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August 24, 2012

By EMAIL (NIH_BRP@od.nih.gov)
and FIRST CLASS MAIL

National Institutes of Health
Attn: NEIDL Risk Assessment
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892-7985

Re: Final Supplementary Risk Assessment for the Boston University National Emerging Infectious Diseases Laboratories

Dear Sir or Madam:

We represent the plaintiffs in federal and state lawsuits regarding the proposed National Emerging Infectious Diseases Laboratories (the “NEIDL”) at Boston University (“BU”)/Boston University Medical Center. *Allen et al. v. National Institutes of Health et al.*, Civil Action No. 06-10877-PBS (D. Mass.); *Ten Residents of Boston v. Boston Redevelopment Authority et al.*, Civil Action No. 5-0109-BLS1 (consolidated with No. 5-02665) (Suffolk Sup. Ct.). This letter provides our clients’ comments regarding the Final Supplementary Risk Assessment (“RA”) for the NEIDL. Although the RA purports to respond to each public comment individually, the responses provided by the National Institutes of Health (“NIH”) still fail to address the concerns raised by community members in response to the draft RA issued in February 2012, particularly those comments concerning feasible alternatives to the NEIDL and its proposed location and the potential risks of the NEIDL to nearby environmental justice (“EJ”) communities, including the risk of malevolent attack. For these reasons, and those set out in further detail below, we incorporate by reference our comments on the draft RA submitted on May 1, 2012, and continue to request that NIH withdraw the RA and initiate a public process to reconsider alternative uses for the NEIDL.

A. The RA remains overly dense and inaccessible to a lay audience.

In its Letter Report dated December 15, 2011 regarding the 90% Draft of the RA (the “Letter Report”), the National Research Council’s Committee on Continuing Assistance to the National Institutes of Health on Preparation of Additional Risk Assessments (the “NRC”) noted that the draft was “an extremely large and technically complex document.” It strongly recommended that “both an Executive Summary written for the lay audience and a summary of Chapter 11 that

synthesizes and interprets the major findings of the RA in plain language be developed to facilitate public understanding.” Letter Report at 8. Although NIH has included a summary of public comments and responses in the RA, it has not added any useful summaries or taken other steps to address this fundamental issue of readability. As noted in our May comments, a dense and meandering RA fails to comply with Council on Environmental Quality (“CEQ”) guidance urging federal agencies to prepare “concise,” “plain language” NEPA documents that “focus on significant issues” and discuss impacts “in proportion to their significance” rather than producing “an encyclopedia of all applicable information.” Nancy H. Sutley, Chair, CEQ, *Memorandum for Heads of Federal Departments and Agencies re: Improving the Process for Preparing Efficient and Timely Environmental Reviews under the National Environmental Policy Act* (Mar. 6, 2012).¹

B. The RA, like previous risk assessments of the NEIDL, fails to meaningfully analyze alternatives or the risk of a malevolent attack.

Despite the urgings of courts, the NRC and the public, the RA, like previous drafts, avoids meaningful discussion of why the risks associated with the NEIDL justify its placement in a densely populated urban neighborhood rather than an alternative, less dense one. In particular, the discussion of the potential for secondary transmission between sites is inappropriately brief given its importance to the ultimate siting decision and the Massachusetts Supreme Judicial Court’s emphasis on a study of alternatives in the context of secondary transmission. *Allen v. Boston Redev. Auth.*, 450 Mass. 242 (2007). The RA also continues to suffer from a lack of data on commuting patterns that have the potential to greatly affect the probability of an infected person’s contact with other members of the public. Although NIH claims this information is unavailable, that is not the case; portions of the NEIDL are currently staffed and operational, providing real data on commuting patterns.

The RA responds to prior requests for a fuller alternatives analysis by noting that to study alternatives, NIH would have to develop alternatives to a “comparable level of detail.” Even if this were the case, the RA does not actually develop the other alternatives studied to comparable levels of detail. Instead, it “assumed the risk of a release from the facility was constant regardless of location” and that building design and operations would not differ by location. RA at Appendix O-102. The RA thus effectively substitutes the Boston urban location’s details for all of the unstudied details of the alternative rural and suburban site. Not surprisingly, after doing so, the alternatives locations do not seem so different. An analysis of alternatives that assumes that the alternatives are the same in almost every meaningful respect (and that the resulting risk will be the same) is insufficient and, in fact, no analysis at all.

The disregard for differences in potential threats among the potential sites is most apparent in the RA’s treatment of the risk of a malevolent attack. The RA, particularly in NIH’s response to public comments, repeatedly asserts that, since the consequences of malevolent acts are

¹ Despite NIH’s assertions to the contrary, the “*Readers’ Guide*”, on which it sought no public comments and which does not provide a summary of its conclusions, does not satisfy this purpose.

presumed to be similar to those from accidental or natural occurrences such as needlestick incidents and earthquakes, no further analysis of the probability of such attacks is necessary.

As we explained in our May letter, this cursory treatment is flawed for two reasons. First, the consequences of a natural disaster and those of a malevolent attack *intended* to harm a large number of individuals are fundamentally different. An earthquake cannot target the most vulnerable points of the NEIDL structure, but the planner of a malevolent attack can, and presumably would, focus on specific portions of the laboratory or the release of specific pathogens. Further, a malevolent attack may have non-pathogen related consequences (*e.g.*, fire, building collapse, violence in order to obtain pathogens) that are not included within the worst-case natural disaster scenarios.

Second, even if the consequences of a malevolent attack and an accidental or natural occurrence were equal, their probability is not. The RA ignores this argument, responding only with the irrelevant statement that NIH used several variables, not only the CAP Index, to define potential threats at each of the three sites. RA at Appendix O-162; O-102. This is an insufficient response to one of the central questions raised repeatedly in the decade since the NEIDL was first proposed. The likelihood that the NEIDL would attract malevolent activity is a demonstrated key concern of both the local community and the courts and should be addressed in determining the suitability of its location and the adequacy of its structural and operational protections. *See Ten Residents of Boston v. Boston Redevelopment Authority*, 21 Mass. L. Rptr. 324, 2006 WL 2440043 at *10 (Mass. Super. 2006) (listing several categories of risks of potential malevolent attack).

C. The “community outreach” and local oversight institutions referred to in the RA do not adequately involve or protect the public.

In its responses to public comments, NIH claims that it has “actively and extensively engaged the community and has sought community input throughout the supplementary risk assessment process.” RA at Appendix O-117. The community members we represent, as named plaintiffs to the aforementioned litigation and members of the Conservation Law Foundation and Lawyers Committee for Civil Rights, disagree. As explained in our May letter, BU’s Community Liaison Committee (the “CLC”) has been an ineffective and illusory link with community members due to its lack of rotation in membership and inconvenient meeting times, and its meetings are thus sparsely attended. Other examples of public outreach referenced in the RA, such as the telecasting of meetings online (often with significant technological flaws) and the use of the Federal Register, can hardly be expected to fill the gap of a meaningful public process in which community members are consulted and listened to. For instance, throughout the RA’s Appendix O, NIH either dismisses or glosses over community member’s comments or declares them beyond the RA’s scope. In fact, except in response to comments from BU and a limited number of our May comments regarding the earthquake risk, NIH did little to revise the text of the RA in response to public comments.

The local oversight institutions referred to in the RA are also unresponsive to community concerns. BU's Institutional Biosafety Committee ("IBC") is an internal organization and not accountable to community members. The Boston Public Health Commission (the "BPHC"), which the RA asserts "represents residents," includes BU executives on its board. It has also earned community members' distrust by refusing to provide meaningful access to public records regarding the NEIDL for well over a year since they were requested. Further, NIH's reliance on the BPHC as a regulator of lab safety is misguided. No BSL-4 laboratories currently exist in the City of Boston and the BPHC has not shown any aptitude or experience in regulating the risks from such facilities. Finally, even if BPHC were accountable to community members, the RA fails to discuss how the BPHC will provide day-to-day enforcement and oversight of NEIDL operations and safety protocols.²

D. The RA once again ignores the EJ issues surrounding the NEIDL.

In our May comment letter, we noted that the draft RA inadequately address the NRC's comments that the document included statements that "imply that the major concern in [the EJ] area is differences in population density among sites." Letter Report at 9. We noted that "[w]here a discussion of EJ does exist, it is often limited to identifying EJ communities rather than addressing the potential impacts of the NEIDL on them" and that there was limited discussion of the specific features of Boston's EJ communities. In response, NIH has offered a list of citations in the RA where Medically Vulnerable Subpopulations are discussed. RA at O-102. As important as the discussion of MVSPs may be, it is no substitute for an analysis of the environmental justice issues involved in siting the NEIDL in a densely-populated urban environment.

As we stated in May, the data required for NIH to engage in this discussion are not beyond its reach. The effects of factors such as density of dwelling units, the use of public transportation and commuting patterns are knowable; they can be documented through census data and transportation and sociological studies. Such data would be expected to demonstrate that individuals with a lower economic status are more likely to live in densely populated dwellings (including public or subsidized housing) and to use public transportation more frequently than individuals with a higher economic status. These factors bring individuals into contact with others, including potentially infected NEIDL workers, more frequently than individuals residing in single-family housing or commuting in personal vehicles, and thus could affect secondary transmission in urban, suburban, and rural areas differently. Similarly, the RA points to a lack of published data on the effect of particular pathogens on EJ communities as an explanation for its failure to assess that particular risk. Remarkably, however, NIH makes *no* attempt to extrapolate from data on similar diseases or symptoms to better understand the potential and effect of secondary transmission on these communities. Relevant comparable data should be analyzed to determine if locating the lab in this EJ community is riskier than locating it at other sites. This analysis is integral to a proper comparison of alternatives.

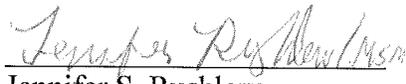
² NIH falsely states that our clients failed to comment on a Community Outreach Plan. In fact, our clients filed such a plan with the federal district court on January 10, 2007.

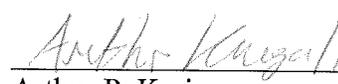
E. Conclusion

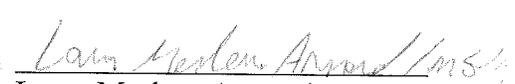
For the reasons above, our clients remain frustrated with NIH's latest attempt to use the NEPA process to offer a post-hoc rationalization of an ill-conceived idea rather than an honest analysis of alternatives. Although several paragraphs were revised in response to comments from BU and the BPHC, most comments by NEIDL opponents were dismissed, explained away by the very language they called into question, or simply glossed over. It is clear from the RA, and particularly NIH's responses to these comments, that it has not engaged in a thoughtful consideration of why a project involving dangerous research like the NEIDL can justifiably be located in a densely populated, urban, EJ neighborhood, especially when undeniably safer alternatives exist. We therefore repeat our request that NIH withdraw the RA, adequately address the comments presented above and in prior public comments fully and fairly, and reconsider the need for BSL-3 and 4 research at the NEIDL through an open public process.

Thank you for your consideration.

Sincerely,


Jennifer S. Rushlow
Conservation Law Foundation


Arthur P. Kreiger
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Laura Maslow-Armand
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Rights Under Law of the Boston
Bar Association

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