at-risk laboratory workers.

As research on the agents of bioterrorism becomes more widespread, an increase in occupational exposures to bioterrorist agents may be expected.¹ However, many institutions working with these agents may have limited clinical experience or procedures in place for the medical management of exposures to these agents.

Although information on preventing laboratory exposures to potentially high-risk agents is available,²⁻¹⁵ literature on medical management of these exposures is sparse. This is the second in a series of articles on the medical management of laboratory exposures to agents considered bioterrorism threats. The first

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article focused on United States Army Medical Research Institute of Infectious Diseases (USAMRIID's) methods for evaluating potential exposures and provided risk assessment and management guidelines for institutions to consult in the development of their occupational exposure policies (submitted for publication).

USAMRIID, and in particular the Special Immunization Program (SIP), has extensive experience in managing and preventing exposures and disease in at-risk laboratory workers. In addition to engineering controls and personal protective measures, the vaccination of at-risk laboratory personnel and immediate evaluation of all potential exposures are key risk reduction measures. This analysis of our potential exposures provided us with the opportunity to evaluate the success of our risk-management program. Although every attempt is made to eliminate hazards, we recognize that work in containment laboratories is inherently hazardous because of the need to work with sharp objects (ie, needles) and animals, which can be unpredictable. In addition, personal protective equipment may inadvertently increase the potential for incidents by limiting the field of vision, tactile sensation, and communication. We reviewed all exposure incidents to assess our program between 1989 and 2002. This information may be beneficial to other institutions involved in bioterrorist agent research and management.

Methods

Policy

Research laboratories at USAMRIID range from biosafety levels (BSLs) 1 through 4. The specific vaccination requirements or recommendations (including investigational vaccines) with documented acceptable antibody titer levels before employees may enter the research suites are listed in Table 1.16-24 USAMRIID policy requires that a physician immediately evaluate all (1) potential occupational exposures that occur within a containment suite or laboratory, (2) breaches in laboratory technique, and (3) febrile illnesses with temperatures greater than 100.4[degrees]F in individuals who recently worked in a laboratory containment suite.

TABLE 1 Special Immunizations Program Vaccines, Vaccine Dosage
Schedules, and Post-vaccination Clearance Prior to Laboratory Entry [16-24]

Review

Exposure incident reports on file with the Safety Office and Medical Division of potential exposures to infectious agents of bioterrorism (bacterial, viral, or rickettsial agents) from 1989 to 2002 were reviewed, and data were abstracted on the following: agent of exposure, route of exposure, assessed risk of exposure and disease, vaccination status, medical management, and outcome.

Results

A total of 448 individuals were evaluated in the SIP clinic for potential exposure to both bioterrorist and nonbioterrorist agents. Of these, 214 records involved potential exposures to nonbioterrorist agents (ie, herpes B exposures), potential toxin exposures, febrile illness determined to be community acquired infection on initial evaluation, no agent of exposure, or records with incomplete documentation (16 persons only). These were excluded from further review, resulting in a final sample of 234 records.

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The number of persons evaluated per year varied (average of 16.7 per year; median of 14 per year; range 6 to 50), with the upper limit resulting generally from potential aerosol exposures involving multiple persons. However, the number of exposure incidents remained relatively constant, with an average of 13 exposure events per year (median 11 per year; range 6-40). The number of percutaneous needlestick exposures also remained relatively constant at an average of 1.7 per year.

Individuals evaluated for a potential exposure incident were generally evaluated for exposure to one agent and occasionally evaluated for exposure to two or more agents, resulting in 234 persons being evaluated for potential exposure to 289 agents, occurring mainly by aerosol and percutaneous routes (Fig. 1). Potential bacterial exposures were more likely to have resulted from aerosolized events (59%), whereas viral exposures more commonly resulted from percutaneous Events (64%). Percutaneous exposures occurred mainly by needlesticks or razors, animal bites and scratches, and cuts on edges or glass (Fig. 2). A total of 44 of 234 (19%) exposures occurred while working with animals.

Fig. 1. Bacterial, viral, and rickettsial laboratory exposures by Exposure route.

Fig. 2. Methods of percutaneous exposure.

Initial risk assessment involved two steps: first, the assessment of the risk associated with the exposure itself, and second, given an exposure, and the vaccination and health status of the exposed worker, the risk of actual infection. The risk of disease was generally downgraded if (1) the individual had received a prior vaccination against the agent, (2) the agent was a nonpathogenic strain, or (3) prophylactic antibiotics were prescribed (Fig. 3). The actual dose of exposure could not be determined in most cases and thereby was not a major factor in the assessment of disease risk in this review. Vaccination against the infectious agent had been given to 182 of 234 (78%) individuals prior to the exposure.

Fig. 3. Initial assessment of risk of exposure and risk of disease of potential laboratory exposures (N = 234).

Only 67 of 234 (29%) persons evaluated were assessed as moderate- (exposure likely) or high-risk (exposure highly likely), with the majority of persons (162 of 234; 70%) having exposure risk assessed as minimal (exposure unlikely), negligible (exposure highly unlikely), or no risk (Fig. 3). The risk of disease was assessed to be moderate or greater in 12 of 234 (5.5%) persons (Fig. 3).

Most moderate or high-risk percutaneous exposures were associated with (1) sharps that had been in contact with a viable infectious agent; (2) direct contact (or indirect by a needle or cage) with an ill, infected animal; or (3) from cuts on objects likely to be contaminated, such as centrifuges or culture flasks. Minimal risk percutaneous exposures were commonly associated with (1) direct contact (or indirect by a needle or cage) with a recently infected, non-ill animal or (2) from cuts on objects unlikely to be contaminated with viable agent. Negligible-risk exposures were

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commonly associated with percutaneous injuries resulting from contact with an object highly unlikely to be contaminated with a viable agent, such as a sterile needle or a desk corner.

Aerosolized exposures determined to be of high or moderate risk were commonly associated with splashes of the agent outside the biological safety cabinet (BSC) or during centrifugation, without wearing proper respiratory protection. Minimal-risk aerosolized exposures were often associated with (1) liquid spills of cultures within the BSC, (2) liquid spills outside the BSC of Materials unlikely to contain viable agent, or (3) dropping culture plates outside the BSC with the loss of the plate cover, in the absence of proper respiratory protection. Negligible-risk exposures were generally exposures to a solution highly unlikely to have viable organisms.

Five of 234 (2%) potential exposures to agents of bioterrorism resulted in confirmed disease (glanders, 25 Q fever, vaccinia, chikungunya, and Venezuelan equine encephalitis infections), with four of these five cases presenting initially to the SIP clinic as per Institute protocol with symptoms of disease.

Bacterial Agents

Of 150 individuals with potential exposures to 172 bacterial agents, 132 (88%) individuals had been vaccinated prior to the exposure, and 75/150 (50%) individuals received postexposure antibiotic prophylaxis (Tables 2 and 3).

TABLE 2 Postexposure Antibiotic Prophylaxis Regimens

TABLE 3 Bacterial and Rickettsial Exposures: Vaccination Status Before Exposure and Number of Persons Receiving Postexposure Antibiotics

Recommendation of postexposure antibiotic prophylaxis was determined mainly by the risk of exposure but also was influenced by vaccination status and virulence of the organism. Postexposure antibiotic prophylaxis was initiated in nearly all moderate- or high-risk bacterial exposures (41 of 46; 89%), regardless of vaccination status, except for exposures to nonpathogenic strains (eg, Sterne strain of *Bacillus anthracis*; Table 4).

TABLE 4 Individuals Receiving Postexposure Antibiotic Prophylaxis after Potential Exposures to Bacterial Agents based on Vaccination Status and Exposure Risk

Vaccinated individuals with minimal-risk exposures were less likely to have received antibiotic prophylaxis (18 of 53; 34%) than unvaccinated individuals with minimal-risk exposures (7 of 10 persons; 70%; $P = 0.042$). Two of the unvaccinated individuals not given postexposure prophylaxis were minimal-risk exposures to *Brucella* sp. Institute policy was to observe (with follow-up serologies) minimal-risk exposures to *Brucella*, as the prophylaxis regimen involved prolonged (3 weeks) therapy with both doxycycline and rifampin. Individuals with minimal-risk exposures who routinely received antibiotic prophylaxis included those who had sustained percutaneous exposures to needles that had been in contact with recently infected animals that were not ill (or direct contact with these animals) or those who had dropped culture plates onto

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bench tops or floors resulting in loss of the lids.

Postexposure prophylaxis in vaccinated individuals with negligible risk exposures was generally not recommended, and given in only 4 of 32 (12.5%) cases. No individuals evaluated for postexposure antibiotic prophylaxis developed infection.

B. anthracis.

Postexposure antibiotic prophylaxis was recommended in 36 of 41 (88%) persons evaluated for moderate- to high-risk exposures to B. anthracis, 15 of 49 (31%) minimal risk, 3 of 30 (10%) negligible to no risk, and 3 undetermined risk exposures. The four individuals with moderate-risk exposures who were not given antibiotics were exposed to nonpathogenic strains of B. anthracis, and a fifth person had been vaccinated and their potential exposure involved a dose of less than 200 spores of B. anthracis.

Nares cultures to confirm B. anthracis exposures were not performed routinely but were performed on occasion, mostly for high-risk inhalational exposure events and for epidemiological purposes. In the fall of 2001, USAMRIID received the anthrax letters for analysis that were sent to the offices of Senators Tom Daschle (D-SD) and Patrick Leahy (D-VT). Seventeen individuals who were involved in the analysis of the powdered substance in the Daschle letter were evaluated at the time. Even though the letter was opened within a BSC, the SIP proactively evaluated all 17 persons involved in the letter handling who were considered at potentially significant risk for exposure due to the readily aerosolizable spores.

Initial evaluation of persons in contact with the letters identified eight persons to be at moderate or high risk of exposure, one at minimal-risk, six persons at negligible or no risk of exposure, and two evaluations without a determined risk of exposure. Nares cultures were performed on 16 of the 17 persons, and all were negative. Antibiotic prophylaxis (30 days) was recommended to the eight individuals (all vaccinated) assessed to have a moderate- or high-risk exposure. Antibiotics were discontinued at 14 and 21 days in two individuals as the result of side effects. The six individuals assessed to have negligible or no risk exposure only handled the biohazard bag containing the letter (had no direct contact with the letter). Although three of these individuals received antibiotic prophylaxis for 1 to 3 days until the situation could be fully assessed, continued antibiotic prophylaxis was not recommended for these negligible or no-risk exposures as well as the vaccinated minimal risk exposures.

One of the two individuals with an undetermined risk of exposure received postexposure antibiotic prophylaxis because she had photographed the anthrax letter within the BSC, with her face approximately 6 inches from the opening of the BSC, thus meeting criteria for a moderate-risk exposure. This individual also had no prior anthrax vaccination and completed a 30-day course of ciprofloxacin in addition to the primary series of six doses of the anthrax vaccine. The other individual with an undetermined risk of exposure had received the anthrax vaccine and wore a respirator while working with the organism within a BSC, consistent with criteria of a negligible or no risk exposure. This person was not recommended to receive postexposure prophylaxis.

In a separate incident, an exposure to B. anthracis was confirmed by nares culture in one researcher in 2002.26 B. anthracis spores from a 250-mL liquid culture of B. anthracis in a 2-L flask had crusted on the mouth of the flask and also the paper towels covering the mouth of the flasks (mouth of flask was covered with paper towels with the screw top loosely screwed to allow for aeration of the culture) during incubation on a rotating incubator. Based on

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environmental cultures, the exposure most likely occurred after the paper towel was removed from the flask within the BSC and deposited into the waste container outside the BSC. As the towel was carried through the BSC's air curtain, the air turbulence could have aerosolized dried spores on the paper towel. The individual had received three injections of the anthrax vaccine primary series, with his last injection given 3 months prior. As a precautionary measure, an anthrax booster was administered to ensure anthrax antibody titers remained adequate for the next 2 months prior to his 6-month dose of vaccine. The researcher and a vaccinated coworker who had negative nares cultures both received postexposure prophylaxis with ciprofloxacin for 30 days.

Environmental cultures were obtained periodically when needed to evaluate the presence and extent of exposure and for subsequent documentation of successful decontamination. For example, in 1999 environmental cultures were obtained to evaluate contamination from a flood in a laboratory suite as a result of a water main break, where Petri dishes within a biohazard bag were found in the flood waters. Cultures from the biohazard bag containing the Petri dishes and from the hallway where the water had flooded grew *B. anthracis*, as did a pair of shoes of one laboratory worker in the suite during the flood. Cultures of socks or from benchtops or walls where the water had not been in contact did not grow *B. anthracis*- documenting that the risk of aerosolization of spores was low or unlikely. Postdecontamination cultures were negative for *B. anthracis*. Further analysis by polymerase chain reaction testing on a small sample of the culture demonstrated one strain of contamination was from a nonpathogenic delta Ames-type (attenuated) *B. anthracis*, with amplification of the origin of replication of pXO2 and for capsular genes but negative tests for protective antigen and lethal factor. As the presence of pathogenic strains could not be entirely excluded, all nine individuals in the laboratory during the flood received postexposure antibiotic prophylaxis.

Yersinia pestis.

Thirteen inhalational and 25 percutaneous potential exposures to *Y. pestis* were evaluated. Antibiotic prophylaxis was administered to all 4 moderate- to high-risk exposures, 13 of 17 (76%) minimal-risk exposures, and 3 of 17 (18%) negligible-risk exposures. A previously vaccinated individual with a puncture from a needle contaminated with *Y. pestis* (syringe had contained a high concentration of organisms) presented 6 h after the incident with a 4 cm by 2.5 cm area of swelling, erythema, and induration at the puncture site on her hand. Symptoms resolved within 48 h after doxycycline prophylaxis. Although the etiology of the cellulitis was suspected to represent a vaccine "breakthrough" from a high percutaneous inoculum of *Y. pestis*, culture was not performed, and therefore the infection could not be confirmed.

Burkholderia mallei.

A case of glanders occurred in an individual with type I diabetes mellitus who initially presented to a health care facility outside USAMRIID with a febrile illness and tender axillary adenopathy and was subsequently diagnosed with hepatic and splenic abscesses as the result of *B. mallei*.²⁵ The individual, after a diagnostic liver biopsy, subsequently went into respiratory failure, necessitating intubation. The individual was treated initially with imipenem and doxycycline for 2 weeks, followed by imipenem and azithromycin, and finally received long-term oral therapy with azithromycin and doxycycline to complete a 6-month course of treatment. The route of exposure was assumed to be percutaneous, as laboratory exposures to *B. mallei* have been most commonly acquired by the organism entering through microabrasions of the skin.²⁵ This individual admitted to not wearing latex protective gloves at times while working in the laboratory. Three individuals evaluated at other times for potential exposure to *B. mallei* were given postexposure antibiotic

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prophylaxis and remained asymptomatic.

Rickettsial agents (*Coxiella burnetii*).

One confirmed case of Q fever was diagnosed in an individual who worked with high concentrations of *C. burnetii*, who had been vaccinated 5 months before exposure. He initially presented with a nonspecific flu-like illness. Diagnosis of Q fever was confirmed by a rise in serological titers. The route of exposure was probably inhalational as the result of a malfunction (leak) of the filter in the BSC that was subsequently discovered. Symptoms resolved on doxycycline. This case represents our only "breakthrough" of symptoms from Q fever infection after the receipt of the Q fever vaccine.¹⁷ Serologies of a vaccinated coworker who also worked with high concentrations of the organism using the same BSC showed no evidence of infection.

Viral Agents

There were 77 individuals evaluated for potential exposures to 107 viral agents (Table 5). Because no vaccine existed for many of the viral agents, only 46 of 77 (60%) individuals had vaccination before their exposure. Nearly all individuals with exposures to Venezuelan equine encephalitis (VEE), Western and Eastern equine encephalitis, orthopoxviruses, yellow fever virus, and Rift Valley fever virus were vaccinated before exposure as a result of institute policy for receipt of these vaccines prior to working with the agents (submitted for publication; Table 5). Laboratory work with Ebola, Marburg, and Lassa fever viruses were conducted in BSL 4 laboratory conditions, and work with yellow fever, Junin, and TBE viruses was performed under BSL 3 laboratory conditions. Because no postexposure prophylaxis was available for most viral agents, the risk assessment of exposure and disease was less critical to determining the need for postexposure prophylaxis. However, investigational uses of antiviral agents were considered in significant exposures to highly virulent viral agents in unvaccinated individuals and given to two individuals. No individuals required level 4 patient isolation during this period.²⁷ Three confirmed viral infections were diagnosed: Venezuelan equine encephalitis virus, Chikungunya virus, and vaccinia infections.

TABLE 5 Viral Exposures: Vaccination Status of 77 Individuals with Potential Exposures to 107 Viral Agents

Confirmed Infections

VEE.

A vaccinated individual who had worked with animals infected with enzootic IE and IIIA strains of VEE during the previous 5 days developed symptoms consistent with VEE infection. Viral culture of the pharynx was positive for VEE strain IIIA. However, acute and convalescent serologies did not show a fourfold rise in titer to VEE IIIA, with plaque-reduction neutralization (PRNT₈₀) titers remaining less than 1:10. The individual's symptoms resolved within 10 days. The individual had previously received the investigational VEE TC-83 vaccine and had demonstrated an adequate PRNT₈₀ titer of 1:80. However, the VEE TC-83 vaccine is more antigenically related to the epizootic Trinidad strains IA, IB and IC, and is known to have poor cross-protection against the enzootic strains such as IE and IIIA.²⁸

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Chikungunya.

One of two needlestick exposures to chikungunya virus resulted in a confirmed infection. The individual developed symptoms within 2 days of a needlestick, with an estimated dose of exposure to 10,000 to 100,000 PFU of chikungunya virus strain IBH 35 (Nigerian isolate). Symptoms consisted of fever, headache, arthralgias, fatigue, and blurred vision. The diagnosis was confirmed by replication of chikungunya virus from blood cultures on days 2 and 5 of illness, by serological titers (rise in chikungunya IgM and neutralizing antibody levels), and by electron micrographs showing viral particles consistent with chikungunya virus from cells inoculated with serum from days 3 and 4 of illness. The individual had a full recovery after a slow convalescence with intermittent joint pains, headaches, and blurred vision over the ensuing months. The individual had received an inactivated chikungunya vaccine 13 years earlier, but use of this vaccine was discontinued in early clinical trials due to poor vaccine immunogenicity. The individual did not develop antibody titers after this vaccine. Also, the individual had received vaccination to other alphaviruses (VEE, Western and Eastern equine encephalitis), which may have potentially offered crossprotection or decreased the immune response to other alphaviruses.²⁹ Subsequently, an investigational live attenuated chikungunya vaccine became available and was given to individuals at-risk of exposure to chikungunya virus.²²

Vaccinia.

Three days after sustaining a splash of IHD-J-strain of vaccinia onto abrasions of the hand, a researcher noted 3 localized erythematous pruritic papules at the site of the splash. He presented 3 days later (day 6) with two 3-mm pustules with central crusting within a 1.5-cm erythematous lesion on his index finger, and a crusted papule on his thumb that was consistent with localized vaccinia. The individual was afebrile, without adenopathy, and the abrasions on the hand were still present. Medical records confirmed a "take" from his last vaccinia booster given 7 months before the exposure. The lesions resolved without treatment.

Postexposure Antiviral Prophylaxis

Ribavirin.

Oral ribavirin was given to an individual who had a high risk exposure to 7 mL of cell culture supernatant from Sin Nombre virus (strain cc107) at a concentration of 105 PFU/mL. While she was expressing the supernatant through a filter inside a BSC, the filter cracked and the liquid sprayed out of the BSC onto her scrub tops, which she immediately sprayed with Lysol and removed. Prophylaxis with ribavirin (1200 mg a day) was initiated.³⁰ Therapy was discontinued at day 21 of a planned 30 day regimen due a hemoglobin decrease from 14 to 10.3g, a known side effect of ribavirin. The anemia resolved readily with discontinuation of the drug. Reverse-transcription polymerase chain reaction and enzyme-linked immunosorbent assay tests for the virus performed twice weekly for 3 weeks and then every 2 weeks for another 2 months remained negative for Sin Nombre virus.

Cidofovir.

A laboratory worker was evaluated for a potential ocular exposure to orthopox viruses resulting from a splash of condensate from a cord of an incubator where orthopox viruses were incubated. The individual failed to decontaminate his eye at the time of the exposure. Cidofovir with probenecid was administered prophylactically without sequelae.³¹

Discussion

In recent years, especially since the anthrax letters of 2001, the civilian public health and medical research and development communities have developed an increasing interest in research on defensive measures against agents of biowarfare. However, Fort Detrick has maintained an active research program on potential biowarfare agents for more than 60 years, initially for offensive purposes but solely for defense against these agents since 1969. Before the 1960s, numerous occupationally acquired infections involving these agents occurred, but the availability of vaccines in the 1960s; improvements in engineering controls (ie, biological safety cabinets); and advances in biosafety equipment, awareness, and site laboratory practices (ie, needleless systems) greatly contributed to the decrease in exposures and infections. In this review of exposure incidents from 1989 to 2002, 5 infections resulted from the 234 potential exposures to bioterrorist agents.

A decrease in laboratory-acquired infections resulting from vaccination with investigational vaccines such as the live, NDBR 101 Tularemia, Q fever, and VEE TC-83 vaccines, as well as with Food and Drug Administration-approved vaccines such as anthrax and yellow fever vaccines, has been noted.³ Vaccine "breakthroughs" with an enzootic strain of VEE, localized lesions from vaccinia virus, or chikungunya virus infection (from the earlier poorly immunogenic chikungunya vaccine) were not unexpected. No infections with epizootic strains of VEE have been documented at USAMRIID since the usage of the live, attenuated VEE TC-83 vaccine in 1963. All "breakthrough" infections to the vaccine evaluated were with enzootic strains, to which the vaccine has demonstrated relatively poor persistence of antibody titers in both horses and humans.²⁸ Breakthroughs with localized vaccinia in vaccinated individuals have been previously reported, and are not unexpected.³²⁻³⁴ And although a vaccinated individual had a "breakthrough" infection with Q fever, it is quite possible that the vaccine may have provided a protective effect in that symptoms may have been worse without prior vaccination. The individual with chikungunya infection had received a vaccine that in early trials was deemed poorly immunogenic, did not result in antibody titers in the person, and therefore was not expected to be protective. It is unclear whether prior vaccination against other alphaviruses, which may inhibit or potentiate antibody responses to chikungunya, affected his response to chikungunya virus.

However, vaccination should not be considered a substitute for personal protective measures, education of employees on laboratory safety practices, and safety monitoring of the laboratories. The wearing of gloves "at all times" would have most likely prevented two of the five infections in our review. Also, vaccine "breakthroughs" may occur, as occurred with our case of Q fever after exposure to high doses of the organism.

Postexposure antibiotic prophylaxis after moderate- or high-risk exposures has been the policy and practice at USAMRIID both before and after the availability of vaccines. Early evaluation of potential occupational exposures allowed for early intervention with postexposure prophylaxis, without failures of the postexposure prophylaxis policy based on risk assessment (Fig. 4). In addition, aggressive management of potential exposures has a risk-benefit ratio leaning toward benefit, with only slight risk from the use of antibiotics. This proactive approach makes sense not only from the standpoint of preventing infection for the individual, but also for minimizing the risk of introducing communicable illnesses into the community at large.

Fig. 4. Flow chart of policy of postexposure antibiotic prophylaxis in potential bacterial exposures based on assessment of disease risk and vaccination

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Alexandra Gorman

Status and organism.

Our duration of postexposure prophylaxis before October 2001 ranged from 7 to 14 days in vaccinated persons after aerosol exposure to *B. anthracis* (as opposed to 30 to 60 days currently recommended).³⁵⁻³⁸ However, there were no "confirmed" exposures to provide data to support effectiveness of this shorter duration of prophylaxis for aerosolized exposures in vaccinated individuals.

Although it has been our policy to provide postexposure prophylaxis for moderate- and high-risk percutaneous exposures with *B. anthracis*, the Centers for Disease Control and Prevention does not currently recommend Postexposure prophylaxis for preventing cutaneous *B. anthracis*.³⁸ Anthrax vaccine alone has been effective in preventing cutaneous anthrax in wool sorters using an older protective antigen-based anthrax vaccine similar to the current licensed vaccine but is grown under aerobic conditions with an alum precipitate instead of microaerophilic conditions with an alum-adsorbed vaccine.³⁹ However, percutaneous exposures in the laboratory to cultures may involve exposures to higher concentrations of the organism and potentially not be prevented by the vaccine.

This was demonstrated by two at-risk laboratory workers with vaccine "breakthroughs" of cutaneous anthrax with the older antigen-based anthrax vaccine, occurring during the period of the offensive biological warfare program (unpublished data). One case occurred a day before the time of his scheduled 6-month booster (dose 4 of vaccine), and the other case occurred in a person who had only received two doses of vaccine. There have been no "breakthroughs" with the current licensed anthrax vaccine. However, individuals are now required to have a minimum of three doses of anthrax vaccine before they enter the laboratory containment suite, and occasionally physicians have elected to give an early booster for higher risk exposures if within 1 to 2 months of a due dose of anthrax, in addition to postexposure antibiotic prophylaxis if indicated. Our proactive approach to managing "known" potential exposures with postexposure prophylaxis may have reduced our ability to detect whether the vaccine alone was protective. However, historically the majority of individuals, over 80% in one report, diagnosed with laboratory-acquired infections, could not identify a known incident or breach in laboratory policy responsible for their infection.¹⁵ Our review did identify a case of cellulitis after a high-risk needlestick exposure that was likely secondary to *Y. pestis* that responded while on doxycycline.^{40,41} This case represents a probable vaccine "breakthrough" and thus raises concern of the possibility of breakthrough infections with other agents, such as anthrax, even in vaccinated individuals.

Prophylaxis with tetracycline 2 g daily for 14 days was demonstrated to be highly effective for preventing tularemia in humans after aerosolized exposure to 25,000 *F. tularensis* SCHU-S4 when given within 24 h of exposure.⁴² Although the added effect of postexposure prophylaxis to vaccination is unknown, the failure of the vaccine to protect against ulceroglandular tularemia supports the practice of postexposure prophylaxis after higher-risk percutaneous exposures with this organism. In addition, retrospective diagnosis of two possible cases of mild typhoidal tularemia in vaccinated individuals during the time of the offensive biological warfare program was made by serological and skin testing. Both individuals had recent febrile illnesses treated with antibiotics by their family physician (USAMRIID, unpublished data).

Antibiotic prophylaxis with Q fever has been demonstrated to be effective if administered 8 to 12 days after exposure but may only prolong the onset Of disease if given within 7 days of exposure.⁴³ It is not known whether the vaccine alone is adequate for preventing disease in a laboratory setting with high-risk exposures or the effect of immediate postexposure prophylaxis

LETTER 47

Alexandra Gorman

(within 7 days of exposure) in vaccinated individuals. Again, the development of symptoms after a high-dose aerosolized exposure supports the continuation of postexposure prophylaxis in moderate- or high-risk exposures.

Currently there is no literature concerning the efficacy of postexposure prophylaxis for glanders. Trimethoprim-sulfamethoxazole and quinolones have antimicrobial activity against *B. mallei*, but their efficacy as postexposure prophylaxis in preventing disease is not known. However, antibiotic prophylaxis for melioidosis has been demonstrated to be effective in 100% of white rats against subcutaneous exposure with a 10-day course of either trimethoprim-sulfamethoxazole or quinolones.⁴⁴

Safer needle systems were introduced in some laboratories starting in 1990. Because the number of needlestick exposures per year was already low, no effect from this intervention could be determined with an average of 1.7 needlesticks per year remaining constant. Similar to a medical center, one might expect that needlesticks will occur at a certain frequency as long as needles are used in research involving animals. Therefore, laboratories must have a method in place to evaluate such potential exposures. We postulate that even if a laboratory does not have any known needlesticks, they should not assume that they are not occurring. It is more likely that they are occurring but are not being reported.³

In summary, we reviewed available medical and safety records at USAMRIID from 1989 to 2002 and reported on 234 evaluations of potential exposures and illnesses to bacterial, rickettsial, and viral disease agents. During this period, there were five confirmed infections. The large number of exposure incidents reported in this time period serves as a reminder that work in a laboratory of this type is inherently hazardous. Therefore, it is imperative for laboratories that elect to work with highly hazardous agents to be fully cognizant of the risk of occupationally acquired illnesses and institute policies and proactive employee health procedures to evaluate potential exposures. Other reviews have noted that some infections are identified only through employee medical surveillance. Evaluation of potential exposures must be openly encouraged by senior leadership and be non-punitive, lest the exposures be driven "underground" and not reported at all. Much of our knowledge about biosafety has come from investigations into the mechanisms and activities that caused workers to become infected. Future improvements in protecting workers will likely come from similar evaluations.

Conclusions

Our review of exposure incidents involving potential bioterrorism threat agents indicates that vaccination and proactive occupational exposure evaluation are important elements in minimizing the risk of exposure, disease, and fatalities among at-risk laboratory workers. However, these medical interventions are not a substitute for ongoing continued safety training, laboratory practices and procedures, and personal protective measures to reduce the morbidity and mortality in at-risk laboratory workers.

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Alexandra Gorman

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Alexandra Gorman

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

Dear Ms. Nottingham,

48.1 As a resident of the Greater Boston community, I do not believe that the supplemental
48.2 environmental impact statement (SDEIS) concerning Boston University's proposed
48.3 biolab seriously addresses my concerns. It was not prepared by an organization
48.4 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.

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

It is now time to Just Say No.

Sincerely,

Susan Macey
18 Monmouth Court
Brookline

LETTER 48

Susan Gracey

48.1 See Response to Comment 1.1.

48.2 See Response to Comment 1.2.

48.3 See Response to Comment 1.3.

48.4 See Response to Comment 1.4.



Boston University
School of Medicine

May 9, 2005

Collamore 608
88 East Newton Street
Boston, MA 02118-2308
Tel: 617 638 7933/4
Fax: 617 638 7965

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

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

Department of
Otolaryngology
Head and Neck Surgery

Dear Ms. Nottingham:

Kenneth M. Grundfast, M.D., FACS
Professor and Chairman

I am writing to express support for the National Emerging Infectious Diseases
Laboratories at Boston University Medical Center (BUMC).

Gregory Grillone, M.D., FACS
Vice Chairman
Residency Program Director

The Biosafety Level 4 Laboratories in North America have a very good safety
record. With more than 77 years of combined operations, there has never been
a community incident or an environmental release.

Physician Faculty
Anand Devaliah, M.D.
Stanley M. Shapshay, M.D., FACS
Jeffrey H. Spiegel, M.D. FACS
John R. Stram, M.D.

I am familiar with the design of the proposed laboratory at BUMC and believe
that it is being designed and built using some of the most sophisticated and
state-of-the-art safety and security systems. I firmly believe that BUMC has a
deep commitment to ensuring the safety of the laboratory, the researchers and
the community.

Basic Science Faculty
Remco Spanjaard, PhD
Zhi Wang, M.D.

Communication Sciences
L. Clarke Cox, PhD
George Charpied, M.S.

A BSL-4 laboratory will provide much needed capacity to study emerging
infectious diseases and will be very beneficial for scientists and researchers
throughout the region who are looking for cures and vaccines for some of the
world's deadliest diseases. This laboratory will safely conduct research on
infectious diseases that threaten the safety and security of our city, of the
nation and indeed, of the world.

Anne Bulkovitz
Practice Manager

Elizabeth A. Foley
Residency Coordinator

Nina Leech
Executive Assistant

I support BUMC research efforts and its plans to build the NEIDL.

Sincerely,

Gregory A. Grillone, M.D., FACS
Associate Professor
Vice Chairman
Department of Otolaryngology

BOSTON UNIVERSITY MEDICAL CENTER
Boston Medical Center
Boston University School of Medicine
Boston University School of Public Health
Boston University Henry M. Goldman School of Dental Medicine

LETTER 49

Gregory A. Grillone, M.D., FACS

GREATER BOSTON CHAMBER
75 STATE STREET, BOSTON, MA 02109-1814
617.227.4500 FAX 617.227.7505 bostonchamber.com

May 5, 2005

Ms. Valerie Nottingham
National Institutes of Health
B13/2W64
9000 Rockville Pike
Bethesda, MD 20892



RE: Supplemental Draft Environmental Impact Statement for the National Emerging Infectious Diseases Laboratories

Dear Ms. Nottingham:

The City of Boston is the ideal location for the BioSafety laboratory because of our city's preeminence in biomedical research, world-renowned hospitals, scientists and researchers and its reputation as a desirable location for visiting scientists. Boston University Medical Center has long been a driving force behind biomedical innovation and advancement made in the region and has cultivated the necessary partnerships between academia and industry to take the lead in this critical facet of our nation's fight against infectious diseases.

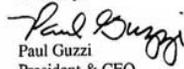
The Greater Boston Chamber of Commerce believes that BioSquare is a uniquely qualified site on which to locate this facility due to its offerings and environment. In addition this facility will serve as an economic engine for the region spurring job creation and capital investment for years to come. The \$128 million NIH grant for construction and future operational monies are expected to generate an additional \$1.7 billion in federal research and spending over the next 20 years. This dramatic infusion of federal dollars into our city will be a boon for the local economy.

The lab is expected to create 1,200 construction jobs and 660 permanent jobs ranging from scientists to laboratory technicians to security to environmental services. There will be opportunities for community residents to secure training and well paying positions with the lab.

The Chamber is confident that the stringent safety standards employed in the design, construction and operation of this facility will ensure that both researchers and community residents alike will be safe and secure. The superior safety records exhibited by the other BSL-4 Labs in North America help substantiate the effectiveness of the security measures this facility will employ.

The Chamber is grateful for the opportunity to express its support for the Biosafety Laboratory at Boston University Medical Center.

Sincerely,


Paul Guzzi
President & CEO

LETTER 50
Paul Guzzi

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

Dear Ms. Nottingham,

- 51.1 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
- 51.2 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
- 51.3 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.
- 51.4 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,



LETTER 51

Amy Hendricksen

- 51.1 See Response to Comment 1.1.
- 51.2 See Response to Comment 1.2.
- 51.3 See Response to Comment 1.3.
- 51.4 See Response to Comment 1.4.

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

**Re: Supplemental Draft Environmental Impact Statement-National Emerging
Infectious Diseases Laboratories**

Dear Ms. Nottingham:

Our community needs projects like the proposed biosafety laboratory.

The biosafety lab will create jobs. Boston University Medical Center (BUMC) has said that 1300 construction jobs and 660 permanent jobs will be created. Our community needs these jobs.

In addition, BUMC has committed \$1 million to training Boston residents to be lab technicians. The training will be part of the City Lab program. After nine months, the graduates are able to find meaningful jobs at a laboratory at the medical center or in a similar laboratory in the City. This will be a great partnership and illustrates BUMC's strong commitment to our community.

I support the Biosafety Lab.

Almarita Hendrix

LETTER 52

Almarita Hendrix

LETTER 53

Sherwood S. Hughes

Nottingham, Valerie (NIH/OD/ORF)

From: Hughes, Sherwood [SHUGHES2@PARTNERS.ORG]
Sent: Sunday, May 08, 2005 9:20 AM
To: NIH NEPA Comments
Subject: Support Letter for BUMC Bio Lab Level 4

Valerie Nottingham
Division of Environmental Protection
The National Institutes of Health
B13 RM 2W64, 9000
Rockville Park
Bethesda, MD 20892

Dear Valerie:

I am a resident from Saint George Street, two blocks from where the BUMC is proposing to build the Bio Lab Level 4. I am also the President of the Blackstone/Franklin Square Neighborhood Association.

The purpose of my letter is to let you know that I am in support of having the Bio Lab level 4 in the South End. I have had the opportunity to attend many of the public and private meetings that BUMC and the BRA have held to address questions, concerns and issues that the community has brought to the forefront. BUMC has spent a great deal of time and effort making sure that the area residents have answers to the questions they are concerned about by speaking at public meetings, holding breakfasts, holding office hours and supplying packages of information to anybody who has asked.

Additionally, BUMC officials and BRA officials also met with me to answer a list of difficult questions last year. Their answers reassured me that the Bio Lab will be operated in a responsible and safe manner. BUMC has also promised to keep area community groups apprised of their ongoing quality and safety reporting which is an important component of accountability to area residents. I've also been lucky to confer with my neighbor Chris Brayton who took a trip to Atlanta, Georgia to see the facility at Emory. Chris met with and toured the Georgia State University Bio Labs and with the neighborhood civic association which surrounds the Emory University CDC facility.

LETTER 53

Sherwood S. Hughes

Finally, as a member of the medical community in Boston, I believe this facility is absolutely necessary to ensure important research into potential cures for deadly diseases.

If you have any questions, please feel free to contact me at 617-429-9934.

Sherwood S. Hughes
1 Saint George Street #3C
Boston, MA 02118
617-429-9934

President
Blackstone/Franklin Square Neighborhood Association

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,

Gretchen Klotz
19 Dennison St
Waltham MA 02453

LETTER 54

Gretchen Klotz

54.1 See Response to Comment 1.1.

54.2 See Response to Comment 1.2.

54.3 See Response to Comment 1.3.

54.4 See Response to Comment 1.4.

Beth Israel Deaconess
Medical Center

Chief, Division of Gastroenterology



Harvard Medical School

J. Thomas LaMont, M.D.

Beth Israel Deaconess Medical Center
330 Brookline Avenue • Boston, MA 02215 USA
617 667-8377 • Fax 617 667-2767
Internet: jlamont@caregroup.harvard.edu

Charlotte F. & Irving W. Rab
Professor of Medicine

March 02, 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). I am a federally -funded researcher carrying out basic and clinical research on an infectious pathogen. Our laboratory routinely handles human and animal pathogenic bacteria and their toxins. We are very familiar with the safety issues recommended for the safe handling of infectious agents.

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

Beth Israel Deaconess Medical Center, Boston, is a major teaching hospital of Harvard Medical School.
A founding member of CAREGROUP,SM an organized system of quality healthcare serving the individual, family, and community.

LETTER 55

J. Thomas Lamont, MD

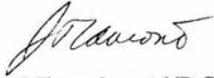
LETTER 55

J. Thomas Lamont, MD

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,



J. Thomas Lamont, MD, Chief
Division of Gastroenterology

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,

*Elisabeth Leonard
4 Hillside Court
E. Boston, MA 02128*

LETTER 56

Elisabeth Leonard

- 56.1 See Response to Comment 1.1.
- 56.2 See Response to Comment 1.2.
- 56.3 See Response to Comment 1.3.
- 56.4 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.

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It is now time to Just Say No.

Sincerely,

Edward L. Loech
Brookline, MA

LETTER 57

Edward L. Loech

57.1 See Response to Comment 1.1.

57.2 See Response to Comment 1.2.

57.3 See Response to Comment 1.3.

57.4 See Response to Comment 1.4.

Bayha, Ryan (NIH/OD/ORS)

From: Nottingham, Valerie (NIH/OD/ORF)
Sent: Tuesday, May 24, 2005 11:01 AM
To: Bayha, Ryan (NIH/OD/ORS)
Subject: FW: Comments on the Supplemental Draft Environmental Impact Statement (SDEIS) for the BU Lab

From: Eve Lyman [mailto:evelyman@gmail.com]
Sent: Wednesday, May 18, 2005 7:49 PM
To: NIH NEPA Comments
Subject: Comments on the Supplemental Draft Environmental Impact Statement (SDEIS) for the BU Lab

Comments on the Supplemental Draft Environmental Impact Statement (SDEIS) for the BU BSL4 Lab

I feel that the environmental impact statement (SDEIS) for Boston University's BSL4 Lab has the following problems:

- 58.1 • I oppose locating the lab in the South End/Roxbury;
- 58.2 • There should be a thorough analysis of other locations for the lab, including other locations in Massachusetts and the locations of the other applicants;
- 58.3 • The worst case scenario should include all the select agents that might be in the lab, not only anthrax;
- 58.4 • The worst case scenario should include a terrorist causing a release from the lab;
- 58.5 • The analysis of terrorism threats to the lab must be made public;
- 58.6 • there must be an analysis of a release of an agent within Boston during transport to the lab; and
- 58.7 • How will the research comply with the Boston ban on rDNA research in a BSL4 lab?
- 58.8 • 13 out of 19 preparers were either hired consultants or members of the BU medical center despite claims of lack of interest in the problem.
- 58.9 • Transportation accidents from the regional centers to the national center between Harvard, MIT and Roxbury/South End are not discussed they can lead to problems
- 58.10 • There is no serious treatment in the SDEIS of all the alternative scenarios including insect release, the formation of carriers, scratches in the lab upon decontamination
- There is no discussion as to how infiltration into this system from within is to be prevented. The Anthrax used in the postal attacks is likely to have come from Fort Detrick Maryland and the Batelle Army Center in Columbus. How is security breaches from within from staff who intimately know the security system to be prevented.
- There is no discussion as in the event of an accident, how is fault going to be established and how people are to be held accountable, in the light of the tuleremia outbreak why should we believe that the public will ever be told about the problem

LETTER 58

Eve Lyman

- 58.1 See Response to Comment 19.2.
- 58.2 See Response to Comment 78.2
- 58.3 See Appendix 11, Executive Summary Threat and Vulnerability Analysis.
- 58.4 See Appendix 11, Executive Summary Threat and Vulnerability Analysis.
- 58.5 As stated in Section 2.2.5.1, any research that may be conducted in the proposed Boston-NBL would comply with all applicable Federal, state, and local laws, including laws governing the use of recombinant DNA.
- 58.6 The EIS is an NIH document. Some of the preparers are affiliated with Boston University since they were needed to provide information about the proposed project and its potential environmental impacts. The fact that some of the preparers are affiliated with Boston University does not affect the NIH's ability to make an informed, independent, and objective decision on the proposed action.
- 58.7 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 policies address appropriate notification, packaging, routing, and delivery protocols including delivery personnel screening, predetermination of routes, date and time of travel and delivery, and GPS monitoring to allow for vehicle tracking and response to incidents during travel time. See Section 2.2.6 of the FEIS.

LETTER 58

Eve Lyman

- 58.8 Insect release and inventory precautions are described in Section 4.2.1.1 "Community Safety and Risk – Other Potential Risk Scenarios (c)" and in Response to Comment 26.11. It is unclear what is meant by "formation of carriers". All personnel with potential exposures to infectious agents that pose a risk to other individuals because of possible person to person transmission would be quarantined for the duration of the incubation period of the agent in question. Individuals who are exposed to potentially infectious agents through "scratches in lab" would be evaluated to determine their risk of acquiring the infectious agent and for the risk of person to person transmission. Quarantine of the individual would depend on the nature of the agent and the exposure.
- 58.9 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. Incidents of non-compliance or systems malfunctions would be reported immediately to responsible officials. Checks and balances includes researchers having access to and information about research areas only, security personnel having access to and information about security areas and protocols only and facilities personnel having access to and information about facilities areas and protocols only. Individuals with access to select agents would not have knowledge of or access to security access and audit systems. See Sections 2.2.5, and 2.2.6 of the FEIS.
- 58.10 Any breach in security or safety procedures would be thoroughly investigated by the appropriate responsible parties and reported to the Executive Committee as well as appropriate local, state and/or federal agencies.

LETTER 58

Eve Lyman

- 58.11 The BMBL provides guidelines and risk assessment information. It does not attempt to provide a biosafety level for every organism. The 4th edition (1999) as referenced does not provide guidance on avian influenza. The draft 5th edition does. USDA also regulates work with this agent because it is considered an agricultural select agent or high consequence pathogen.
- 58.12 The worst possible case does not indicate there would be an accident that requires payment for damages.
- 58.13 The waste disposal system and procedures are fully described in the 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. All waste discharged from this facility ultimately would be treated in the MWRA's treatment plant.
- 58.14 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.

- 58.11 • The NIH security classifications are capricious so that Avian Flu can be investigated now at BSL3 labs even though it has potentially very high potential spread possibilities and has 60% mortality in humans.
- 58.12 • Who is going to pay for damages in the event of an accident is not clear. In particular it took a few hundred million dollars to clear the Post Offices in Washington of Anthrax. Is Harvard, BU and other members of the research consortium willing to assume the risk of paying for the cleanup.
- 58.13 • The Waste disposal system is not adequately described. What recourse does that State and City Have if pollution problems are not solved. This is not academic Plum Island off long Island is a Major Polluter and local citizens the EPA and others cannot stop it.
- 58.14 • Why don't we abide by democracy and ask the citizens of Boston to vote on this issue? Why do we let bureaucrats decide on all issues of importance to the population and the innocent bystanders allowed to bear the cost of the "leaders decisions".

Sincerely,
Eve Lyman

--
We Are One World
Eve Lyman
Director
Boston Mobilization
971 Commonwealth Ave #20
Boston, MA, 02215
617.782.2313
www.bostonmobilization.org

Nottingham, Valerie (NIH/OD/ORF)

From: tdmann@att.net
Sent: Thursday, April 21, 2005 5:10 PM
To: NIH NEPA Comments
Subject: commnets on BUMC NEIDLf - Boston, Draft EIS

82 Montgomery Street
Boston, Massachusetts 02116

April 21, 2005

Ms. Valerie Nottingham
Chief, Environmental Quality Branch
Division of Environmental Protection
National Institutes of Health
B13 - Room 2W64
9000 Rockville Pike
Bethesda, MD 20892

Re: Supplemental Draft EIS
National Emerging Infectious Diseases Laboratory
Boston University Medical Center Campus
600-620 Albany Street, Boston

Dear Ms. Nottingham:

59.1

I have reviewed the above captioned EIS and determined that inadequate consideration was given to the fact that the proposed site of the facility is located on the extended centerline of Runway 9-27 at Boston-Logan International Airport and within 2 1/2 miles of the end of that runway. As such, it lies within a Potential Aircraft Impact Zone (PAIZ) if there were to be an emergency involving an aircraft departing from the airport on Runway 27.

59.2

In the event such an emergency were to occur, the severity of the potential disaster would be magnified immensely if an impact were to affect the site of this proposed facility. Therefore, the proximity of the proposed site to this well-used departure path is a critical factor to consider when determining whether the facility meets applicable site evaluation criteria.

I suggest the proposed cite must be rejected because of this conflict and that an alternate location be required for the facility location which is farther away from any existing PAIZ created by arrivals or departures from Boston-Logan International Airport.

Sincerely,

Thomas D. Mann, Jr.

5/4/2005

LETTER 59

Thomas D. Mann, Jr.

- 59.1 Based on discussions with the Federal Aviation Administration (FAA) and Massport, there are no identified "Potential Aircraft Impact Zones" for the site. There is a protected surface zone that emanates in a trapezoidal shape, terminating 10,000 feet from the end of the runway. The location of the proposed project is beyond the limits of this zone. FAA has determined that this project poses no hazard to air navigation.
- 59.2 In compliance with the FAA Advisory Circular 70/7460.2k, a Notice of Proposed Construction or Alteration was filed with the FAA. On May 10, 2005, the FAA issued a Determination of No Hazard To Air Navigation and would not require any marking or lighting of the building for safe navigation.

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

Dear Ms. Nottingham,

60.1 As a resident of the Greater Boston community, I do not believe that the supplemental
60.2 environmental impact statement (SDEIS) concerning Boston University's proposed
60.3 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.

60.4 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,

C. Martinez
20 Ware St
Cambridge, MA
02138

LETTER 60

C. Martinez

60.1 See Response to Comment 1.1.

60.2 See Response to Comment 1.2.

60.3 See Response to Comment 1.3.

60.4 See Response to Comment 1.4.

BOSTON UNIVERSITY MEDICAL CENTER
127th Ave. • BOSTON UNIVERSITY MEDICAL CENTER • BOSTON UNIVERSITY MEDICAL CENTER • BOSTON UNIVERSITY MEDICAL CENTER • BOSTON UNIVERSITY MEDICAL CENTER



Boston University
School of Medicine



DEPARTMENT OF VETERANS AFFAIRS
VA Boston Healthcare System

The
Arthritis
Center

715 Albany Street, E5
Boston, Massachusetts
02182-2936
Tel: 617.638.4310
Fax: 617.638.3226

May 5, 2005

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

Dear Ms. Nottingham,

I am writing to strongly support the proposed Biosafety Laboratory scheduled to be built on the Boston University Medical Center Campus. In particular, I reference the detail plans in the Final Project Impact Report/Environmental Impact Report filled with the Boston Redevelopment Authority in July of this year.

As a biomedical scientist working in the field of complex autoimmune diseases and as a practicing internist and rheumatologist, I strongly support this important new laboratory. There is a critical need for such facilities since there are not enough Level 4 laboratories in the nation to accommodate the work that needs to be done in emerging infectious diseases. Such devastating infections as HIV, SARS, and even but common, but still deadly influenza viruses, all require more research to help us control, and, hopefully, eventually eradicate these infections from human populations. It is only with this type of sophisticated laboratory, that can take advantage of the tremendous scientific knowledge and expertise in the Boston area, will further advances be made.

Additionally, it should not be underestimated the collateral knowledge benefit that can come from the types of infectious disease research planned for this center. In my own field of autoimmune diseases there has long been a feeling that some of these diseases are infectious in origin and bio-discovery projects that could be performed at this laboratory could have profound impact on many members of society.

I am familiar with Boston University Medical Center's proposal for the Biosafety Laboratory and know it to be adherent to the highest safety standards and under expert and responsible leadership. This laboratory will be a benefit to Boston's medical centers, our Boston community, and quite literally all people.

Thank you for your consideration in this matter.

Sincerely,

Peter A. Merkel, M.D., M.P.H.
Associate Professor Medicine
Boston University School of Medicine

PAM/jtc

LETTER 61

Peter A. Merkel, M.D., M.P.H.

April 24, 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 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,

Phyllis J. Miller

Phyllis J. Miller

427 Marlborough St. #4

Boston, MA 02115

LETTER 62

Phyllis J. Miller

- 62.1 See Response to Comment 1.1.
- 62.2 See Response to Comment 1.2.
- 62.3 See Response to Comment 1.3.
- 62.4 See Response to Comment 1.4.

Acambis Inc.
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May 4, 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:

We support the National Emerging Infectious Diseases Laboratories at Boston University Medical
Center (BUMC), which establishes a state-of-the-art facility for research on emerging and re-
emerging infectious diseases that threaten national security and the health of nations around the
world.

BUMC conducted exhaustive studies on the selection of proposed site for the NEIDL facility. We
agree with the conclusion of these studies that the best location for this facility is the BioSquare
Research Park in Boston. In this location, the new NEIDL becomes a part of a large medical
research complex and draws on many strengths of an integrated multi-disciplinary research
environment. This aspect would be undermined by locating the facility in another location.

In regards to concerns regarding the safety of the proposed facility and in particular, the Biosafety
Level 4 laboratory, there is no question that the facility will be safe. Similar laboratories
throughout the United States have operated safely for decades, and new BSLK4 laboratories are
being established in similar proximity to urban centers. The safeguards build into the design and
operations of NEIDL are more than sufficient to ensure that there is no risk to residents in the
surrounding area.

Sincerely,



Thomas P. Monath, MD
Chief Scientific Officer

Adjunct Professor,
Dept. of Molecular Biology & Immunology
Harvard School of Public Health

Acambis

LETTER 63

Thomas P. Monath, MD

David S. Mundel
36 Gray Street
Boston MA 02116

May 18, 2005

Mr. Leonard Taylor, Jr.
Acting Director, Office of Research Facilities
Development and Operations
National Institutes of Health

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

(sent by e-mail to nihnepa@mail.nih.gov)

Dear Mr. Taylor,

This letter responds to the request for comments regarding the Supplemental Draft Environmental Impact Statement (SDEIS, dated March 2005) for the National Emerging Infectious Diseases Laboratory and National Biocontainment Laboratory proposed to be built by University Associates Limited Partnership at the Boston University Medical Center (BUMC) campus in Boston.

The proposed operation of this laboratory raises many concerns that need to be addressed prior to approving the building of this project in Boston's South End neighborhood. In assessing this proposed project and preparing the Final Environmental Impact Statement, I urge you and your colleagues at the NIH (and your colleagues at the Boston University Medical Center and its consultants) to carefully consider the potential environmental and health effects on the residents of Boston's nearby neighborhoods, the inmates incarcerated in the nearby South Bay correctional facilities, and the vulnerable patients served at the Boston University Medical Center, itself.

Regrettably, these concerns were not adequately addressed in the DEIS and remain inadequately addressed in the SDEIS.

This comment letter addresses two issues that deserve substantial additional attention and review.

1. Can we expect the leaders of the BUMC and the NIH -- the proponents, eventual operators, and financial supporters of the laboratory -- to be responsive to the important concerns, issues, and questions raised by residents of the neighborhoods that surround the proposed facility?

Letter from DSMundel to NIH -- May 18, 2005

Page 1

LETTER 64

David S. Mundel

- 64.1 BUMC is committed to safety of its workers and the general population. The proposed lab would be operated in conformance with all applicable federal, state and local regulations many of which pertain to safety. See Response to Comment 4.28.

64.1

LETTER 64

David S. Mundel

64.2 See Response to Comment 19.1.

64.3 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.

64.2

2. Can we expect that the operations of the proposed biocontainment laboratory will not create a threat to the safety of the surrounding residential neighborhoods?

In summary, the answer to the first question is “no” – although the repeated promises and statements of both BUMC and NIH personnel suggest that responsiveness to neighborhood concerns is one of their important goals, their actions indicate that their likely performance will fall far short of what is required.

In summary, the answer to the second question is unclear – the so-called “worst case hazard and risk assessments” included in the DEIS and the SDEIS are so incomplete and seriously flawed that they provide no credible basis for establishing the level of anticipated or expected threat or risk.

Issue 1 – Responsiveness to Neighborhood Concerns, Issues, and Questions

The SDEIS contains numerous statements suggesting a high concern for responsiveness to issues facing residents of the surrounding neighborhoods. For example, the SDEIS states that “BUMC has made an institutional commitment to informing and educating the public about the proposed Boston-NBL facility” (see SDEIS page 1-15). The SDEIS also states that “small group meetings have been held to ensure that the community is able to obtain information about the project” (see SDEIS page 1-17, emphasis added). In addition, the SDEIS reports that “more than 130 community meeting have been held in the Dorchester, Roxbury, and South End Neighborhoods to provide factual information, answer questions and respond to concerns.”

But the actions of the BUMC and NIH personnel do not indicate that responsiveness to neighborhood residents has been a high priority during the last several months, while the DEIS and SDEIS were being prepared and reviewed.

64.3

Throughout several months following the exposure of BUMC research personnel to a highly infectious strain of Tularemia bacteria, no one from the Medical Center communicated anything about this incident to members of the community.

In the summer of 2004, I contacted RWDI (the consultant responsible for the “worst case risk and hazard assessments” included in both the DEIS and the SDEIS) to discuss their modeling efforts. I was told (by e-mail, dated September 9, 2004) that “RWDI is not authorized to speak directly with members of the public” and that RWDI had forwarded my request to its client and asked BUMC to contact me directly to answer my questions.

The questions that I discussed with RWDI have never been answered.

On December 13, 2004, I and other members of the Ellis South End Neighborhood Association met with BUMC representatives to discuss our neighborhood’s concerns. In advance of this meeting, I sent BUMC representatives a brief memorandum outlining a small number of issues and questions that we would like to discuss (see Attachment A). During this meeting and subsequent conversations and e-mail communications, BUMC representatives repeatedly promised to promptly provide us with information that was responsive to our concerns – e.g., the BUMC Executive Director of Operations and Public Safety wrote that “we will continue to share information and analyses.” Later, in

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David S. Mundel

- 64.4 BUMC, in accordance with instructions from NIH, responded to public requests for information to the entire interested public in documents that have been distributed to requestors and placed in public libraries in Boston. Individual requests for information were not addressed until they could be included in the comprehensive responses as described above.
- 64.5 The assessment reviewed the potential release of agent as compared to known health benchmarks. The universally accepted benchmarks are 8,000 – 10,000 Anthrax spores for inhalation exposure per event (U. S. DIA 1986), and over 500 spores as a time weighted average over an eight hour period (Brachman et al. 1966). The total predicted exposure over the event is less than a spore and there is no documented evidence of any infection caused by inhalation of a single anthrax spore. The worst case scenario concludes that under the worst case an individual could be exposed to less than one *B. anthracis* spore. This dose of organisms is not infectious for normal or immuno-compromised individuals.

January 2005 after I again requested that the promised information and analyses be provided, the BUMC Director of Community Relations wrote to me that "we have held individual meetings with you to try to provide some direct face time with the resource people best suited to answer your questions and concerns" and that "interesting enough, one issue is that your requests are extremely insightful; responses to them and the information needed to answer them, are really of benefit to a much broader audience."

To date, none of the important information and analyses that BUMC representatives promised to share with us has been provided.

64.4

On May 3, 2005, I sent an e-mail to NIH and BUMC representatives (see Attachment D) requesting copies of the comment letters written in response to the DEIS and a copy of a key reference cited in the "Hazard and Risk Assessments" included in the DEIS and SDEIS. In addition, I requested that the information that had been promised in December 2004 be sent to me so that I could prepare a full and more accurate review of the SDEIS.

To date, I have received none of the requested information. In addition, I have not even received a response to my e-mail.

Actions speak louder than statements, meetings, and face time. There is little reason to expect that leaders of the BUMC and NIH will be responsive to the important concerns, issues, and questions raised by residents of the neighborhoods surrounding the proposed facility.

Issue 2 -- Flaws in the so-called "Worst Case Hazard and Risk Assessments"

The "worst case Hazard and Risk Assessments" included in the DEIS and SDEIS are seriously flawed and thus they do not provide a basis for assessing whether or not the proposed facility represents a potential threat to the safety of the residents in the surrounding neighborhoods.

The review of the hazard and risk assessments contains no careful analysis of why the incident chosen for the 'worst case' assessments represents the type of incident that would result in the highest levels of hazards and risks.

64.5

Although the SDEIS notes that the residents of the surrounding neighborhoods have high rates of asthma (see page 3-22), there is no description of the substantial populations of immuno-suppressed individuals and other highly susceptible individuals in the surrounding neighborhoods, hospitals, and prisons. The 'worst case analyses' include no assessments of the impact of potential bacterial and viral releases on these vulnerable populations. (This omission is discussed more fully in Attachment B).

Although many of the SDEIS' conclusions reported in the so-called 'worst case hazard and risk assessment' are based on simulation models that are described as demonstrating that the "predicted maximum exposure to any member of the community" is small, these models create estimates of average concentration levels and average exposure levels, not estimates of maximum exposures. As reported in a technical report referenced in the SDEIS ("User's Manual for SLAB" by Donald Ermak), the simulation "model results are

averages” and “even if a model were 100% accurate, individual observations would be expected to vary about the predicted value.” (see Attachment C)

64.6

The “hazard and risk assessments” included in the DEIS and the SDEIS contain no sensitivity analyses indicating how the simulated findings of environmental impact would be different if different assumptions were used in estimating the impact of the incident reviewed in the assessments. Because of the range of estimates resulting from the two models (0.0024 and 0.1755 spores) and the one wind tunnel simulation (0.2925 spores) are so different, it is clear that the sensitivity of the estimated impacts resulting from the models or simulations must be assessed.

The impact of many key assumptions must be assessed. In particular, the modeled and simulated results appear to depend critically on the assumption that only 400,000 anthrax spores are released into the air, although 10 Billion spores are released in the assumed laboratory accident. The basis for this assumption is not described in either the DEIS or the SDEIS and the potential impact of alternative assumption is never addressed. The only referenced source for this key assumption is a ‘personal communication’ with Deborah Wilson, the Director of Occupational Safety and Health at the NIH, the project proponent. Although I have asked for a copy of this ‘personal communication’, I have not received any response to this request.

The four attachments to this letter clearly indicates that these concerns about the “worst case hazard and risk assessments” have been raised repeatedly during the last several months. During this time, these concerns have not been addressed and the “worst case hazard and risk assessments” presented in the SDEIS are as inadequate and flawed as those that were available over nine months ago in the summer of 2004.

64.7

As a result, the so-called “worst case hazard and risk assessments” included in the DEIS and the SDEIS do not provide a credible basis for evaluating whether or not the operations of the proposed biocontainment laboratory will create a threat to the safety of the surrounding residential neighborhoods.

Before preparing the Final Environmental Impact Statement and making a decision to build and operate the proposed biocontainment laboratory at Boston University Medical Center, I urge the National Institutes of Health to carefully assess the Medical Center’s ‘public responsiveness’ actions and plans and to completely revise the so-called “worst case hazard and risk assessments.”

To proceed forward on the basis of recent actions, current plans and reported analyses would be a serious mistake.

I thank you, in advance, for your consideration these recommendations.

Sincerely yours,

David S. Mundel
(Attachments A, B, C, and D included)

Letter from DSMundel to NIH – May 18, 2005

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LETTER 64

David S. Mundel

64.6 The Maximum Possible Risk, or MPR model, was used to further evaluate risks associated with siting and operation of the proposed BSL-4 laboratory at Boston University. In order to provide quantitative data for input into the model, laboratory studies simulating accidental releases of anthrax spores were conducted. A modified Henderson Apparatus, operated in a static mode, was used to model accidental release of a *B. subtilis* spore preparation (1011 cfu/gm) as a surrogate for *B. anthracis*. The spore concentration was verified by titer on tryptic soy agar. In a biological safety cabinet, the static aerosol chamber was oriented so that the sampling ports and main hatch entry were parallel to the laboratory bench; the chamber exhaust was attached to house vacuum protected by a HEPA filter. The aerosol generator port and annular ring were sealed and not used in this set of experiments. The pressure relief port on the apparatus was also protected by a HEPA filter, to provide make up air when the chamber was placed under vacuum to clear aerosols from the chamber in between experimental runs and between releases of spore preparations. In between each accidental aerosol release experiment, the chamber was washed, decontaminated with bleach solution, and dried with an alcohol wash.

Procedure for Release of Aerosols within the Chamber:

Sampling ports on either side of the main chamber hatch were used to insert the sampling probes from particle counters. One counter was calibrated to count and determine the total number of particles within the respirable range of man (0.3 – 10 microns). The other port was fitted with a probe sampling total particles generated. Background measurements were obtained prior to “accidental” release of the spores. A spore preparation contained in a 15 cc conical bottom Falcon tube with the cap loosened and simply sitting on the tube was held parallel to the bench and dropped into the chamber from a height of 15 inches, just at the height of the open hatch. The gasketed hatch was fitted into place as soon as the drop was accomplished. Particle counting was begun prior to the “drop” to establish background, and continued for as long as it took to stabilize at, or close to, zero particle counts after the “drop”.

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David S. Mundel

The chamber was held static during background and test sampling. The drop experiment was performed 19 times. The average number of respirable particles generated in accidental release experiments, over the 19 trials, was 319,701. The standard deviation was 155,950 particles. Six standard deviations ("six sigma") were added to the mean number of respirable particles generated equaling 1,255,396. For use in the MPR model, the respirable number of spores was 1,255,396 P (1,255,396 < .000000001). See Section 3 in Appendix 12.

64.7 The NIH performed a third risk assessment using the Maximum Possible Risk Model for the proposed BSL-4 facility at Boston University. Fifteen release scenarios were evaluated to investigate the impact of the laboratory and its operation on the surrounding urban environment. The assessment is attached in Appendix 12. See Responses to Comments 4.6 and 64.6.

-- Attachment A --

Issues and questions for the 12/13/2004
discussion of the hazard and risk assessment

The following is a preliminary set of issues and questions for our discussion. Some of these issues and questions were discussed with RWDI representatives in July and early September, prior to RWDI describing its lack of authorization to speak directly with members of the public.

1. **Agent selection** – Appendix 3 of the “Final Project Impact Report – Final Environmental Impact Report” and Appendix 2 of the “Draft Environmental Impact Statement” describe over 50 diseases that may be studied at the proposed laboratory. But the “Summary Report – Hazard and Risk Assessment” only addresses Anthrax and provides only a summary of a “screening-level assessment.”

What is the basis for the selection of Anthrax as the agent for the “worst-case scenario”?

What other scenarios were considered, and rejected, in selecting the particular scenario that was summarized?

What are the environmental risks and hazards to residents and employees present in the surrounding residential and commercial communities that may result from other agents that “may be studied” in the proposed facility?

2. **Population vulnerabilities** – The “Draft Environmental Impact Statement” states that the “relationship of smoking and drinking to susceptibility to pulmonary anthrax is unknown, but it would be reasonable to conclude that these factors would increase sensitivity to infection (page 4-10).” But this report and others distributed to the public do not include analyses of the potential sensitivity to infection and the potential severity of the results of infection for the other diseases that “may be studied” in the proposed facility. In addition, the various reports do not include any assessment of the numbers and distribution of potentially susceptible populations in the surrounding neighborhoods.

What are the characteristics of the at-risk populations that are most susceptible to the agents that “may be studied” in the proposed facility?

How many individuals with these characteristics reside, work, and are hospitalized or incarcerated in the surrounding neighborhoods?

3. **Sensitivity of the “worst-case scenario” results to alternative assumptions** – The report describes a series of scenarios but does not assess the sensitivity of the results to alternative assumptions and the reasonableness of the alternative assumptions chosen for study.

For example:

The RWDI Report states that although the “worst-case scenario” involved 10 billion spores, the analysis (based on simulations by NIH) “determined that of the 10 Billion anthrax spores only 400,000 spores (0.004%) would become airborne and respirable (RWDI, page 3)”.

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David S. Mundel

How reliable are the NIH simulations? What range of results did these simulations produce?

What would be the results and implications of the various event simulations if a larger percent (above the level simulated by NIH) of the spores became airborne and respirable?

The "dispersion modeling was conducted from the top of the building exhaust stack (page 3, RWDI)" assuming that the density of the spore cloud dissipates as the cloud mixes with the air brought into the laboratory space assuming a ventilation rate of 12 air exchanges per hour (see pages 5 and 6, RWDI).

How would a change in the ventilation rate (potentially caused by a simultaneous failure of the building ventilation system) alter the concentration of the spores released (as presented in Figure 3.1) and the results of the various simulations?

The various modeling or simulations were "conducted using a range of weather conditions that may be encountered (page 4, RWDI)".

How would the results differ in other weather conditions that may be encountered – e.g., lower wind speeds and temperature inversions?

What are the probabilities of various types and ranges of weather conditions that are likely to be encountered given the historical weather patterns occurring in Boston?

4. **Interpretation of the results of the various simulations** – The various figures and the summary section of the RWDI report and the descriptions of the RWDI findings in other reports suggest that the simulations provide an estimate of the "maximum number of inhaled spores." Based on this interpretation, RWDI summarized its findings as follows "since the release and inhalation of a partial spore is not feasible, this number may practically be considered zero (RWDI page 10)."

I believe that this interpretation is incorrect. On the face of it, to assume that given a release of 400,000 spores that no one would inhale any of them seems illogical and unrealistic. By analogy, imagine 400,000 piranhas in a pool of muddy water where the likelihood of a single piranha being at any particular point is less than one. When a child asks you if she can go into the pond to retrieve a small ball, would you say "no, it's not safe" or would you reply "since a partial live piranha is not feasible, the number of piranhas near the ball may practically be considered zero, so it's perfectly okay for you to go into the pond."

I believe that simulations and models like those used by the RWDI analysts allow one to estimate (under a set of chosen assumptions) the "expected number of spores that an individual would inhale" not the maximum number. Using the "expected number of inhaled spores" estimate and an estimate of the number of individuals breathing while the plume passes by, one could (but the RWDI analysts did not) estimate the likely number of individuals who would inhale 0, 1, 2, 3, 4, or more spores.

What is the basis for the interpretation of the simulations results that have been presented in the publicly available reports?

Have alternative interpretations been considered?

LETTER 64
David S. Mundel

-- Attachment B --

David S. Mundel
36 Gray Street
Boston MA 02116

January 2, 2005

Mr. Leonard Taylor, Jr.
Acting Director, Office of Research Facilities
Development and Operations
National Institutes of Health

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

(sent by e-mail to nihnepa@mail.nih.gov and by FAX to 301.480.8056)

Dear Mr. Taylor,

This letter responds to the request for comments regarding the Draft Environmental Impact Statement (DEIS) for the National Emerging Infectious Diseases Laboratory and National Biocontainment Laboratory proposed to be built by University Associates Limited Partnership at the Boston University Medical Center campus in Boston.

The proposed operation of the laboratory raises many concerns that need to be addressed prior to locating this project within Boston's South End residential neighborhood and close to several other residential communities in the City. In assessing this proposed project and preparing the Final Environmental Impact Statement, I urge you and your colleagues at the NIH (and your colleagues at the Boston University Medical Center) to carefully consider the potential environmental and health effects on the residents of Boston's nearby neighborhoods, the inmates incarcerated in the nearby South Bay correctional facilities, and the vulnerable patients being served at the Boston University Medical Center, itself.

Regrettably, many of these concerns are not addressed adequately in the Draft Environmental Impact Statement. In fact, four additional alternatives were eliminated from detailed study during the preparation of the DEIS (see page A-1) and thus it is impossible to subject the proposed project to a careful, comparative review.

The DEIS clearly mentions the convenience that the proposed location would provide to the researchers who would use the facility:

"The proposed Boston-NBL would be located in very close proximity to proposed Principal Investigators and is conveniently accessible to all the Principal Investigators of the other RCEs" (page 2-33).

Letter from DSMundel to NIH – May 18, 2005

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LETTER 64

David S. Mundel

But the potential environmental and health risks to the residents, patients, workers, inmates, and others are reviewed almost dismissively. Although the DEIS states that "as demonstrated in the "worst case" analysis included in Chapter 4, locating the facility in a lower density area would not in any way reduce the risk to the public" (see page 2-33), the 11 page "worst case" analysis (summarized in Chapter 4 and reprinted in full in Appendix 6) does not address the changes in risk associated with locating the proposed facility in a lower density area. In fact, as stated in the DEIS, the potential impacts of locating the proposed laboratory at other possible locations were not subjected to detailed study.

In preparing the Final Environmental Impact Statement, I urge you to fully consider the potential environmental risks associated with the proposed project and to fully address the potential impacts (on both convenience and risk) of alternative locations for the proposed facility.

The following detailed issues should be addressed in the Final Environmental Impact Statement:

- The Final Statement should fully assess all of the potential environmental risks and impacts (to the adjacent residential and other communities) associated with the diseases that may be studied at the proposed facility. Appendix 2 of the Draft Statement lists 57 diseases "which may be studied" at the laboratory but the current environmental risk and hazard analysis only addresses one of these diseases.
- The Final Statement should contain a full and completely revised "worst case analysis", addressing the woefully inadequate and unconvincing analysis contained in the September 1, 2004 Summary Report - Hazard and Risk Assessment included in the DEIS. The current analysis contains no sensitivity analysis indicating how the simulated findings of environmental impact would be different if different assumptions were used in examining the nature of the incident leading to the release. The current analysis contains no assessment regarding whether the range of weather conditions considered is representative of the full range of weather conditions occurring in Boston. The statistical component of the current analysis is naïve and incorrect – the reported data do not portray the 'maximum number of inhaled spores', they portray the expected number of spores that would be inhaled by a single individual. The data included in the current report actually suggest that some individuals may inhale zero spores, some may inhale one spore, and some may inhale more spores.

In addition, the current 'worst case analysis' includes no assessment of the impact of a potential release on the vulnerable populations living, working, hospitalized, and incarcerated in nearby neighborhoods and facilities. In previous reports, Boston University Medical Center has noted that the "precise dose of Bacillus anthracis (anthrax) spores required to cause human pulmonary anthrax is not known" and that "this number would vary considerably from person to person depending upon age (and) overall medical history" but, these issues of population sensitivity are not addressed anywhere in the so-called 'worst case analysis.'

I thank you, in advance, for your consideration these recommendations and look forward to receiving and reviewing the revised Final Environmental Impact Statement.

Sincerely yours,

David S. Mundel

Letter from DSMundel to NIH – May 18, 2005

Page 8

-- Attachment C --

**Comments on the Supplemental Draft Environmental Impact Statement (SDEIS)
for the proposed Boston University Medical Center Biocontainment Laboratory**

Prepared for presentation at the
NEPA SDEIS Public Meeting on April 25, 2005

My comments briefly address two questions:

1. Does the Supplemental Draft Environmental Impact Statement (SDEIS) address the issues raised in the public comments received by the National Institutes of Health (NIH) and the Boston University Medical Center (BUMC)?
2. Does the SDEIS demonstrate that "the risk of public harm is so minute it could be described as zero"?

The brief answer to both questions is ... NO

Does the draft SDEIS address the public comments and concerns?

The cover letter accompanying the Impact Statement (dated March 25, 2005) states that "the SDEIS addresses concerns ...and comments received during the comment period." In addition, the SDEIS states that "small group meetings have been held to ensure that the community is able to obtain inform information about the Project" (see page 1-17).

But the comments that were submitted by the public are not included in the Impact Statement and thus it is impossible to assess whether or not they have been addressed. I have written to representatives of both the NIH and the BU Medical Center asking for copies of the public and questions. To-date, I have not received any response to these requests.

Based on my experience with the comments that I submitted to NIH and the questions that I have raised with BUMC representatives, I believe the SDEIS does not address the public comments and the community has not been provided with needed information. In early December 2004, I met with several BU representatives and shared with them a brief memorandum outlining several concerns and issues regarding the risk assessment that had been included in the Draft Environmental Impact Statement. During this meeting, the BU representatives promised that they would provide me with information and analyses that addressed these concerns and issues. Subsequently (later in December), I received an e-mail from a senior BU representative stating the "we will continue to share information and analyses"

- But, none of the promised information or analyses has been provided to me

In response to my continued requests for the promised information and analyses, another BU representative sent me an e-mail, with the following message -- "Interestingly enough, one issue is that your information requests are extremely insightful (and) responses to them and the information needed to answer them are really of benefit to a much broader audience. This is

Letter from DSMundel to NIH - May 18, 2005

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David S. Mundel

LETTER 64

David S. Mundel

precisely why (a later Impact Statement) is the best mechanism to address some of your more technical issues as they are grounded in some very fundamental concerns you and others may have with the draft EIS”

- But, the promised information and analyses have not been included in the SDEIS and the SDEIS does not adequately address the issues and concerns that I raised in December.

Does the SDEIS provides convincing evidence that “the risk of public harm is so minute it could be described as zero”

First, although many of the SDEIS’ conclusions reported in the so-called ‘worst case risk assessment’ are based on simulation models that are described as demonstrating that the “predicted maximum exposure to any member of the community” is small.

But these models do not estimate the maximum exposure levels, they estimate average concentration levels and average exposure levels. As reported in a technical report referenced in the SDEIS – “User’s Manual for SLAB” by Donald Ermak – the simulation “model results are averages” and “even if a model were 100% accurate, individual observations would be expected to vary about the predicted value”

Second, the results of these simulation models depend significantly on many assumptions, for example the authors of the ‘worst case risk assessment’ base all of their predictions on the assumption that only 400,000 anthrax spores are released into the air, although 10 Billion spores are released in the assumed laboratory accident. This assumption assumes that only 1 out of every 25,000 spores is released into the air.

But the basis for this assumption is never described, although the source of the assumption is noted in a list of literature found at the back of the SDEIS. The only referenced source for this key assumption is a ‘personal communication’ with Deborah Wilson, the Director of Occupational Safety and Health at the NIH, the project proponent.

Third, the SDEIS statement of minimal impact also appears to directly contradict other NIH statements.

In December 2000, the Director of the Division of Intramural Research of the NIH National Institute of Allergy and Infectious Diseases (the agency proposing the BUMC biocontainment laboratory) wrote in describing the advantages of a proposed level-4 laboratory in rural Western Montana – the rural site is “well removed from major population centers (and this) location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster.” (This memorandum was released to the public by NIH on January 9, 2003 in response to Freedom of Information Case No. 27890)

-- Attachment D --

May 3, 2005 e-mail

From: David Mundel

To: Valerie Nottingham
Kevin Tuohey
Carla Richards

Subject: request for information related to full review of SDEIS

In October 2004, the NIH issued a Draft Environmental Impact Statement (DEIS) for a proposed National Emerging Infectious Diseases Laboratory at the Boston University Medical Center, Boston, Massachusetts.

With this e-mail, I am again requesting copies of all comments received by the NIH from individuals, private for-profit and not-for-profit organizations, labor unions, and government agencies in response to this Draft Environmental Impact Statement.

In December 2004, I met with senior Boston University Medical Center representatives and was promised that I would promptly be provided with analyses and information related to a series of issues and questions that I shared with the University representatives in writing. To-date, I have not received any of the promised information and analyses.

With this e-mail, I am again asking for the promised information and analyses.

In March 2004, the NIH released a Supplemental Draft Environmental Impact Statement (SDEIS). On page 4 of a section entitled "Literature Cited", a reference is made to a communication with Deborah Wilson, the Director of Occupational Safety and Health, NIH, dated September 2, 2004. This communication appears to be the source of a key assumption that was used in the so-called 'worst case hazard analysis' included in the SDEIS.

With this e-mail, I am requesting that you provide me with a full copy of this communication.

Given that the public comment period for the SDEIS is scheduled to end within two weeks, I request that you respond quickly and fully to these three requests and that you extend the public comment period to a date 30 days after you have provided the requested comments, information, analyses, and correspondence.

Thank you, in advance, for your prompt and thorough response to these requests

David S. Mundel
36 Gray Street
Boston MA 02116

LETTER 64

David S. Mundel

David S. Mundel
April 25, 2005

page 1

**Comments on the Supplemental Draft Environmental Impact Statement (SDEIS)
for the proposed Boston University Medical Center Biocontainment Laboratory**

prepared for presentation at the NEPA SDEIS Public Meeting on April 25, 2005

My comments briefly address two questions:

1. Does the Supplemental Draft Environmental Impact Statement (SDEIS) address the issues raised in the public comments received by the National Institutes of Health (NIH) and the Boston University Medical Center (BUMC)?
2. Does the SDEIS demonstrate that "the risk of public harm is so minute it could be described as zero"?

The brief answer to both questions is ... NO

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But the comments that were submitted by the public are not included in the Impact Statement and thus it is impossible to assess whether or not they have been addressed. I have written to representatives of both the NIH and the BU Medical Center asking for copies of the public and questions. To-date, I have not received any response to these requests.

Based on my experience with the comments that I submitted to NIH and the questions that I have raised with BUMC representatives, I believe the SDEIS does not address the public comments and the community has not been provided with needed information. In early December 2004, I met with several BU representatives and shared with them a brief memorandum outlining several concerns and issues regarding the risk assessment that had been included in the Draft Environmental Impact Statement. During this meeting, the BU representatives promised that they would provide me with information and analyses that addressed these concerns and issues. Subsequently (later in December), I received an e-mail from a senior BU representative stating the "we will continue to share information and analyses"

- But, none of the promised information or analyses has been provided to me

In response to my continued requests for the promised information and analyses, another BU representative sent me an e-mail, with the following message -- "Interestingly enough, one

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David S. Mundel

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April 25, 2005

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issue is that your information requests are extremely insightful (and) responses to them and the information needed to answer them are really of benefit to a much broader audience. This is precisely why (a later Impact Statement) is the best mechanism to address some of your more technical issues as they are grounded in some very fundamental concerns you and others may have with the draft EIS”

- But, the promised information and analyses have not been included in the SDEIS and the SDEIS does not adequately address the issues and concerns that I raised in December.

Does the SDEIS provides convincing evidence that “the risk of public harm is so minute it could be described as zero”

First, although many of the SDEIS’ conclusions reported in the so-called ‘worst case risk assessment’ are based on simulation models that are described as demonstrating that the “predicted maximum exposure to any member of the community” is small.

But these models do not estimate the maximum exposure levels, they estimate average concentration levels and average exposure levels. As reported in a technical report referenced in the SDEIS – “User’s Manual for SLAB” by Donald Ermak – the simulation “model results are averages” and “even if a model were 100% accurate, individual observations would be expected to vary about the predicted value”

Second, the results of these simulation models depend significantly on many assumptions, for example the authors of the ‘worst case risk assessment’ base all of their predictions on the assumption that only 400,000 anthrax spores are released into the air, although 10 Billion spores are released in the assumed laboratory accident. This assumption assumes that only 1 out of every 25,000 spores is released into the air.

But the basis for this assumption is never described, although the source of the assumption is noted in a list of literature found at the back of the SDEIS. The only referenced source for this key assumption is a ‘personal communication’ with Deborah Wilson, the Director of Occupational Safety and Health at the NIH, the project proponent.

Third, the SDEIS statement of minimal impact also appears to directly contradict other NIH statements.

In December 2000, the Director of the Division of Intramural Research of the NIH National Institute of Allergy and Infectious Diseases (the agency proposing the BUMC biocontainment laboratory) wrote in describing the advantages of a proposed level-4 laboratory in rural Western Montana – the rural site is “well removed from major population centers (and this) location of the laboratory reduces the possibility that an accidental release of a biosafety level-4 organism would lead to a major public health disaster.” (This memorandum was released to the public by NIH on January 9, 2003 in response to Freedom of Information Case No. 27890)

LETTER 64

David S. Mundel

David S. Mundel
April 25, 2005

page 3

In summary,

- The Draft Environmental Impact Statement (released in October 2004) and the Supplemental Draft Environmental Impact Statement (released in March 2005) do not contain complete, convincing, or accurate assessments of the potential environmental impacts of the proposed level-4 biocontainment laboratory.
- I urge the NIH and the BU Medical Center to address these concerns prior to moving forward with the preparation of a final environmental review

LETTER 64

David S. Mundel

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: Proposed BU Bioterrorism Laboratory

From: carolyn nikkal [mailto:ni2k_c@comcast.net]
Sent: Wednesday, May 18, 2005 9:26 AM
To: NIH NEPA Comments
Subject: Proposed BU Bioterrorism Laboratory

National Institutes of Health,

I am writing to express my grave concerns about the proposed construction of a Level 4 Biolab in Boston.

1. The placement of a facility that is slated to house the most dangerous pathogens in the world in the middle of a densely populated area is extremely irresponsible. Such facilities are necessary, but should be located far away from highly congested population centers. The population density in the area of the proposed Lab is increasing quickly and shows no signs of slowing anytime soon.

2. Not only is the Lab's proposed site in a densely populated location, it is very near regional, national and international means of transport that could turn a local disaster into a global one within an hour or less. Again, the old refrain: location, location, location. This is the wrong location as would be any urban center near the means to spread a pathogen worldwide. Containment is the key in any accident. Placement of a level 4 lab in a densely populated area, any densely populated area, is a recipe for disaster. It is a disaster that does not need to take place if there is proper planning and placement.

3. Boston University has not been responsible in the management of its labs in the past. They have proven that they are irresponsible in the management of less toxic pathogens. It would be very irresponsible to entrust them with anything even more dangerous.

I urge you to reject the proposal for the proposed Level 4 Biolab in Boston and find a site for the lab that is not conducive to wildfire spread of any leaked pathogen.

Sincerely,

Carolyn Nikkal, EdD
14 Gay Head Street
Jamaica Plain, MA 02130

5/24/2005

LETTER 65

Carolyn Nikkal, EdD

65.1 See Response to Comment 19.2.

65.2 See Response to Comment 19.1.

65.3 BUMC has a strong and well managed laboratory safety program. There are over two dozen environmental health and safety professionals including environmental engineers, industrial hygienists, health physicists and biosafety professionals providing training, inspection and overall safety services. As is typical of any large complicated campus, BUMC has received regulatory notices, orders and violations. Nonetheless, BUMC has an excellent safety record, receives strong support from senior management, and enjoys a solid reputation with government regulators.

65.1

65.2

65.3

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

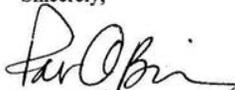
Dear Ms. Nottingham,

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,


24 Chestnut St
Cambridge MA 02139

LETTER 66

Pat O'Brien

66.1 See Response to Comment 1.1.

66.2 See Response to Comment 1.2.

66.3 See Response to Comment 1.3.

66.4 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



Boston University
School of Medicine

The Pulmonary
Center

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02115-5000
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Affiliated with:
Boston Medical Center
Boston
Veterans Administration
Medical Center

May 2, 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,

A handwritten signature in black ink, appearing to read "G. O'Connor".

George T. O'Connor, MD, MS
Associate Professor of Medicine

LETTER 67

George T. O'Connor, MD, MS

LETTER 68
Kenneth Olken

Nottingham, Valerie (NIH/OD/ORF)

From: NEKLO@aol.com
Sent: Thursday, May 12, 2005 12:54 PM
To: NIH NEPA Comments
Cc: Carla.Richards@bmc.org
Subject: Re: Supplemental Draft Environmental Impact Statement-National Emerging Infecti

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

Dear Ms. Nottingham:

I write to you in support of the Biosafety Lab at BUMC.

When I first heard about the laboratory, I must admit I was a bit apprehensive. However, the staff at Boston University Medical Center took the time to address my concerns and answer all my questions about the project.

I feel that this lab is important to find cures for infectious diseases. We need to have the appropriate facilities to do this important research. I believe that this lab will be built safely and that the redundant systems and the security plans will ensure that we are all safe.

Also, the development of this laboratory will create 1,300 construction jobs and 660 permanent jobs—jobs at all levels. This lab will have a positive economic impact at all levels in our community.

Sincerely,
Kenneth Olken, South End Resident

5/12/2005

Nottingham, Valerie (NIH/OD/ORF)

From: m.pellet [mpellet@hotmail.com]
Sent: Sunday, May 15, 2005 10:04 PM
To: NIH NEPA Comments
Subject: comment on proposed BSL4 at Boston University

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

Re: Supplemental Draft Environmental Impact Statement for the National Emerging Infectious Diseases Laboratory, Boston, MA

Dear Dr. Nottingham:

I am writing these comments to Boston University Medical Center's (BUMC) Supplemental Draft Environmental Impact Statement (SDEIS). I write these comments with the experience of 20 years working in biomedical research labs. My degrees are in biochemistry, microbiology and biology.

- 69.1 1) The infection in 2004 of three BU researchers with tularemia revealed a total collapse of biosecurity in a BUMC lab. This incident is very informative of what could happen with BUMC's proposed BSL4. Their system failed on many levels. One of the most disturbing failures was that researchers did not realize that they were working with an infectious strain of the bacterium when they thought they were working with an avirulent strain. This is especially troubling since these are exactly the type of experiments that BU is planning on carrying out in their proposed BSL4 laboratory, but with much deadlier and more contagious bioterrorism agents. In a letter to the Boston Public Health Commission in July 2004, Dr. Mark Klempner states that BU will be moving select agents from BSL4 labs to BSL3 at their discretion, when they believe that they have attenuated such organisms. This tularemia outbreak has shown that BU is not capable to make this judgement. BU claims that they will follow all federal, state and local laws when working with select agents. However, B.U. failed to comply with state regulations that required them to report any suspicion of any infection with specified bioterrorism agents. B.U. intentionally broke the law because they did not want to risk approval of their new lab. B.U. estimates that this lab will bring them \$3 billion over the next 20 years. B.U. has shown that they are more interested in their financial interests than they are in public safety. BU has had 8 months to determine the source of the contaminating bacteria that led to the infection of its workers. Using modern DNA analysis, BU should have easily determined the source of the contamination in that amount of time. Either improper procedures have left them unable to trace their contamination, or the results of their analysis is too embarrassing for BU to reveal. BU's responsibility extends to determining how this accident has happened, to ensure that it is not repeated.
- 69.2 2) BUMC states that they will abide by all existing local regulations on recombinant DNA research. Boston has an existing regulation the bans the use of rDNA. In the aforementioned letter to the BPHC from Dr. Mark Klempner, he admits that this regulation is in place but that this does not apply to their self-described "legitimate" research. This comment, as well as the fact that BUMC's SDEIS does not even mention that this ban is in place in Boston, leads one to conclude that BU holds this city regulation in total disregard.
- 69.3 3) BUMC claims that if this lab is sited away from the center of Boston, there will be no interest or use from the scientific community. However, experience shows otherwise. Los Alamos drew the greatest physicists in the country to the middle of the desert. Cyclotrons also draw scientists from many far-flung areas. We are currently building a lab in orbit over earth and no one is complaining of the commute.
- 69.4 4) Their assessment of a worst-case release is extremely superficial at best. RWDI West Partners have chosen anthrax as their released organism. Study of the anthrax release in Sverdlovsk showed that

5/16/2005

LETTER 69

Marc Pelletier

- 69.1 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 Mass. 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.
- 69.2 See Response to Comment 4.33.
- 69.3 The purpose of siting the laboratory at the proposed location in the Bio Square Research Park is to allow for dynamic collaborations among investigators at multiple research entities such as Boston University School of Medicine, Harvard Medical School, Massachusetts Institute of Technology, Massachusetts General Hospital, Brigham and Women's Hospital, University of Massachusetts Medical Center, the Massachusetts Biological Laboratories, Tufts University, New England Medical Center, Brandeis University, and others. Section 2.3.2 describes the alternatives considered but eliminated from detailed study.

LETTER 69

Marc Pelletier

69.4 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 800 feet 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. See Response to Comment 90.2.

69.5 BUMC has utilized several mechanisms, outside the NEPA process, to respond to requests for information and address community concerns. In addition to attendance and participation at more than 150 community meetings to provide an overview of the project, address specific issues and answer questions on the Boston-NBL, BUMC has set up information repositories that include key documents and materials at four local public libraries in neighborhoods near the project; some documents have been translated into Spanish to facilitate access for non-English and bilingual speakers. In addition, members of BUMC's Biosafety Laboratory Advisory Group comprised of community members from various Boston neighborhoods serve as focal points for community information exchange on the Boston-NBL.

69.6 Historically, Boston Medical Center and Boston University's Medical and Charles River campuses have participated in job and training and other outreach activities to showcase programs and best practices. In the past, each institution has done so separately and distinctly. BUMC's 1st Annual Boston University Campus Wide Fair held in January 2005 was an effort to coordinate resources in order to provide residents of the Greater Boston area with maximum access and exposure to the employment and educational opportunities available across the Boston University campus.

69.4

↑ localized wind patterns can lead to concentrations of anthrax spores in discreet spots within the neighborhood. This fact has been neglected in their assessment. The danger posed to community depends not only on the nature of the released organism, but also on the health and available healthcare of the resident population. It is known that the population around the proposed site suffers abnormally high incidences of asthma and other respiratory diseases. The population is also under-insured and may not have access to medical care. These factors have once again been ignored in this SDEIS. The SDEIS does not take into account the much greater danger posed by a true contagion. Accidental or intentional release of an organism that is spread from person to person poses a very different set of very serious health risks. This must also be included in a true assessment of a worst-case release. The tularemia infections in 2004 went undetected by BUMC for over 6 months, allowing researchers to traffic through the densely populated Boston neighborhoods while infected, highlighting what BU had previously said was "impossible".

69.5

◆ 5) B.U. claims that they have held many sought public input in the wide array of public meetings that they have held. I attended one of their highly-touted breakfast meetings. To attend this "public meeting", I had to take time away from work, since it was scheduled from 8-9am on a Tuesday. Once there, I had to pass two locked doors and two uniformed guards who asked for ID and whether I had been "invited" to this "public" meeting. Once in the meeting, I found that we were squeezed into a tiny room that was already half-filled with BU employees. My experience is that BU has been invited to take part in many public discussions on this issue and has never accepted an invitation to an event that I have attended. This includes events on the radio, on television and in public meetings. BU is only interested in meetings that they can control. BU is more interested in spreading propaganda about their project than they are in an honest discussion.

69.6

◆ 6) In Jan. 2005, BU has hosted their first job/training fair for the community. Since BUMC has been in this community for decades without making this kind of outreach, one has to question the sincerity of this sudden effort.

◆ In this SDEIS, BUMC has not sufficiently answered questions of safety and impact that their proposed lab would have on the community. The potential dangers from the bioterrorism laboratory are too real and too serious to allow the laboratory to complete the approval process on the basis of the seriously flawed and inadequate DEIS. Thank you very much for the opportunity to comment.

Sincerely,
Marc Pelletier
8 Glade Ave. #2
Boston, MA 02130

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5/16/2005

Bayha, Ryan (NIH/OD/ORS)

From: Nottingham, Valerie (NIH/OD/ORF)
Sent: Tuesday, May 24, 2005 10:58 AM
To: Bayha, Ryan (NIH/OD/ORS)
Subject: FW: Boston University Bioterrorism Lab

-----Original Message-----
From: Bill Perkins [mailto:wsperkins@igc.org]
Sent: Tuesday, May 17, 2005 10:35 PM
To: NIH NEPA Comments
Subject: Boston University Bioterrorism Lab

To Whom It May Concern;

I would like to record my opposition to the Boston University Bioterrorism Laboratory planned for construction in our city. If it is needed at all, and I would contend that it is not, then the last place you want it is in an urban center, certainly not in the largest urban center in New England.

Given Boston University's sordid record handling even modestly infectious pathogens, this lab should not be built against the wishes of the people who will be forced to live in its shadows.

Respectfully,

Bill Perkins
3 Chestnut Terrace
Jamaica Plain, MA 02130

LETTER 70
Bill Perkins

LETTER OF SUPPORT

May 10, 2005

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

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

Dear Ms. Nottingham:

I write to you with enthusiastic support of the Biosafety Lab at BUMC.

Boston University has always showed itself to be a good neighbor and has consistently shown a willingness to add value to the city of Boston.

When I first heard about the laboratory, I must admit I was a bit apprehensive. However, the staff at Boston University Medical Center took the time to address my concerns and answer all my questions about the project. Those concerns were quickly resolved with the information and clarity provided on this issue.

I feel that this lab is important to find cures for infectious diseases. We need to have the appropriate facilities to do this important research. I believe that this lab will be built safely and that the redundant systems and the security plans will ensure that we are all safe.

Also, I am especially supportive because the project will bring about economic opportunities. As I understand it, the development of this laboratory will create 1,300 construction jobs and 660 permanent jobs—jobs at all levels. Given this, the lab will have a positive economic impact at all levels in our community.

Sincerely,

Kevin C. Peterson

Community Resident and Activist
City of Boston

LETTER 71

Kevin C. Peterson

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

**Re: Supplemental Draft Environmental Impact Statement-National Emerging
Infectious Diseases Laboratories**

Dear Ms. Nottingham:

Our community needs projects like the proposed biosafety laboratory.

The biosafety lab will create jobs. Boston University Medical Center (BUMC) has said that 1300 construction jobs and 660 permanent jobs will be created. Our community needs these jobs.

In addition, BUMC has committed \$1 million to training Boston residents to be lab technicians. The training will be part of the City Lab program. After nine months, the graduates are able to find meaningful jobs at a laboratory at the medical center or in a similar laboratory in the City. This will be a great partnership and illustrates BUMC's strong commitment to our community.

I support the Biosafety Lab.

Ana Peria

LETTER 72
Ana Peria

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

**Re: Supplemental Draft Environmental Impact Statement-National Emerging
Infectious Diseases Laboratories**

Dear Ms. Nottingham:

Our community needs projects like the proposed biosafety laboratory.

The biosafety lab will create jobs. Boston University Medical Center (BUMC) has said that 1300 construction jobs and 660 permanent jobs will be created. Our community needs these jobs.

In addition, BUMC has committed \$1 million to training Boston residents to be lab technicians. The training will be part of the City Lab program. After nine months, the graduates are able to find meaningful jobs at a laboratory at the medical center or in a similar laboratory in the City. This will be a great partnership and illustrates BUMC's strong commitment to our community.

I support the Biosafety Lab.



LETTER 73
Eujenie Pires

LETTER 74
Maria Pires

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

**Re: Supplemental Draft Environmental Impact Statement-National Emerging
Infectious Diseases Laboratories**

Dear Ms. Nottingham:

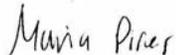
I write to you in support of the Biosafety Lab at BUMC.

When I first heard about the laboratory, I must admit I was a bit apprehensive. However, the staff at Boston University Medical Center took the time to address my concerns and answer all my questions about the project.

I feel that this lab is important to find cures for infectious diseases. We need to have the appropriate facilities to do this important research. I believe that this lab will be built safely and that the redundant systems and the security plans will ensure that we are all safe.

Also, the development of this laboratory will create 1,300 construction jobs and 660 permanent jobs—jobs at all levels. This lab will have a positive economic impact at all levels in our community.

Sincerely,



Ms. Valerie Nottingham
NIH B13/2W644
9000 Rockville Pike
Bethesda, MD. 20892

Carolyn Poiselli
36 Prince St #12
Boston Ma 02113
May 18, 2005

LETTER 75
Carolyn Poiselli

Dear Ms Nottingham,

Having reviewed the supplemental Draft Environmental Impact Statement, for the National Emerging Infectious Diseases Laboratories for the Bioscience II site in the South End of Boston, I am even more convinced that a BSL4 Lab not be located in Boston, Ma., or indeed at any of the other proposed sites owned by Boston University.

In reviewing the composition of the neighborhood, (i.e. the diversity of people living in close proximity to the project, the income and quantity of people currently being serviced by the Medical Center), I do not think it advisable to locate a facility dedicated to the research, and development of vaccines, for such incredibly dangerous viruses and pathogens, this close to such a vulnerable population. The area has many children, and elderly, and low income individuals, who would especially be vulnerable and affected by even minute adverse changes to their environment. While the study is designed to show how air, water, noise, and waste treatment facilities are all in compliance with standards, I feel as if laboratories of this nature present, not only a danger in themselves, but a potential overload to facilities. Air quality standards seem to be stable for the last 3 years, but in saying that, it implies that they had not been in

LETTER 75

Carolyn Poiselli

- 75.1 The use of autoclaves to treat pathological wastes is regulated by the state Department of Public Health. Pursuant to 105 CMR 480.500, the DPH has approved the use of certain autoclave models for such purposes. The Project would utilize autoclave devices approved by the Department.
- 75.2 As noted in Sections 4.6 and 4.7, the project would create temporary construction related air and noise impacts. To offset temporary air quality impacts, the project has committed to participating in the state Department of Environmental Protection's (DEP) diesel retrofit program for construction vehicles. Mitigation measures would be employed as necessary to minimize potential impacts of noise operations. Construction activities at the project site would comply with state DEP regulations that forbid unnecessary emissions of sound due to neglect or through failure to provide the necessary equipment or maintenance. Construction activities would also comply with the City of Boston's Noise Regulation which sets quantitative limits on noise from construction devices, applicable at the lot line of the construction site, but not closer than 50 feet from the nearest active construction device.

75.1 compliance in the past. This would make air quality a very vulnerable factor, in an area with very high asthma rates already, and it would be unwise to further discharge air that has been double filtered into the area. With the pathogens being worked on this could be life threatening. Similarly with the water system, while I'm sure it could manage the amount of water going through the system, under the most ideal situations, I'm not sure that autoclaving, and high temperatures will completely destroy all of the agents, before they are discharged into our sewerage system, and eventually into Boston Harbor. Dust, noise and construction impacts are being felt throughout Boston, in the various projects that are being, and have been constructed. Compensation to owners is not necessarily forthcoming, and the impact on the quality of life not readily realized, unless you are living next to a construction site. They are however a reality of city life, and I do expect the proposed site to be developed (hopefully in a way that will impact the surrounding neighborhoods more positively.) The depression of the Central Artery in Boston, and its incumbent flaws in construction, and leaks, being one such project. I might also point out that Boston, being a rather small city geographically, is very well used by most of the population. While I do live in another neighborhood of the city, I feel very much connected to the proposed area, through cultural and educational resources. It also is an area that many people commute through to get to other areas. The dangers incumbent on locating a BSL4 lab here are too great to be considered. Too many people of all incomes and backgrounds would be affected.

75.2

LETTER 75

Carolyn Poiselli

75.3 While diseases such as Crimean-Congo Hemorrhagic fever and Marburg Hemorrhagic fever have not been seen in the United States, other diseases such as Lassa fever and Ebola have been reported in the United States. Hantavirus has been especially prevalent in areas in the desert southwest. International travel and intentional release can make these tropical diseases local very quickly, which is why it is vital to study these agents in the effort to develop vaccines, diagnostics, and therapeutics to protect the public health from emerging infectious diseases and acts of bioterrorism.

75.3

And the types of agents being worked on in a BSL4 lab, are not found or native to the area. They would have to be imported. The viral hemorrhagic fevers, Ebola, Congo-Crimean hemorrhagic fever, Marburg, Lassa fever etc. are totally unknown to us. Indeed in reviewing the list, there are viruses from Central America, Africa, Central Asia including India and Asia itself. Rabies, tick born encephalitis, herpes, strep, staph the STD's and tuberculosis are found locally. But even diseases like Hanta virus are not found locally. And I don't think we should be importing them. We don't want, what happened to our original native population to happen to us. Even with all of your protections and safety measures if you look at major disasters worldwide, they were never designed to happen. Disasters in the nuclear industry, disasters in the Chemical Industry and I feel as if it is just a matter of time with the Biological Sciences. This facility would operate 7 days a week 24 hours a day. There is no rest built into the system. In the Judeo-Christian tradition even God had a day of rest, and called for one. I feel as if this is not only creating a highly unnatural environment, but that it goes against nature itself. To quote, "Biosafety level 4 is required for work with dangerous and exotic agents that pose a high individual risk of laboratory infections and life threatening diseases and for which there is no vaccine and no cure." I hadn't realized before I read the book, that animals including mice, possibly hamsters, guinea pigs, non human primates, wild rodents or other animals such as lambs are used, to test the vaccines. In spite of all the assurances of the ethicalness and humane treatment of the animals being tested, I would like to

LETTER 75

Carolyn Poiselli

75.4 Animal research is an essential element of defining the pathogenesis of infectious diseases and such knowledge is essential for finding diagnostic tests, treatments, therapies, and vaccines for these infectious diseases. All animals are treated according to the rules set forth by the Institutional Animal Care and Use Committee, the USDA Animal Welfare Act regulations, 9 CFR Subchapter A, and the Guide for the Care and Use of Laboratory Animals (National Research Council 1996).

75.5 There is a detailed mechanism for the recruitment of subjects, both normal volunteers and individuals with particular conditions, that complies with regulations of the Human Investigation Review Committee. This institutional committee functions under the authority of the Office for Human Research Protections at the DHHS. All protocols which involve human subjects are reviewed prior to approval. Part of the materials that are reviewed includes how subjects would be recruited. All flyers and advertisements would be approved by the Institutional Review Board before posting. In virtually all cases adult individuals are required to give informed consent prior to enrollment in an approved study. The risks and benefits of all protocols are thoroughly explained to each potential participant prior to their informed consent. BUMC does not intend to solicit any individuals who are unable to provide informed consent. Federal Regulations (45 CFR 46 Subpart C) require that an IRB must be constituted with at least one member who participates in reviews who is a prisoner or prisoner representative in order for the IRB to review research involving prisoners as subjects. The BUMC IRB does not currently review research involving prisoners as subjects. Homeless people that would like to volunteer for a study would need to give informed consent in order to participate in any study at the NEIDL; this is true of any volunteer regardless of their housing situation.

75.6 See Response to Comment 75.5.

- 75.4 Know what type of a life a laboratory animal can look forward to, when it has been infected with a disease for which there is no cure? This is unbelievably barbaric and should violate any known ethical standards within the 'civilized' world. There should be a Geneva Convention for animals, and standards which we do not violate. Things outside of this should be viewed as criminal. And to quote further, 'Clinical research space would be provided to support clinical research protocols. The clinical research facility would include reception, nursing administration and exam rooms. The facility would accommodate approximately 3000 ambulatory visits of healthy normal volunteers per year with no overnight stays. Should individuals need acute medical care, they would be transferred to the Boston Medical Center BMC.' My question is where would you get a healthy normal volunteer to go into a facility that deals with diseases, for which there is no known cure. And does society want these 3000 volunteers mixing with the general population. A further question is whether you are planning to use inmates from the adjacent house of correction in your experimentation? Will you use the homeless population, as there are shelters nearby? Will you use the physically or mentally handicapped in your experimentation? Will you use the low income and minority population in your experimentation these are some of my general questions and reservations.
- 75.5
- 75.6 To locate the facility approx 150 feet from adjacent vehicular ways, and if applicable 100 feet from pedestrian areas, is not only ludicrous, but outrageous scary. Do you actually expect this distance to serve as a buffer zone from danger or terrorism? Being in close proximity to an area such
- 75.7

LETTER 75

Carolyn Poiselli

75.7 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. The risk to the public has been found to be negligible. See Section 4.2.2.1 "Community Safety and Risk", and also Appendices 11 and 12.

LETTER 75

Carolyn Poiselli

75.8 See Response to Comment 69.5.

75.8

as a highway could also serve as an agent for transportation of disease, and infection to an outlying population. Being in close proximity to other Universities could serve to reduce the replication of services, but it could also threaten the most educated, leadership of our society. Some of the most educated critic of the BSL4 project come from our local universities. David Ozonoff from Boston University, who deplores the use to Public Health, while we fund laboratories such as this one which would research disease, that not only do not affect our population, but also proportionally do not affect the majority of the world's population. Jonathan King from MIT who regularly gives compelling argument against the construction of such a laboratory, himself a microbiologist. Sheldon Krinsky from Tufts who has also spoken out. And many others. A list of signers to the "No Place to Hide Letter." If they coming from a place of education and knowing have such a committed opposition to this project, how do you think the general population feels toward this project, which will make quince parts of us all in subjecting us and our environment to your incurable diseases. US our elected officials are salivating over the money they stand to make on this project and the taxes that accrue. But I'm sure this site will be developed, and with a Medical consideration, whether it be for less lethal testing or for additional clinical services to be used by the neighborhoods and outlying areas even more jobs could be generated, and people would definitely feel safer were such a project initiated. Indeed the community has felt that Boston University has ignored community concerns and requests for information in spite of all

the meetings they have called. Professionals on both sides have never been called together, to debate each other. This and the feeling that the project, has lacked transparency with no change to this policy. Just alot of official rhetoric.

I haven't addressed the threat of terrorism, which I feel could be significant. Haven't addressed the lack of compensation to the neighborhood, which I feel is insignificant. Haven't addressed the waste of money, and resources which I feel as if this project ignores, at the expense of public health. Haven't addressed the lack of good jobs for the neighborhood which this project will not address. Haven't addressed the public's right to know and lack of oversight over the laboratories activities.

I will say that this laboratory does not belong in a residential neighborhood, where so many people are left vulnerable. No other BSL4 lab is located within a population center, and it is unfair to place one here. The city of Boston has not come up with an evacuation plan for the city should a worst case scenario be created. Further I attended a city of Boston city council meeting, untitled due, BZ violations of Boston University since 2000. BZ violations from a variety of laboratories run by Boston University, is alot of violations in 4 or 5 years. Examples such as dumping mercury into our sewerage system are not minor offenses to be dealt with by a fine. In a situation such as a BSL4 lab, such oversight could be catastrophic for the neighborhood and the city. It is for these reasons that I request that Boston University's request for this facility be denied. It is being pushed by the developers, not the people. We don't want it. Whether Public Health should

LETTER 75

Carolyn Poiselli

be funded or laboratories for exotic, life threatening diseases is the question of our times. Medicine for the people or medicine for the corporate profit, and military establishment. People I talk to all have serious reservations about this laboratory, and you should too. It's a matter of national policy and what will serve the nation as a whole. A healthy population with access to services, or laboratories which test exotic diseases, for which there is no known cure, and which the majority of people will never suffer from, should these labs not be built. Especially vulnerable are the residents in close proximity to the project, and in many cases, they have been most vulnerable. But the rest of US stand to loose as well. The economy, as my city council argues, is not a good reason to build this lab. So I ask you to consider not funding this project at this time, and rethinking what would serve the community and nation most at this time.

Thank you for your time and consideration in sending me this book for review. While I have not covered all of my concerns I have touched on many, and plan to continue using the data in the book, to look at medical alternatives which would best benefit the community. Boston University does not have a health and safety record that would give me confidence in having a facility built in the heart of Boston. And I look forward to hearing from you in the future.

Sincerely,
Carolyn Poiselli

LETTER 75

Carolyn Poiselli

Virginia Pratt
7 Segal Street #3
Jamaica Plain, MA

April 25, 2005

02130

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

Dear Ms. Nottingham,

76.1 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.

76.2

76.3

76.4 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,



LETTER 76

Virginia Pratt

76.1 See Response to Comment 1.1.

76.2 See Response to Comment 1.2.

76.3 See Response to Comment 1.3.

76.4 See Response to Comment 1.4.



United States Department of the Interior

OFFICE OF THE SECRETARY
Office of Environmental Policy and Compliance
408 Atlantic Avenue - Room 142
Boston, Massachusetts 02210-3334

May 13, 2005

ER 05/323

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

Dear Ms. Nottingham:

The Department of the Interior has reviewed the March 2005 Supplemental Draft Environmental Impact Statement (SDEIS) for the National Emerging Infectious Diseases Laboratories, Boston, Suffolk County, Massachusetts. The Department has the following comment on the SDEIS:

Page 3-35, Section 3.10.10 Groundwater Quality, first sentence. Ground-water quantity is not described explicitly in the report. However, if depth to ground water at the site is 5 to 11 feet, a building foundation and basement(s) are likely to penetrate the ground-water table. Impacts including dewatering during construction, drainage during operation, and any possible diversions of local ground-water flow paths around the foundation or basement(s) should be considered in the assessment. If you have any questions concerning this comment, please contact Mr. Lloyd Woosley, Chief, U.S. Geological Survey Environmental Affairs Program, at (703) 648-5028 or at lwoosley@usgs.gov.

Thank you for the opportunity to review the SDEIS. Please feel free to contact me at (617) 223-8565 if I can be any further assistance.

Sincerely,

Andrew L. Raddant /s/
Regional Environmental Officer

LETTER 77

Andrew L. Raddant

77.1 The depth to groundwater at the project site is between 5 and 11 feet. The grade at the site would be increased by 1 to 2 feet above existing grade. Because the proposed building does not have a basement but would consist of a concrete slab foundation constructed to a depth of 4 to 8 feet below the finished grade of the site, there would be no penetration of the groundwater table.

77.1

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: BU bioterrorism lab

-----Original Message-----

From: monica raymond [mailto:tiferet@postmark.net]
Sent: Wednesday, May 18, 2005 10:18 AM
To: NIH NEPA Comments
Subject: BU bioterrorism lab

Dear NIH--

I'm writing to express my profound concern about siting the D4 bioterrorism lab in the South End/Roxbury area of Boston.

78.1



This is a far more populous area than other D4 labs around the country, and BU (notably in the recent tularemia scandal) has shown in the past that it is capable of a level of carelessness that would be absolutely inappropriate for a lab containing toxins like the ones proposed for research here.

78.2



The worst case scenario should include the other toxins that might be worked on at this lab, not only anthrax; it should include the possibility of a release during transport through the streets of Boston, and it should be made public.

I live in Cambridge, just across the river from BU, but I cannot expect that disease causing agents will be any respecter of civic boundaries. Moreover, there has already been substantial objection from those living in the immediate vicinity of the lab. That there has not been more has less to do with people's faith in BU's safety precautions, and more with the onslaught of things that confront us all daily, and, perhaps, people's inability to really envision the disastrous outcome of an accident at this proposed lab.

It makes so little sense to me to site a lab dealing with such toxic substances in the middle of a highly populated and intellectually crucial area that I wonder why you are even considering this choice.

Thank you for your attention to these objections, and your consideration of alternative sites.

Yours sincerely,

Monica Raymond

monica raymond
tiferet@postmark.net

LETTER 78

Monica Raymond

78.1 See Responses to Comments 29.9 and 19.2.

78.2 Anthrax was chosen for use in the worst case scenario evaluations because the Centers for Disease Control and Prevention determined that second to smallpox (possession is restricted under international agreement), anthrax has the greatest potential for public health harm. The 2002 report, *Public Health Assessment of Potential Biological Terrorism Agents* (Rotz, et al. 2002) outlines the overall selection and prioritization process used to determine the biological agents for public health preparedness activities. This report was used as a basis for using anthrax in worst case modeling.