AN OPEN LETTER TO BIODEFENSE DECISION MAKERS
April 2012

Three years ago citizen groups from around the country expressed their concerns about the proliferation of high containment biodefense laboratories**.** These concerns are detailed in the attached report. Citizens facing the reality or prospects of high containment biodefense labs in their communities were troubled by the absence of a coherent federal policy for how much laboratory capacity is needed, what should be the research priorities, and how to insure the safety of these labs.

Now, others nation-wide join those who petitioned three years ago in making clear our united conviction that the spread of these labs makes us all less safe. Our understanding of the risks associated with the proliferation of biodefense laboratories has only intensified in the ensuing years. And so we, the undersigned, write again to urge federal and state decision-makers to heed the call of those most affected and to place a moratorium on the opening of new biodefense facilities until there has been a serious and transparent reevaluation of the entire program.

The overall decrease in funding for bio-defense research in the 2013 budget, the absence of funding for construction of the NBAF lab in Kansas, and the decision to halt plans for the Medical Countermeasures Test & Evaluation Facility at Ft. Detrick provide an opportunity to re-evaluate priorities and restrict further growth. But the funding cutbacks may also threaten the maintenance of safety standards and encourage the competitive race for research grants and facilities, regardless of their contribution to health security, or the safety performance of the institutions. Indeed, we worry that the cutbacks at particular sites make others such as the NEIDL at Boston University more vulnerable. We are concerned that if approved for operation, the NEIDL as well as other labs will be used for unknown purposes. We still do not see a coherent overall policy, as made shockingly clear by Wil S. Hylton in the New York Times in late October 2011.

We have learned a great deal in recent years about risks we were not told about by those promoting laboratory expansion. Controversy over the dangers posed by the creation of a highly contagious form of bird flu points to the limits of government control over critical decisions. The Center for Disease Control took a year and a half to report the plague-related death of a University of Chicago researcher. Similarly, the *Salmonella* typhimurium outbreak that sickened 109 people in 38 states has finally been linked by the CDC to faulty lab training practices. The secrecy and lack of transparency of the incident reporting process means communities most directly affected by the presence of these dangerous labs are often the last to learn of mishaps.

There has been a great deal of discussion in Washington and in the biodefense industry during the past several years about virtually all of the issues communities raised in the attached letter. Additional safety procedures have been promulgated. Some policies have been modified. However, there has been little progress on the core issues associated with the proliferation of biodefense research, as discussed in our letter. Instead, Public Health funding has been slashed**.** Meaningful evaluation of the U.S.'s approach to dealing with natural or manmade biological threats has not occurred**.** Transparency about the research agenda remains elusive. And consequently, the U.S.'s research intent continues to be suspect internationally even as the Biological Weapons Convention is being reviewed.

We are dismayed about how relevant the attached letter remains, all these years later. We ask again, urgently, that our government take a fundamental look at what it is doing with its biodefense research programs and halt construction and commissioning of new BSL-3 and 4 biodefense laboratories until it has done so.

Biodefense Research and Development Policy: A Citizen Perspective

*The U.S. does not yet have a rational approach to determining **how much** biodefense laboratory capacity is needed, **what research** we should be doing, and **how to ensure** it is being conducted **safely.***

Part 1: The concern

We, the undersigned, face the reality or prospect of federally-funded high containment biodefense labs being situated in our communities. We represent citizen groups from many localities throughout the U.S. who have specific health, safety and environmental concerns about their presence in our neighborhoods and cities. We are united in our belief that the proliferation of these laboratories represents a significant threat not just to our communities, but also to our nation, and the world. We agree with Biological Weapons Convention non-proliferation experts that we risk creating a biowarfare arms race with those who do not trust and cannot verify U.S. intentions. The spread of these labs makes us all less safe.

Since the August 2008 revelations that the 2001 anthrax letters originated from within the premier U.S. biodefense lab, it has become tragically clear that Congress must move quickly to re-evaluate the nation's biodefense programs. We share many concerns about the expansion of bio-safety level 3 and 4 laboratories in federal facilities, and in the hundreds of poorly regulated or unregulated academic and private sector laboratories around the country.

- **Failure to acknowledge community concerns.** We have tried in numerous ways to call attention to problems of community safety and the limited roles afforded citizens in communities where laboratories are proposed and sited. And we have experienced years of dismissive responses to these concerns from those promoting and funding laboratory expansion. The anthrax letters case, bio-lab accidents and security breaches reported in the last several years make clear that the specific and repeatedly dismissed health, safety, and environmental concerns communities have raised are real and require a more adequate response.

- **Flawed risk assessments.** In each of our communities, we have found that environmental impacts and hazards associated with these labs have not been analyzed with thoroughness, clarity and scientific rigor. It is not possible to mitigate unacknowledged risks. In particular, we have been appalled by the failure to take environmental justice considerations into account in siting laboratories. Additionally, there has been inadequate community input to the planning and design of risk assessments, resulting in assessments that do not reflect community concerns.

- **Accidents.** Initially we were told that there was virtually no possibility of accidents in high containment labs; it has become clear however that many laboratory accidents have occurred and many have gone unreported. This is demonstrated by the tularemia infections at Boston University, revealed by a whistle blower, and the Brucella infections at Texas A & M, uncovered by the Sunshine Project. The CDC has records on more than 100 reported accidents in the past several years in Level 3 and 4 labs.

- **Lack of effective regulation.** It has also become clear that laboratory regulation and oversight are poor, as detailed by the Government Accountability Office in 2007 and 2008. The GAO reports that safety programs and protocols are inadequate and have not been followed with consistency and rigor. Many

private and academic BSL-3 laboratories are essentially unregulated.

- **Lack of transparency.** Transparency is a prerequisite for effective oversight, for establishing trust with communities and with others who may not trust the intentions of the United States. It is required to make the Biological Weapons Convention a viable treaty. Yet the work conducted in U.S. biodefense labs is not transparent. Despite great effort, community groups have been unable to obtain vital information about what is actually happening or planned for these laboratories. Security concerns are used as an excuse to restrict citizen access to reports of ongoing or planned studies. Freedom of Information Act requests about accidents and the minutes of Institutional Biosafety Committee meetings are routinely denied.

- **Defining acceptable risks.** "Low-probability" but "high-consequence" accidents that could result in a public health disaster in our communities are of great concern. Who decides what is an acceptable level of risk? Should an academic institution, a corporation, or a federal agency decide what is acceptable risk for the at-risk citizens?

Our concerns extend far beyond our individual communities.

- **Dangerous growth in labs and workers handling select agents.** We are sobered by the fact that since the anthrax letter attacks, the number of workers in these labs has grown from a small number to over 16,000; bio-safety laboratory space has grown up to twenty-fold since 2001. Yet by most accounts, including the GAO and the World at Risk report, the "unbridled increase" in research and development with bio-warfare pathogens has made the world less safe.

- **Poor research agenda oversight.** The research agenda of U.S. biodefense programs has also expanded greatly in the wake of the 2001 anthrax letters. Who sets priorities for biodefense research? For example, who decided it was acceptable to genetically recreate, transport, and do research on the formerly extinct 1918 flu virus, regardless of the risks involved? There are far too many comparable examples.

- **Misplaced funding priorities.** Since 2001, there has been an exponential increase in funding for biodefense research on exotic pathogens posing theoretical risks, while funding for infectious disease research has declined slightly. In 2005, more than 750 scientists, including Nobel Prize-winners, decried the diversion of funds to biodefense programs away from vital and pressing research of broad applicability on infectious diseases and pandemics.

- **Dual-use research hazards.** We are concerned about the threats associated with exotic, genetically modified pathogens, which can serve as bio-weapons agents. Dual-use research is either offensive or defensive, based only upon intent. Much BSL-3 and BSL-4 research is dual-use by its very nature, which increases the risk of misuse, and can raise serious questions about U.S. compliance with the Biological Weapons Convention.

- **Risk of internal sabotage.** Now we also know that the possibility of internal sabotage is quite real. We have been told officially that both the weaponized anthrax and the perpetrator of the only bio-terror attack in our history came from within the U.S. biodefense program.

We need a new policy and a new model for responding to biothreats.

We cannot afford to simply continue the uncritical bio-defense building boom of the last eight years.

- **We need an integrated, coherent federal policy.** Since 2001, biodefense funding has provided a $60+

billion economic boon, much of it for the private sector. Biodefense programs are spread among many federal departments. However, according to the GAO and others these programs are frequently duplicative and poorly coordinated. We have seen no evidence of an integrated federal policy, still less one openly debated by Congress. Congress needs to evaluate current research and development priorities, funding levels and research requirements in relation to verifiable threats to human and livestock health. Our country needs a fact-based assessment of biological threats, both natural and man-made.

- **We need to demilitarize biomedical research.** We are aware that intense debate is taking place within the scientific community about whether or not much of the current biodefense research agenda is relevant to, or would be effective in protecting the population against natural or intentional biological threats. The emphasis on national defense in biomedical research results in profoundly different programs than those that would be based upon a public health and civic model. For instance, the focus of biodefense research on "one bug, one drug" strategies has become dominant at the expense of the development of broad-spectrum counter-measures which could be much more useful in situations like the current swine-flu pandemic. At the same time, funding has been cut for public health programs and local preparedness against potential natural or lab-generated outbreaks.

- **We need a stand down and a time out.** We need a national moratorium on the opening of new biodefense facilities and, simultaneously, a serious and transparent reevaluation of the big picture. We need a great many more answers before our government pours yet more money into these programs and creates new public health risks and international strain.

Will the concerns of citizens be heard?

The concerns of citizens are easily drowned out or dismissed amid the many voices representing financial, academic and political interests. We offer the following recommendations in hopes that the perspective of the public will at last be heard in this new Congress and Administration. We do not attempt to address all aspects of bio-defense policy, but focus specifically on the need to curb the proliferation of high containment bio-safety laboratories in our communities and to create a transparent, integrated system for federal oversight and regulation of research and development activities with select agents and other dangerous pathogens.

Part 2: Actions for the Congress and the Administration

We believe that there is an urgent need for action by the current Congress and by the Obama administration. In September 2009, the Government Accountability Office made many of these same recommendations. Consistent with standard procedures for other federal science programs that pose potential threats to health and safety, we call upon our elected representatives to:

1. Call an immediate halt to development of new biodefense facilities and those that are not yet operational, until the many serious questions have been resolved:

Questions include those related to:

- public safety,
- appropriate locations for high containment laboratories,
- biosafety and biosurety compliance,

- laboratory regulation,
- select agent use and control,
- dual-use research,
- citizen involvement,
- risk of bioweapons proliferation.

2. Conduct a top-to-bottom review of the biodefense program and spending priorities, based upon scientifically credible assessments that are independent of economic interests.

The review should include:

- A complete evaluation of the nation's current bio-research capacity.

- A sound risk assessment of natural bio-threats and potential bio-terrorism threat, and ways that threat can be addressed.

  *Note: We are familiar with earlier assessments, and the serious criticisms by the National Research Council about how they were conducted. (*http://www.nap.edu/catalog.php?record_id=12206) *We also note that the 2006 Homeland Security risk assessment was conducted by Battelle laboratories, a leading beneficiary of biodefense laboratory funding.*

- Evaluation of the efficacy of dual-use research with select agents in protecting the population from bio-threats.

3. Make a real commitment to other approaches to threat mitigation such as international diplomacy and public health measures.

- Make the U.S. a real partner to the Biological Weapons Convention by agreeing to international monitoring and signing the implementation protocols of the treaty.

- Work diplomatically to contain the bio-weapons arms race that has begun to flourish amid the increased research.

- Refocus research onto existing public health risks.

4. Create a single, integrated, comprehensive system for federal oversight of <u>all</u> biodefense and bio-safety lab research, federal, academic and private.

- Consolidate the current diffuse, multi-agency regulatory and oversight systems.

- Develop and implement mandatory lab practices standards against which oversight can be conducted.

- Develop and implement a system of mandatory licensing and high level security clearances for all who work with select agents, and other dangerous pathogens.

- Establish a National Bio-Safety Facilities Safety Board to implement a system of independent safety reviews of <u>all</u> bio-labs, with mandatory compliance for remediation of safety violations, and

reporting directly to Congress. This Board could be based upon the successful model of the Defense Nuclear Facilities Safety Board, which monitors the nuclear weapons complex. *See attached proposal for details.*

- Require transparency to Congress and the public, about lab practices, accidents, research agenda and what pathogens are being used at labs.

  Note: Recommendations such as these have been made by virtually every governmental and non-governmental report dealing with U.S. biodefense in the past several years. Practices involving significant oversight and regulation have long been an assumed way of doing business for those working with nuclear materials. Licensing of professionals who deal with matters of public safety is universal, from medical professionals to airline pilots. In all these cases there is an agreed civic understanding, a social contract that assumes that the public risks associated with the work of these individuals require such regulation. It is time the same is done for work with biological pathogens that represent a danger to the general public.

5. Give citizens a meaningful place at the table as these changes are made.

- There will need to be more hearings in Congress and in local communities in order to determine how best to move forward. **Include the expert testimony of those of us living with current and proposed bio-defense laboratories in our communities.** We have a personal investment in safety, the unique perspective of "front-row seats," and a wealth of detailed knowledge about the issues. We are not paid lobbyists pro or con. We are the people directly impacted.

- Communities are significant stakeholders and should have key roles in the siting, design, regulation and operation of bio-safety laboratories. Both the general public and local governments need to be involved because their interests are not necessarily the same. While local officials may have economic interests in inviting laboratories into their communities, citizens may have different vulnerabilities and concerns. **Citizen input needs to directly inform all aspects of laboratory planning, design, development and operations.** There needs to be a new model, a new mechanism to insure that this happens. What is required is a process and culture of accountability to communities, rather than a culture that patronizes communities.

<u>In conclusion, we want to emphasize that the difficulty in regulating cannot be an excuse for inaction</u>.

We recognize the unique nature of biological research that makes finding solutions to regulation and oversight difficult. We realize that some beginning steps have been taken to address some of our concerns since the summer of 2008, when the country was focused on the anthrax letters case. We understand and support the importance of basic bio-medical research that bears unexpected and important fruit. Yes, it is the century of biology, with all of its extraordinary promise for human health.

But ***difficult*** cannot be an excuse for the current lack of oversight, and the dangerous practices that have been occurring in so many of these labs. We cannot continue to use the internally generated anthrax letters as a justification for unbridled research with select agents, particularly in high population communities.

First steps have been taken, but without a fundamental look at biodefense research and development policy. It is imperative that we be clear about spending our research dollars to address real and present threats to human health. It is imperative that the nation step off the bio-defense bandwagon, take a deep breath and embark upon a path that does not create more risks than it fixes.

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Testimony of Edward Hammond, the Sunshine Project: http://energycommerce.house.gov/images/stories/Documents/Hearings/PDF/110-oi-hrg.100407.Hammond-testimony.pdf

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