CRG Council for Responsible Genetics

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September 23, 2011

Secretary Richard K. Sullivan, Jr.
Executive Office of Energy and Environmental Affairs
100 Cambridge Street, Suite 900
Boston, MA 02114

Re: National Emerging Infectious Diseases Laboratories,
Boston University MEPA Waiver Request, EOEEA #12021

Dear Secretary Sullivan:

I represent the Council for Responsible Genetics (CRG), a non-profit organization that has served the public interest for over 25 years in addressing the social and ethical implications of emerging issues in biotechnology. CRG was one of the early proponents for Federal guidelines to address safety issues related to recombinant DNA research and worked for many years promoting Massachusetts guidelines on biosafety. We are currently working with Assistant Secretary of Labor for Safety and Health David Michaels to revise OSHA guidelines on biolab safety.

We are writing to urge you to deny Boston University's ("BU's") request for a Phase One waiver from applicable MEPA regulations in connection with its proposed operation of the National Emerging Infectious Diseases Laboratories (the "NEIDL") at Boston University Medical Center. The requested waiver would allow BU to open BSL-1 and BSL-2 laboratories immediately. It would allow BU to open BSL-3 laboratories and conduct research on highly contagious pathogens in the NEIDL, all without further MEPA review. The waiver would circumvent judicially-mandated environmental reviews put in place in order to ensure that the surrounding communities are not subjected to unnecessary risks associated with conducting research on potentially lethal pathogens in densely-populated urban neighborhoods.

The University uses the proliferation of BSL-2 labs as a reason justifying a waiver of review. We believe it merits quite the opposite. BSL-2 labs handle biological materials that pose significant risks to health, safety and the environment. BSL-2 labs employ the largest number of researchers of any type of biolab, they conduct research on the largest variety of organisms and pathogens, including genetically modified organisms and yet they employ the least stringent training programs of any kind of biolab. Furthermore, working practices in these laboratories are not standardized nor are they well documented. This fact is highlighted by the large numbers of infections documented in BSL-2 laboratories as a result of non-compliance with guidelines and regulations. Indeed, the three Boston University laboratory workers that became infected with tularemia (rabbit fever) a few years ago were working with it in a BSL-2 lab. Due to its high virulence, the strain of pathogen in question is considered a category A agent by the Centers for Disease Control and a viable bioweapons agent; it has been included in the biological warfare programs of the USA, Russia and Japan at various times and clearly should have merited enhanced protections including being located in a higher level biocontainment facility. Yet, an investigation by the Boston Public Health

Commission found that "the BU Institutional Biosafety Committee was not able to ensure compliance with appropriate laboratory protocols and procedures." Moreover they found that the University's "failure to identify…and immediately report suspicious work-related illness in staff is a major concern for health officials."

Finally BSL-2 laboratories "seed" higher containment facilities. A lax approach to biosafety and security at BSL-2 laboratories therefore has implications for higher containment facilities, particularly where those facilities are both located in the same complex and integrated with higher biosafety level facilities as proposed by Boston University. Indeed, under certain modified circumstances, research normally confined to BSL-3 labs may be conducted in BSL-2 labs. There have been no assurances from the University that such won't take place.

It is even more egregious that Boston University should seek a waiver for a proposed BSL-3 facility. By definition, BSL-3 labs include work done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by inhalation. Pathogens such as M. tuberculosis, St. Louis encephalitis virus and Coxiella burnetii are regularly studied in such facilities. Significant safety practices and procedures as well as oversight are required.

Since proposing the NEIDL in 2003, BU has repeatedly provided vague and incorrect information regarding the project. Most important, it has failed on multiple occasions to meet its obligation to prepare an adequate and scientifically credible assessment of the risks associated with research in the NEIDL.

For these reasons, we ask that you deny the waiver request and retain full jurisdiction to review the risk assessment for *all* labs located in the NEIDL. Such a denial would allow the project to receive full MEPA review as has been anticipated by both community members and the courts and ensure that public health and safety remain primary considerations.

Sincerely,

Jeremy Gruber
President
Council for Responsible Genetics