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# Biosafety Regulations: Who's Watching the Lab?

## Safety in High Risk Infectious Diseases Research

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### INTRODUCTION

Scientists debate whether the recent recreation of the 1918 flu virus, one of the deadliest diseases known,<sup>1</sup> will help prevent another pandemic or will trigger one.<sup>2</sup> Some scientists have applauded the identification of the full genome sequence of the virus. These scientists have argued that learning how the virus started and why it was so deadly will improve the response to the next potential pandemic flu and help avoid a repetition of the worldwide loss of life experienced in 1918.<sup>3</sup> Other scientists worry that the risk of the virus escaping is too great.<sup>4</sup> For example, Barbara Hatch Rosenberg, a molecular biologist and member of the Federation of American Scientists' Working Group on Biological Weapons, has said that the 1918 flu strain "would be extremely dangerous should it escape, and there is a long history of things escaping."<sup>5</sup>

Research on the 1918 flu and other highly infectious and deadly diseases has the

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<sup>1</sup> The 1918 flu virus, also known as Spanish influenza, is thought to have killed approximately 50 million people. Andreas von Bubnoff, *The 1918 Flu Virus is Resurrected*, 437 NATURE 794, 794 (Oct. 2005).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

<sup>5</sup> *Id.* at 795.

potential to make great advances in science and protect the public from the potentially devastating consequences of a disease outbreak;<sup>6</sup> however, it must be done in a safe manner. Government regulations from a number of different agencies address certain aspects of infectious disease research<sup>7</sup> and voluntary federal guidelines provide recommended laboratory safety standards,<sup>8</sup> but the current targeted regulations and voluntary guidelines are not enough. Laboratories and institutions are, for the most part, left to decide for themselves what safety protocols are needed for a particular experiment.<sup>9</sup>

Currently, there are no government regulations on biosafety that mandate the proper procedures to follow when handling infectious viruses such as the 1918 flu.<sup>10</sup> This allows a dangerous situation to continue unchecked, where laboratories may not be taking enough precautions to properly contain potentially deadly microorganisms.<sup>11</sup> Operators of biological research laboratories working with biohazardous materials should be required to maintain a comprehensive safety program to protect workers and the public from risk of infection or injury from exposure. The safety program should mandate the proper procedures for handling dangerous biohazards, such as infectious viruses, require regular medical surveillance of workers, include a system for monitoring and oversight of laboratories, and require reporting of significant biosafety incidents to the

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<sup>6</sup> *Id.* at 794. See also Michael T. Osterholm, *A Weapon the World Needs*, 435 NATURE 417, 418 (May 2005) (advocating for an international effort to develop a new type of influenza vaccine to avoid the global panic, disease, death, and economic devastation that a new flu pandemic may cause); Shinji Watanabe et al., *Production of Novel Ebola Virus-Like Particles from cDNAs: an Alternative to Ebola Virus Generation by Reverse Genetics*, 78 J. VIROLOGY 999, 999 (Jan. 2004) (explaining a new research system that may help produce a vaccine against the Ebola and Marburg viruses that cause severe hemorrhagic fever with high mortality rates); B. Brett Finlay et al., *Rapid Response Research to Emerging Infectious Diseases: Lessons from SARS*, 2 NATURE REV. MICROBIOLOGY 602, 602 (July 2004) (advocating for rapid response research to respond to dangerous new infectious diseases that plague the world, such as severe acute respiratory syndrome (SARS)).

<sup>7</sup> Regulations from the Centers for Disease Control and Prevention (CDC) and the Occupational Safety & Health Administration (OSHA) and guidelines from the National Institutes of Health (NIH) will be discussed *infra* in Parts I & II.

<sup>8</sup> U.S. DEPT. OF HEALTH AND HUMAN SERVICES (DHHS), CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) AND NATIONAL INSTITUTES OF HEALTH (NIH), BIOSAFETY IN MICROBIOLOGICAL AND BIOMEDICAL LABORATORIES [hereinafter BMBL] VII (4TH ED., APR. 1999), <http://bmb1.od.nih.gov/select.pdf> (select .pdf version hyperlink).

<sup>9</sup> As will be discussed *infra* in Parts I & II, the government has delegated the responsibility for ensuring that proper procedures are used for each experiment to Institutional Biosafety Committees.

<sup>10</sup> The CDC has implemented regulations that control the possession, use, and transfer of certain biological agents and toxins; however, the section on biosafety does not mandate specific procedures for handling select agents, instead leaving it up to institutional biosafety committees and researchers to determine what protocols to follow to “contain” the agents. See *Select Agents and Toxins*, 70 Fed. Reg. 13294 (Mar. 18, 2005) (to be codified at 42 C.F.R. pts. 72 & 73) (announcing select agents and toxins regulations). The CDC added the previously unregulated 1918 influenza virus to the HHS select agent and toxins list on October 20, 2005, effective immediately. *Select Agents and Toxins*, 70 Fed. Reg. 61047-01 (Oct. 20, 2005).

<sup>11</sup> See, e.g., John Dudley Miller, *Beltsville E. Coli Infection was Not First*, THE SCIENTIST, June 30, 2005, <http://www.the-scientist.com/article/display/22718/> (documenting several laboratory-acquired E. coli infections caused by the lack of proper precautions during experiments); John Dudley Miller, *US Lab is Sent Live Anthrax*, THE SCIENTIST, June 11, 2004, <http://www.the-scientist.com/article/display/22224/> (documenting the exposure of unsuspecting laboratory workers to potentially deadly anthrax, where insufficient testing and processing allowed the live anthrax, instead of the safe dead version, to be shipped to the laboratory).

government. The government currently requires this type of comprehensive institutional safety program for research with radiation<sup>12</sup> and rDNA,<sup>13</sup> which is in sharp contrast to the lack of biosafety regulations for research with infectious diseases.

The 1918 flu strain is just one example; there are many other dangerous agents currently being experimented with in unregulated laboratories all over the United States.<sup>14</sup> A recent survey of facilities at universities, biotechnology companies, pharmaceutical companies, and other laboratories in the United States indicated that there are at least 273 laboratories, located in 46 states, designed to handle potentially lethal agents.<sup>15</sup> The survey also found that the majority of these laboratories are currently working with highly infectious agents.<sup>16</sup> Biosafety regulations are important because if an accident occurs, the facility's researchers and workers can become seriously ill or die. In addition, depending on the type of infectious disease material involved in the accident, an infected researcher could unknowingly infect his or her family, friends, and members of the community at large with a life threatening disease.<sup>17</sup> A comprehensive system of federal biosafety regulations would increase accountability and improve public safety.<sup>18</sup>

Instituting mandatory government controls on research laboratories is particularly important at this time because, in addition to the rapid scientific advances creating potential risks, such as the 1918 flu research discussed *supra*, the government is dramatically increasing investment in biodefense research.<sup>19</sup> The fear of bioterrorism<sup>20</sup> and concerns over the emergence of new life-threatening infectious

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<sup>12</sup> Nuclear Regulatory Commission (NRC), Standards for Protection Against Radiation, 10 C.F.R. §§ 20.1001-2402 (2005) (regulating radiation research under the authority of section 2134 of the Atomic Energy Act of 1954, as amended, codified at 42 U.S.C. §§ 2011-2281). In certain instances, the NRC has delegated their authority to the states for implementation. *See, e.g.*, 105 CMR §§ 120.100-120.146 (providing Massachusetts requirements for licensing radioactive material).

<sup>13</sup> U.S. DEPT. OF HEALTH AND HUMAN SERVICES (DHHS), GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES [hereinafter NIH GUIDELINES] 1 (Apr. 1998), <http://www.niehs.nih.gov/odhsb/biosafe/nih/rdna-apr98.pdf>.

<sup>14</sup> *Supra* note 11. *See also* Clare Kittredge, *BU BSL-4 Lab Faces More Scrutiny*, THE SCIENTIST, Jan. 24, 2005, <http://www.the-scientist.com/article/display/22576/> (documenting the infection of three Boston University researchers with a potentially lethal strain of tularemia, due in part to lax laboratory procedures).

<sup>15</sup> CONSTELLA HEALTH SCIENCES, CTR. FOR HEALTH RESEARCH, SURVEY FOR DETERMINING THE LOCATION, CAPACITY, AND STATUS OF EXISTING AND OPERATING BSL-3 LABORATORY FACILITIES WITHIN THE UNITED STATES 3 (2005), [http://www.niaid.nih.gov/Biodefense/PDF/BSL3\\_survey.pdf](http://www.niaid.nih.gov/Biodefense/PDF/BSL3_survey.pdf). The survey identified a total of about 600 laboratories when multiple laboratories at the same facility were counted. *Id.* at 18.

<sup>16</sup> *Id.* at 20.

<sup>17</sup> For example, two postgraduate students working at the Chinese Institute of Virology in Beijing, China became infected with the SARS virus in separate incidents in April 2004, which led to six other confirmed or suspected cases of SARS and the quarantine of over 200 people. Robert Walgate, *SARS Escaped Beijing Lab Twice*, THE SCIENTIST, Apr. 26, 2004, <http://www.the-scientist.com/article/display/22139/>. The infection spread to three generations, killing the mother of one of the students. Laurence K. Altman, *The Doctor's World: SARS's Second Act*, N.Y. TIMES, May 18, 2004, available at 2004 WLNR 5579438.

<sup>18</sup> As discussed *infra* in Parts II & IV.

<sup>19</sup> Press Release, U.S. Dept. of Health & Human Services, *Biodefense Preparedness: Record of Accomplishment* (Apr. 28, 2004), <http://www.hhs.gov/news/press/2004pres/20040428.html>.

<sup>20</sup> The traumatic events of 9/11, followed by the anthrax letter attacks, dramatically changed the general

diseases<sup>21</sup> are driving the increase in research on dangerous microorganisms. President George W. Bush has identified the “[d]evelopment and deployment of safe, effective medical countermeasures against biological weapons” as “an urgent priority.”<sup>22</sup> Congress increased funding for biodefense research through the National Institutes of Health (NIH)<sup>23</sup> 3,000% from \$53 million in fiscal year 2001 to \$1.6 billion in fiscal year 2004.<sup>24</sup> In late 2003, the National Institute of Allergy and Infectious Diseases (NIAID)<sup>25</sup> announced funding grants for the development and construction of two new national biocontainment<sup>26</sup> laboratories (NBLs)<sup>27</sup> and nine regional biocontainment laboratories (RBLs)<sup>28</sup> to research high risk life-threatening diseases, such as Ebola,<sup>29</sup> anthrax,<sup>30</sup> plague,<sup>31</sup> and tularemia,<sup>32</sup> for which there are

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public’s sense of security and “revealed our vulnerabilities to microbes or toxins that might be used as weapons.” Jerry Jaax, *Administrative Issues Related to Infectious Disease Research in the Age of Bioterrorism*, 46 INST. FOR LABORATORY ANIMAL RES. 8, 9 (2005), available at [http://dels.nas.edu/ilar\\_n/ilarjournal/46\\_1/pdfs/v4601Jaax.pdf](http://dels.nas.edu/ilar_n/ilarjournal/46_1/pdfs/v4601Jaax.pdf).

<sup>21</sup> Since 2001, public health officials have been increasingly concerned about the emergence of dangerous new microorganisms and the prevalence of drug-resistant strains of potentially fatal diseases like malaria and tuberculosis. *Id.* at 8.

<sup>22</sup> Press Release, The White House, Biodefense for the 21<sup>st</sup> Century (Apr. 28, 2004), available at <http://www.whitehouse.gov/homeland/20040430.html> (last visited 9/29/05).

<sup>23</sup> Nat’l Insts. of Health (NIH), U.S. Dept. of Health & Human Services, <http://www.nih.gov>.

<sup>24</sup> Biodefense Preparedness: Record of Accomplishment, *supra* note 19.

<sup>25</sup> Nat’l Inst. of Allergy & Infectious Diseases (NIAID), Nat’l Insts. of Health, <http://niaid.nih.gov>. NIAID, which is part of NIH, supports research to prevent, diagnose, and treat infectious diseases and illness from potential agents of bioterrorism and supports research on transplantation and immune-related illnesses. Press Release, Nat’l Insts. of Health, U.S. Dept. of Health & Human Services, NIAID Funds Construction of Biosafety Laboratories (Sept. 30, 2003), <http://www.niaid.nih.gov/news> (follow “news releases” hyperlink, then follow “archives 2003”).

<sup>26</sup> Biocontainment refers to a structure or system designed to prevent the accidental release of hazardous biological materials.

<sup>27</sup> National biocontainment laboratories will be built at the Boston University Medical Center and at the University of Texas Medical Branch at Galveston. NIAID Funds Construction of Biosafety Laboratories, *supra* note 25. Each institution will be given one-time grants of approximately \$120 million to fund construction. *Id.*

<sup>28</sup> Regional biocontainment laboratories will be built at Colorado State University Foothills Campus in Fort Collins, Duke University Medical Center in Durham, N.C., Tulane National Primate Research Center, in New Orleans, La., the University of Alabama at Birmingham School of Medicine, Argonne National Laboratory at the University of Chicago in Argonne, Ill., the University of Medicine and Dentistry in Newark, N.J., Columbia College of Veterinary Medicine at the University of Missouri in Columbia, the University of Pittsburgh, and the University of Tennessee Health Science Center in Memphis. Each institution will be given one-time grants of approximately \$7 to \$21 million to fund construction of the RBLs. *Id.*

<sup>29</sup> Ebola is a virus that causes fever, vomiting, diarrhea, bleeding from the nose and mouth, and loss of consciousness with up to 80-90% fatality rates. Strict isolation is required to avoid transmission to health care workers and there is no specific treatment. THE MERCK MANUAL OF MEDICAL INFORMATION 1165 (Mark H. Beers ed., 2d Home ed. 2003).

<sup>30</sup> Anthrax is a potentially fatal disease resulting from a skin, lung, or digestive tract infection with gram-positive bacterium *Bacillus anthracis*. It usually passes from animals to people through the skin, but can result from inhaling spores or from eating poorly cooked meat. Infection cannot pass from person to person, however, dormant spores can live in soil or animal products for decades and are not easily killed with heat or cold. Anthrax has been used as a bioweapon because it is highly lethal when inhaled. People at high risk of contracting anthrax can be vaccinated and it can be treated with a combination of antibiotics, however, delay in receiving treatment increases the likelihood of death. *Id.* at 1098.

<sup>31</sup> Plague is a severe infection that causes fever, headache, exhaustion, swollen lymph nodes, and death. There is no vaccine but if treatment with antibiotics begins within 24 hours, the chance of death is

often no known vaccines or effective treatments. Tommy G. Thompson, while he was Secretary of the U.S. Department of Health and Human Services, said that the “awards to build high-level biosafety facilities are a major step towards being able to provide Americans with effective therapies, vaccines, and diagnostics for diseases caused by agents of bioterror as well as for naturally emerging infections”<sup>33</sup> However, given the sheer number of laboratories and researchers that will be handling dangerous microorganisms, the biodefense research build-up may increase the risk to public health because of the greater likelihood of security breaches and accidental infections.<sup>34</sup>

This paper addresses the causes behind the apparent gap in regulations to protect workers and the community from exposure to infectious disease agents used in laboratory research and will make a case for new federal legislation to authorize the creation of comprehensive new biosafety regulations. Part I of this article provides background on methods for controlling infectious disease agents in medical research, examines the federal regulations currently applicable to biosafety, and identifies and clarifies the nature of the gap in the regulations. Part II spells out the components of a comprehensive safety program and provides perspective in the form of a comparison with the regulations and guidelines that currently apply to other areas of hazardous research. Part III explores the responses of the local communities where the two new NIH funded high risk NBLs will be built, specifically addressing whether these local communities are working to close the gap left by the lack of federal legislation. Finally, Part IV analyzes the authority of the CDC and NIH to address biosafety regulation and explains why local regulations are not enough and new federal legislation is needed to create mandatory biosafety regulations for oversight of this complex and dangerous area.

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significantly reduced. The bacteria that causes plague is usually passed from animals to people by fleas although transmission from person to person can occur from coughing and sneezing. Most people die from bubonic, pneumonic, or septicemic plague within the first five days, if left untreated, however, symptoms from *pestis minor*, a mild version of the plague, usually subside within a week. *Id.* at 1107-08.

<sup>32</sup> Tularemia is an infection that causes headaches, fever, chills, nausea, vomiting, and severe exhaustion. Thirty percent of untreated people die but those treated with injections of streptomycin for seven to fourteen days almost always survive. People catch tularemia mostly by eating or touching infected animals, especially wild rabbits, and from infected ticks and deer flies. Laboratory-acquired tularemia often only affects the lymph nodes or lungs and can be difficult to diagnose. *Id.* at 1116.

<sup>33</sup> NIAID Funds Construction of Biosafety Laboratories, *supra* note 25.

<sup>34</sup> Laboratory accidents and security breaches occur when researchers knowingly or inadvertently break the rules; human error is inevitable. COUNCIL FOR RESPONSIBLE GENETICS, BU AND BOSTON OFFICIALS DELAYED DISCLOSING BIOLAB INFECTIONS (January 19, 2005), <http://www.genewatch.org/bubiodefense/pages/tularemia.html>. As the number of laboratories handling dangerous microbiological agents increases, the potential for accidents also increases, although the exact number cannot be quantified because laboratory-acquired infections are not tracked in the United States. David L. Sewell, *Laboratory-Associated Infections and Biosafety*, CLINICAL MICROBIOLOGY REVIEWS 389, 390 (Jul. 1995), available at <http://cmr.asm.org/cgi/reprint/8/3/389.pdf>. Researchers at the Council for Responsible Genetics recently documented six separate incidents of serious laboratory-acquired infections or exposures. COUNCIL FOR RESPONSIBLE GENETICS, MISTAKES HAPPEN: ACCIDENTS AND SECURITY BREACHES AT BIOCONTAINMENT LABORATORIES (2005), <http://www.genewatch.org/bubiodefense/pages/accidents.html>.

## I – Gap in Biohazard Regulations Exposes Public to Biohazards Risk

Researchers have contracted infections while working in their laboratories since microbiology began.<sup>35</sup> Reports of laboratory-associated cases of typhoid,<sup>36</sup> cholera,<sup>37</sup> and tetanus<sup>38</sup> were published as early as a hundred years ago.<sup>39</sup> As researchers and microbiologists gained the skills necessary to isolate, manipulate, and propagate dangerous microorganisms, they also had to develop containment protocols, safety equipment, and appropriate practices and procedures to prevent biohazards<sup>40</sup> from sickening researchers and the public.<sup>41</sup> Over time, generally accepted guidelines detailing the protocols and necessary equipment to maintain an acceptable level of safety when working with infectious agents were developed.<sup>42</sup>

The CDC and NIH, working together, have published guidelines for working with biohazards in laboratory research in a booklet called *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*, now in its fourth edition.<sup>43</sup> However, these guidelines are wholly voluntary;<sup>44</sup> NIH grant recipients are not required to follow the *BMBL* guidelines in order to receive funds.<sup>45</sup>

In the *BMBL* guidelines, the safety facilities, procedures, and equipment needed for biocontainment are divided into four categories, numbered one through four, depending on the level of protection they provide to researchers, the environment,

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<sup>35</sup> *BMBL*, *supra* note 8, at 1.

<sup>36</sup> Typhoid fever is characterized by a prolonged fever, abdominal pain, and a rash that can last for months. Inadequate sewage treatment, poor hand washing after defecation or urination, and flies carrying bacteria from stools to food are the major causes of typhoid fever. Today, more than 99% of patients are cured with prompt antibiotic treatment. *THE MERCK MANUAL OF MEDICAL INFORMATION*, *supra* note 29, at 1117.

<sup>37</sup> Cholera is an infection of the intestines causing mild uncomplicated diarrhea or severe diarrhea and vomiting that can lead to dehydration, kidney failure, shock, coma, and death. More than 50% of untreated people die, but prompt treatment with tetracycline usually stops the diarrhea within 48 hours. *Id.* at 1100-01.

<sup>38</sup> Tetanus is a disease in which a toxin causes severe muscle spasms, particularly stiffness in the jaw, preventing normal breathing and causing oxygen deprivation or fatal suffocation. Preventing tetanus is better than treating it. Regular vaccinations have made tetanus rare in the United States. However, as many as 50,000 people die from tetanus worldwide each year. *Id.* at 1114.

<sup>39</sup> *BMBL*, *supra* note 8, at 1.

<sup>40</sup> A biohazard is “a risk or danger to life or health, especially that resulting from biological experimentation. *WEBSTER’S NEW WORLD COLLEGE DICTIONARY* 140 (Victoria Neufeldt ed., 3rd ed., 1997).

<sup>41</sup> *THE AMERICAN BIOLOGICAL SAFETY ASSOCIATION (ABSA), BIOSAFETY AS A PROFESSION*, <http://www.absa.org/biosafety.html> (last visited Oct. 11, 2006).

<sup>42</sup> *See BMBL*, *supra* note 8, at 3 (providing the history of the development of the *BMBL*).

<sup>43</sup> *Id.*

<sup>44</sup> However, according to Dr. Allan Shipp, NIH Office of Biotechnology Activities, the *BMBL* guidelines are “a widely recognized and broadly observed standard within the biosafety community.” E-mail from Dr. Allan C. Shipp, NIH Office of Biotechnology Activities, to Rebecca F. Emerson, student, Temple University Beasley School of Law (Nov. 1, 2005) (on file with author).

<sup>45</sup> Compare the “recommend their use” language in the *BMBL* (*supra* note 8, at 3) to the language of the NIH Guidelines for Research Involving Recombinant DNA Molecules, which state that as a “condition of NIH funding,” institutions “shall comply with the NIH guidelines.” *NIH GUIDELINES*, *supra* note 13, at 10 (§ 1-D). *See also* NIH, Office of Biotechnology Activities, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules, NOT-OD-04-067 (Sept. 14, 2004), <http://grants.nih.gov/grants/guide/notice-files/NOT=OD-04-067.html> (requiring compliance with the NIH Guidelines on Recombinant DNA Molecules for NIH funding).

and the community.<sup>46</sup> Biosafety Level One (BSL-1) is appropriate for work involving well-known agents that do not cause disease in healthy adults, and where the potential hazard to the environment and the community is minimal.<sup>47</sup> BSL-1 is a basic level of containment that relies on standard practice<sup>48</sup> with no special primary<sup>49</sup> or secondary<sup>50</sup> barriers, other than a sink for hand washing.<sup>51</sup>

Biosafety level two (BSL-2) is appropriate for working with agents of moderate potential hazard to people and the environment.<sup>52</sup> According to the *BMBL* BSL-2 guidelines, safety measures should include special training for laboratory workers in handling disease agents, supervision by competent scientists, immunizations or tests for the agents handled or potentially present in the laboratory,<sup>53</sup> limited access to the laboratory when work is in progress,<sup>54</sup> and the use of gloves, eyewear, and biological safety cabinets<sup>55</sup> or other physical containment equipment.<sup>56</sup>

Biosafety level three (BSL-3) is appropriate when working with indigenous or exotic agents which, when inhaled, may cause a serious or lethal disease.<sup>57</sup> In addition to the standard procedures required for BSL-1 and BSL-2, the *BMBL* BSL-3 guidelines recommend that all procedures that involve infectious materials be conducted within a biological safety cabinet or other physical containment device, or

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<sup>46</sup> *BMBL*, *supra* note 8, at 17.

<sup>47</sup> *Id.*

<sup>48</sup> Standard microbiological practices include: (1) limiting access to the laboratory when experiments are in progress; (2) requiring handwashing after handling viable materials; (3) prohibiting eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use in work areas; (4) the safe handling of sharps; (5) minimizing the creation of splashes or aerosols; (6) decontaminating all work surfaces at least once a day and after any spill of viable material; (7) decontaminating all cultures, stocks, and other regulated wastes before disposal by an approved decontamination method or, alternatively, packaging any materials to be decontaminated outside the immediate laboratory in accordance with applicable local, state, and federal regulations before removal from the facility; (8) posting a biohazard sign at the entrance to the laboratory whenever infectious agents are present; and finally, (9) implementing and maintaining an insect and rodent control program. *Id.* at 17-18.

<sup>49</sup> Primary barriers include both the use of good microbiological techniques and proper safety equipment. They are designed to protect laboratory personnel and the immediate laboratory environment from exposure to infectious agents. Vaccinations are another method used to provide an increased level of personal protection for laboratory personnel. *Id.* at 8.

<sup>50</sup> Secondary barriers include both facility design and operational practices. They are designed to protect the environment outside the laboratory from exposure to infectious materials. *Id.*

<sup>51</sup> *BMBL*, *supra* note 8, at 12.

<sup>52</sup> *Id.* at 21.

<sup>53</sup> *Id.* at 23. Additionally, baseline serum samples for laboratory and other at-risk personnel (such as maintenance staff and animal care workers) should be collected and stored, when appropriate considering the agents handled. *Id.*

<sup>54</sup> In addition, the guidelines recommend that “persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, [should not be] allowed in the laboratory or animal rooms.” *Id.* at 22. This includes people who are immunocompromised. *Id.*

<sup>55</sup> Biological Safety Cabinets (BSCs) are the most commonly used primary containment device. *BMBL*, *supra* note 8, app. A at 202. There are three general types of biological safety cabinets: Class I, Class II, and Class III, where Class III is designed to handle the most hazardous agents. *Id.*

<sup>56</sup> *Id.* at 22-25. Recommended physical containment devices include personal protection, such as face protection, protective laboratory coats, and gloves (sometimes two pairs), lockable doors for facilities that house restricted agents, a sink for hand washing, an eyewash station, adequate illumination, properly installed and maintained class II biological safety cabinets that meet proscribed airflow parameters, and furniture designed and placed with easy cleaning and decontamination in mind. *Id.*

<sup>57</sup> *Id.* at 27.

by people wearing appropriate personal protective clothing and equipment.<sup>58</sup> Only people who have been advised of the potential biohazard, trained on the potential hazards and appropriate precautions, and meet specific entry requirements (such as immunization) should be allowed access to the laboratory or animal rooms.<sup>59</sup>

The *BMBL* guidelines require biosafety level four (BSL-4) “for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease,” for which no vaccine or therapy is available,<sup>60</sup> such as Ebola, Marburg,<sup>61</sup> and Lassa.<sup>62</sup> The *BMBL* guidelines recommend a choice of two models for BSL-4 facilities; either a cabinet laboratory, where BSL-4 agents are only handled within Class III biological safety cabinets,<sup>63</sup> or a suit laboratory, where workers wear protective suits while handling the BSL-4 agents in Class II biological safety cabinets.<sup>64</sup> In addition to the standard procedures required for BSL-1, BSL-2, and BSL-3, the *BMBL* BSL-4 guidelines recommend that workers entering the laboratory should remove all of their personal clothing in an outer clothing change room and put on special laboratory clothing, including undergarments.<sup>65</sup> Then, when exiting the laboratory, workers should remove their laboratory clothing in an inner changing room, shower, and dress in their personal clothes in an outer changing room.<sup>66</sup> This is a time consuming process to go through just to enter and exit the laboratory.<sup>67</sup>

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<sup>58</sup> *BMBL*, *supra* note 8, at 27-28. The *BMBL* guidelines also recommend the use of certain primary and secondary barriers to infection. Primary barriers include gloves (worn at all times and changed frequently), Class II or Class III biological safety cabinets (used when working with all infectious materials), and respiratory and face protection (used when in rooms containing infected animals). *Id.* at 33-34. For secondary barriers, the guidelines recommend the use of specially designed laboratory facilities, which include a passageway with a series of two self-closing lockable doors and a clothes changing room at the laboratory entrance; easy to clean and decontaminate ceilings, floors, and walls, sealed windows; a method for decontaminating laboratory waste, preferably within the laboratory itself; and an exhaust air ventilation system with a visual monitoring device that draws air into the laboratory from “clean” areas and exhausts air outside away from occupied areas and air intakes (or a HEPA-filtered exhaust system). *Id.* at 34-35.

<sup>59</sup> *Id.* at 30.

<sup>60</sup> *Id.* at 37.

<sup>61</sup> Marburg is a hemorrhagic fever similar to Ebola, but slightly less frequently fatal. THE MERCK MANUAL OF MEDICAL INFORMATION, *supra* note 29, at 1165.

<sup>62</sup> Lassa fever is found mainly in West Africa and causes fever, chest pain, diffuse body aches, vomiting, and death. Isolation is important to prevent transmission to family members and health care workers. *Id.* at 1165-1167.

<sup>63</sup> See *BMBL*, *supra* note 8, app. A at 202 (describing the requirements for different levels of biological safety cabinets).

<sup>64</sup> *Id.* at 43. The guidelines indicate that a BSL-4 laboratory should consist of a separate building or should be in a “clearly demarcated or isolated zone within a building.” *Id.* Containment parameters, such as directional air flow, and life support systems should be inspected daily before laboratory work is begun to ensure that everything is in proper working order. *Id.* All liquid waste from the laboratory sinks, floor drains, and the inner (dirty-side) changing room (including toilets) should be decontaminated by a proven method before being discharged into the sanitary sewer. *Id.* at 45. Finally, the air supplied to and exhausted from the cabinet room, inner changing room, and anteroom should pass through HEPA filters and be discharged away from occupied spaces or other air intakes. *Id.* at 46.

<sup>65</sup> *BMBL*, *supra* note 8, at 40.

<sup>66</sup> *Id.*

<sup>67</sup> Additionally, the complicated and expensive processes associated with level four biosafety laboratories may not be safely implemented in private, non-governmental, self-regulating organizations, such as universities. See John Dudley Miller, *Sparks Fly on Boston Lab Plan*, THE SCIENTIST, May 5,

The *BMBL* guidelines recommend that organizations have Institutional Biosafety Committees (IBCs),<sup>68</sup> which ideally consist of groups of at least five people, including at least two from outside the institution, who collectively have experience and expertise in biohazard research and are able to assess the safety of the proposed research.<sup>69</sup> The *BMBL* guidelines suggest that IBCs should perform a complete a risk assessment<sup>70</sup> to determine the appropriate BSL before approving any experiments.<sup>71</sup> The assessment should consider the risks associated with the proposed agent and research methods in order to minimize the risk of dangerous worker and environmental exposure.<sup>72</sup> Important factors to consider when evaluating risk are: the pathogenicity,<sup>73</sup> route of spread,<sup>74</sup> biological stability,<sup>75</sup> origin,<sup>76</sup> and communicability<sup>77</sup> of the agent, the type of testing or procedures to be done with the agent,<sup>78</sup> and the availability of effective vaccines or therapeutic measures.<sup>79</sup> The CDC makes guidance available to IBCs in the form of *BMBL* Agent Summary Statements<sup>80</sup> for use in risk assessments to determine the best

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2004, <http://www.the-scientist.com/news/20040505/02>.

<sup>68</sup> *BMBL*, *supra* note 8, at 77.

<sup>69</sup> NIH Guidelines, *supra* note 13, at 22. IBCs began in response to concerns about the risks of recombinant DNA research. At the historic Asilomar conference in 1975, proponents of recombinant DNA research avoided strict federal regulation by agreeing to a self-regulatory system where IBCs took on responsibility for research safety under a system of federal guidelines. Richard R. Sharp *et al*, *Science & Society: Shaping Science Policy in the Age of Genomics*, 5 *NATURE REVIEWS GENETICS* 1, 1 (Apr. 2004).

<sup>70</sup> “‘Risk’ implies the probability that harm, injury, or disease will occur. In the context of microbiological laboratories, the assessment of risk focuses primarily on the prevention of laboratory-associated infections.” *BMBL*, *supra* note 8, at 77.

<sup>71</sup> *Id.* at 76-83.

<sup>72</sup> *Id.* at 77.

<sup>73</sup> The pathogenicity is the degree to which an agent is likely to cause a serious disease, including disease incidence and severity; the more severe the disease, the higher the risk. *Id.* at 78 (stating “[f]or example, *staphylococcus aureus* only rarely causes a severe or life threatening disease in a laboratory situation and is relegated to BSL-2. Whereas, viruses such as Ebola, Marburg, and Lassa fever, which cause diseases with high mortality rates and for which there are no vaccines or treatment, are worked with at BSL-4”).

<sup>74</sup> The route of spread or transmission may be parenterally (e.g. through a needle stick or open wound), by ingestion, or by aerosol route (i.e. inhalation of airborne particles). *Id.* at 78-79. “Agents that can be transmitted by the aerosol route have caused the most laboratory infections.” *Id.* For example, although they can cause potentially lethal diseases, research with human immunodeficiency virus (HIV) and hepatitis B virus is done at BSL-2 because they do not aerosolize and, in the case of hepatitis B, an effective vaccine is available. *BMBL*, *supra* note 8, at 78-79.

<sup>75</sup> Biological stability involves both the agent’s ability to survive over time in the environment and its aerosol infectivity (from spore-forming bacteria for example). *Id.* at 79.

<sup>76</sup> The “origin” refers to the geographic location (e.g., as disease that is endemic to the tropics), host (e.g. an infected or uninfected human or animal), or nature of the source (e.g. associated with a disease outbreak in humans or an animal disease that could potentially be transmitted to humans). *Id.*

<sup>77</sup> Communicability is a factor of both the infectious dose (i.e. whether it takes one or hundreds of thousands of units to make someone sick) and the concentration (i.e. the number of infectious organisms per unit volume). The risk assessment should also take into consideration the milieu containing the organism (e.g. liquid medium, viscous sputum or blood, or solid tissue) and the laboratory methodology to be used. *Id.*

<sup>78</sup> *Id.* at 79.

<sup>79</sup> *BMBL*, *supra* note 8, at 85-88.

<sup>80</sup> *Id.* at 89-201.

methods for use when working with different agents.<sup>81</sup> At present, the *BMBL* guidelines are voluntary.<sup>82</sup> Research organizations are essentially self-regulating. There are no licensing requirements or mandatory regulations to ensure that organizations have IBCs to assess risk, supervise research, and ensure compliance with safety protocols over time.

Despite the guidelines being voluntary, biohazards in research are not completely unregulated; institutions working with biohazards must comply with OSHA requirements for employee health and safety.<sup>83</sup> In particular, institutions working with blood<sup>84</sup> and certain other potentially infectious materials<sup>85</sup> must comply with the OSHA bloodborne pathogens regulations.<sup>86</sup> The OSHA bloodborne pathogens regulations require that each employer with at-risk employees must establish a written exposure control plan,<sup>87</sup> use basic personal protective equipment,<sup>88</sup> keep the worksite clean and sanitary,<sup>89</sup> and follow universal precautions<sup>90</sup> and specified work practice controls.<sup>91</sup> Additionally, research laboratories working with HIV<sup>92</sup> and HBV<sup>93</sup> must meet more stringent requirements under the bloodborne pathogens

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<sup>81</sup> *Id.*

<sup>82</sup> *Id.* at viii.

<sup>83</sup> 29 U.S.C. § 651 (2005).

<sup>84</sup> The OSHA regulations define blood as “human blood, human blood components, and products made from human blood.” 29 C.F.R. § 1910.1030(b) (2005).

<sup>85</sup> The regulations define “other potentially infectious material” subject to the regulations as the “following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.” *Id.*

<sup>86</sup> 29 C.F.R. § 1910.1030.

<sup>87</sup> A written exposure control plan is designed to eliminate or minimize employee exposure and must contain at least a written exposure determination (a list of job classifications and tasks that have occupational exposure), a schedule and method of implementation for compliance with the regulations, and a procedure for evaluating exposure incidents. 29 C.F.R. § 1910.1030(c)(1).

<sup>88</sup> 29 C.F.R. § 1910.1030(d)(3) (requiring employers to provide and ensure that the employees use “appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks, and eye protection).

<sup>89</sup> 29 C.F.R. § 1910.1030(d)(4) (requiring all worksites to be maintained in a clean and sanitary condition, equipment and working surfaces be cleaned and decontaminated after contact with blood or other potentially infectious materials, and contaminated sharps and other regulated waste be disposed of properly).

<sup>90</sup> 29 C.F.R. § 1910.1030(d)(1). The regulations define universal precautions as an approach to infection control, under which “all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.” 29 C.F.R. § 1910.1030(b).

<sup>91</sup> 29 C.F.R. § 1910.1030(d)(2). The regulations define work practice controls as “controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g. prohibiting recapping of needles by a two-handed technique.” 29 C.F.R. § 1910.1030(b).

<sup>92</sup> Human Immunodeficiency Virus (HIV) is a retrovirus that progressively destroys lymphocytes (a type of white blood cell), weakening the body’s immune defenses, and making the body susceptible to attack by other infectious organisms, which causes many complications, including death. The most severe type of HIV develops into acquired immunodeficiency syndrome (AIDS). THE MERCK MANUAL OF MEDICAL INFORMATION, *supra* note 29, at 1168.

<sup>93</sup> Hepatitis B is a virus causing inflammation of the liver and producing symptoms from minor flu-like illness to fatal liver failure. Joint pain and itchy red hives are also common with Hepatitis B. The main mode of transmission is through contaminated blood and other bodily fluids. A vaccination is available that protects most people but vaccination may provide less protection to people with impaired immune

regulations.<sup>94</sup> These requirements are similar to the *BMBL* BSL-2 guidelines. For example, both require that all activities involving potentially infectious materials be conducted in biological safety cabinets or other physical-containment devices, that access to the work area be limited, that appropriate protective clothing and biohazard signage be used, that all waste be decontaminated before disposal, and that spills be contained and properly cleaned.<sup>95</sup> There are additional regulations that HIV and HBV large scale production facilities must meet that are similar to the *BMBL* BSL-3 guidelines, including self-closing double access doors, washable surfaces, and verifiable directional airflow exhausting to the outside.<sup>96</sup> Also, the bloodborne pathogens regulations likewise address employee training and appropriate vaccinations.<sup>97</sup> Thus, the OSHA bloodborne pathogens regulations overlap somewhat with the *BMBL* voluntary guidelines, particularly for laboratories working with HIV and HBV.<sup>98</sup>

In addition, Congress passed legislation prohibiting the possession, control, transfer, and use of the most lethal pathogens;<sup>99</sup> The USA Patriot Act of 2001<sup>100</sup> prohibits certain individuals from working with “select agents.”<sup>101</sup> See Table A for a list of select agents and toxins. The Public Health Security and Bioterrorism Preparedness Response Act of 2002<sup>102</sup> requires registration by all institutions possessing of select agents.<sup>103</sup> Violations of the regulations relating to possession,

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systems. *Id.* at 802-804.

<sup>94</sup> This section of the regulations “applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV.” 29 C.F.R. § 1910.1030(e)(1).

<sup>95</sup> Compare *BMBL*, *supra* note 8, at 21-27 (listing the BSL-2 guidelines), with 29 C.F.R. § 1910.1030 (providing the bloodborne pathogen requirements).

<sup>96</sup> Compare *BMBL*, *supra* note 8, at 27-37 (listing the BSL-3 guidelines), with 29 C.F.R. § 1910.1030 (providing the bloodborne pathogen requirements).

<sup>97</sup> Compare *BMBL*, *supra* note 8, at 23, 30 (listing the BSL-2 and BSL-3 guidelines for training and vaccinations), with 29 C.F.R. § 1910.1030(f-g) (providing the bloodborne pathogen requirements).

<sup>98</sup> Compare *BMBL*, *supra* note 8, at 27-37 (listing the BSL-2 and BSL-3 guidelines), with 29 C.F.R. § 1910.1030(f-g) (providing the bloodborne pathogen requirements).

<sup>99</sup> See Uniting & Strengthening America by Providing Appropriate Tools Required to Intercept & Obstruct Terrorism Act of 2001, Pub. L. No. 107-56, 115 Stat. 272 (2001) [hereinafter USA Patriot Act] (expanding the biological weapons act); see also Public Health Security & Bioterrorism Preparedness & Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 637 (2002) [hereinafter Bioterrorism Preparedness Act] (requiring the development and implementation of regulations on the possession, use, and transfer of listed agents and toxins).

<sup>100</sup> USA Patriot Act, § 817 (codified at 18 U.S.C. § 175(b)) (criminalizing unjustified possession of certain biological agents and toxins and possession by certain “restricted persons”).

<sup>101</sup> “Select agents are biological agents and toxins that pose a threat to public, animal, and plant health and safety.” John M. Hicks, *An Overview of Terrorism and its Impact on Biomedical Research Facilities*, 32 LAB ANIMAL 41 (Nov. 2003). The U.S. Department of Health and Human Services Secretary has promulgated a list of DHHS select agents that “have the potential to pose a severe threat to public health and safety” and a list of “overlap select agents” that also have the potential to pose a severe threat to animal health or to animal products. 42 C.F.R. §§ 73.3, 73.4 (2005). The United States Department of Agriculture has responsibility for regulating high consequence livestock pathogens and toxins. Public Health Security & Bioterrorism Preparedness & Response Act of 2002, 42 U.S.C.A. § 262a (2005).

<sup>102</sup> Bioterrorism Preparedness Act, §§ 201-203 (codified at 42 U.S.C. § 262(a)) (regulating certain biological agents and toxins by requiring the development and implementation of regulations on the possession, use, and transfer of listed agents and toxins, including registration by users).

<sup>103</sup> Jonathan Y. Richmond & Shanna Nesby-O’Dell, *Biosecurity for Animal Facilities & Associated*

use, and transfer of select agents are punishable by a civil monetary fine of \$250,000 or more.<sup>104</sup>

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*Laboratories*, 32 LAB ANIMAL 32 (2003).

<sup>104</sup> Bioterrorism Preparedness Act, 42 U.S.C. § 262a(i)(1).

Table A – Select Biological Agents and Toxins <sup>105</sup>	
HHS/CDC Non-Overlap Select Agents and Toxins	High Consequence Livestock Pathogens and Toxins/Select Agents (Overlap Agents)
Crimean-Congo haemorrhagic fever virus	<i>Bacillus anthracis</i> (Anthrax)
<i>Coccidioides posadasii</i>	<i>Brucella abortus</i>
Ebola viruses	<i>Brucella melitensis</i>
<i>Cercopithecine herpesvirus 1</i> (Herpes B virus)	<i>Brucella suis</i>
Lassa fever virus	<i>Burkholderia mallei</i>
Marburg virus	<i>Burkholderia pseudomallei</i>
Monkeypox virus	Botulinum neurotoxin producing species of Clostridium
<i>Rickettsia prowazekii</i>	<i>Coccidioides immitis</i>
<i>Rickettsia rickettsia</i>	<i>Coxiella burnetii</i>
South American haemorrhagic fever virus	Eastern equine encephalitis virus
Tick-borne encephalitis complex (flavi) viruses	Hendra virus
Variola major virus (Smallpox)	Francisella tularensis
Variola minor virus (Alastrim)	Rift Valley fever virus
<i>Yersinia pestis</i> (Plague)	Nipah Virus
Abrin	Venezuelan equine encephalitis virus
Conotoxins	<i>Botulinum neurotoxin</i>
Diacetoxyscirpenol	<i>Clostridium perfringens</i> epsilon toxin
Ricin	Shigatoxin
Saxitoxin	Staphylococcal enterotoxin
Shinga-like ribosome inactivating proteins	T-2 toxin
Tetrodotoxin	
1918 Pandemic Influenza Virus	

The CDC promulgated security focused regulations to implement the new select agent legislation.<sup>106</sup> The regulations specify many new security requirements regarding access to select agent material, including obtaining a registration certificate in order to possess, use or transfer select agents, designating a responsible official, and passing a security risk assessment.<sup>107</sup> The explanatory companion

<sup>105</sup> Hicks, *supra* note 101, at 42. Plus, the 1918 pandemic influenza virus was added on October 20, 2005. Select Agents and Toxins, 70 Fed. Reg. at 61047-01.

<sup>106</sup> Select Agents and Toxins, 42 C.F.R. § 73 (2005).

<sup>107</sup> 42 C.F.R. § 73.

materials contend that implementation of the final rule will “require that entities in possession of such agents or toxins develop and implement effective means of biosafety and physical security.”<sup>108</sup> Although the companion materials imply that biosafety will be required as part of the new regulations, the final regulations actually focus more on the physical security aspects of safety (such as controlling access), rather than biocontainment safety.<sup>109</sup>

The select agent regulations do not specify the safety precautions to be followed when handling these biohazards.<sup>110</sup> The regulations contain only one brief section on safety.<sup>111</sup> The safety section requires institutions working with select agents to develop a written biosafety plan “sufficient to contain the select agent or toxin”<sup>112</sup> that takes into consideration the CDC/NIH *BMBL* guidelines,<sup>113</sup> the NIH rDNA guidelines,<sup>114</sup> and the OSHA<sup>115</sup> regulations. The regulations do not require a BSL risk assessment or safety officer charged with ensuring biosafety.<sup>116</sup> They allow great flexibility and discretion as to biocontainment procedures for select agents.<sup>117</sup> Thus, although it is logical to assume that increased security will promote safety to some extent,<sup>118</sup> the regulations do not directly require specific biocontainment standards. Therefore, it is up to the individual institutions, IBCs, and researchers to determine what biocontainment efforts to use to “contain” a given select agent or toxin.<sup>119</sup>

Without government regulations specifying biosafety procedures with appropriate enforcement mechanisms, some organizations will implement ineffective standards or will fail to enforce compliance with the standards. Robert Lamb, of the University of Chicago, argues that BSL-4 labs should not be located on university campuses at all because universities are likely to invest less money in safety than federal laboratories, stating that “[u]niversities are always cutting corners to save money.”<sup>120</sup> The current select agent regulations mandate many security precautions<sup>121</sup> but delegate decisions about laboratory safety, including the proper BSL for a given experiment, to the researchers and IBCs.<sup>122</sup>

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<sup>108</sup> 42 C.F.R. § 73.

<sup>109</sup> Compare 42 C.F.R. §§ 73.10, 73.11 (requiring a detailed security plan meeting listed specific requirements and excluding access by certain types of individuals) with § 73.12 (requiring a sufficient biosafety plan that takes the BMBL guidelines into consideration).

<sup>110</sup> 42 C.F.R. § 73.

<sup>111</sup> 42 C.F.R. § 73.12.

<sup>112</sup> 42 C.F.R. § 73.12.

<sup>113</sup> BMBL, *supra* note 8.

<sup>114</sup> NIH Guidelines, *supra* note 13.

<sup>115</sup> OSHA Workplace Safety Standards, 29 C.F.R. §§ 1910.1200, 1910.1450 (2001).

<sup>116</sup> 42 C.F.R. § 73.

<sup>117</sup> 42 C.F.R. § 73.12.

<sup>118</sup> The security measures are designed to make it more difficult for unauthorized people to enter laboratories and for select agents and toxins to be intentionally removed from laboratories, which will reduce the threat to public health and safety. 42 C.F.R. §§ 73.10, 73.11.

<sup>119</sup> 42 C.F.R. § 73.12.

<sup>120</sup> Miller, *supra* note 67.

<sup>121</sup> Select Agents and Toxins, 42 C.F.R. §§ 73.10, 73.11 (2005).

<sup>122</sup> 42 C.F.R. § 73.12.

Without the oversight that comes from a comprehensive safety program, unregulated biohazards can pose a serious threat to public safety. For example, on April 12, 2005, the World Health Organization (WHO) announced that the potentially deadly H2N2 strain of influenza<sup>123</sup> had been sent to 6,000 laboratories around the world by the College of American Pathologists. This dangerous strain was sent as part of a kit used to confirm the laboratories' abilities to carry out diagnostic tests, and raised concerns that the H2N2 sample unnecessarily endangered laboratory workers and could reignite a pandemic.<sup>124</sup> Reactions to the H2N2 incident from the scientific community have been mixed.<sup>125</sup> Some researchers consider the story to be overblown and argue that there were no adverse consequences.<sup>126</sup> Others say that we were just lucky this time.<sup>127</sup> In response, the CDC has said that it will upgrade the strains of flu virus that have caused pandemics, including H2N2, from BSL-2 to BSL-3.<sup>128</sup> Upgrading these influenzas may provide better guidance for risk assessment and help avoid a similar problem in the future. However, since the *BMBL* guidelines<sup>129</sup> are only voluntary, a similar worldwide shipment of dangerous pathogens to unsuspecting laboratories would still be legal. This lack of federal regulation clearly poses a serious risk to the public health and welfare. The current combination of select agent and OSHA regulations and *BMBL* guidelines creates a confusing mix of standards that should be replaced with a consistent, clear regulatory system.

## II – Regulations Require Comprehensive Safety Program for Radiation Research

The well-established Nuclear Regulatory Commission (NRC) safety regulations<sup>130</sup> for research with radioactive material provide a model for what an effective, comprehensive regulatory safety program looks like in the research setting. For example, all organizations planning to do research with radioactive materials must be licensed by the federal government.<sup>131</sup> In order to receive a license, an organization must show that their “proposed activities will serve a useful purpose proportionate to the quantities of [radioactive] material to be utilized” and they must agree to follow the safety standards established by the NRC to “protect health and to minimize danger to life or property.”<sup>132</sup> The NRC regulations require that each

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<sup>123</sup> “The H2N2 strain caused a world-wide pandemic in 1957, killing millions of people before it disappeared from wide-spread circulation in 1968.” Erika Check, *Heightened Security after Flu Scare Sparks Biosafety Debate*, 434 *NATURE* 943 (2005).

<sup>124</sup> *Id.* These kits usually contain a flu strain not thought to pose a public health risk; however, this time the kits contained the H2N2 strain that people born after 1968 have no immunity to. *Id.*

<sup>125</sup> *BSL: Better Safe than Lucky?*, 2 *NATURE METHODS* 401 (2005).

<sup>126</sup> *Id.*

<sup>127</sup> *Id.*

<sup>128</sup> Check, *supra* note 123.

<sup>129</sup> *BMBL*, *supra* note 8.

<sup>130</sup> NRC, Standards for Protection Against Radiation, 10 C.F.R. §§ 20.1-2402 (2005).

<sup>131</sup> The Atomic Energy Act of 1954, as amended, codified at 42 U.S.C. § 2134(b) (2005). In some states, the NRC has implemented agreements delegating their regulatory authority to the states. *See e.g.* 105 C.M.R. 120.100-142 (2005) (codifying the Massachusetts regulations on licensing of radioactive materials).

<sup>132</sup> 42 U.S.C. § 2133(b)(2) (2005).

licensee “develop, document, and implement a radiation protection program.”<sup>133</sup> Each research organization must review its radiation protection program at least annually,<sup>134</sup> must report emissions in excess of the allowable dose level,<sup>135</sup> and must “promptly take appropriate corrective action to ensure against recurrence.”<sup>136</sup> Radioactive material must be controlled,<sup>137</sup> contamination must be minimized,<sup>138</sup> caution signs must be posted,<sup>139</sup> and radioactive materials must be labeled<sup>140</sup> and disposed of properly.<sup>141</sup> Each licensed organization must keep records of their radiation safety program, including the provisions of the program and records of audits or other reviews of the program content and its implementation.<sup>142</sup> Finally, organizations must report all incidents resulting in “exposures, radiation levels, and concentrations of radioactive material” that exceed the limits set in the regulations.<sup>143</sup> These are regularly enforced, mandatory regulations that all institutions engaging in research with radioactive materials must comply with; otherwise, the government has the authority to revoke the institution’s license and force them to cease operations.<sup>144</sup>

In comparison, research with recombinant DNA (rDNA)<sup>145</sup> uses a different regulatory safety compliance model, although it too has many of the same elements as described above; rDNA research is controlled through mandatory guidelines, which organizations must follow to receive NIH grants.<sup>146</sup> In the 1970s, because rDNA was new and unknown, serious concerns were raised that dangerous microorganisms could be created which might escape from the laboratory and endanger the public and the environment.<sup>147</sup> At the historic 1975 Asilomar conference,<sup>148</sup> proponents of rDNA research agreed to follow federal safety guidelines using a self-regulatory framework in which IBCs were responsible for research safety, thereby avoiding strict federal regulation of rDNA research.<sup>149</sup>

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<sup>133</sup> NRC, Standards for Protection Against Radiation, 10 C.F.R. § 20.1101(a) (2005).

<sup>134</sup> 10 C.F.R. § 20.1101(c).

<sup>135</sup> 10 C.F.R. § 20.2202. Dosimetry badges can be used for surveillance of dose levels of radiation.

<sup>136</sup> 10 C.F.R. § 20.1101(d).

<sup>137</sup> 10 C.F.R. §§ 20.1801-1802.

<sup>138</sup> 10 C.F.R. § 20.1406.

<sup>139</sup> 10 C.F.R. §§ 20.1901-1902.

<sup>140</sup> 10 C.F.R. §§ 20.1904-1905.

<sup>141</sup> 10 C.F.R. §§ 20.2001-2007.

<sup>142</sup> 10 C.F.R. §§ 20.2101-2107.

<sup>143</sup> 10 C.F.R. §§ 20.2202-2203.

<sup>144</sup> 10 C.F.R. § 20.2401 (2005).

<sup>145</sup> Recombinant DNA or rDNA is any recombined deoxyribonucleic acid (DNA), “especially that formed in the laboratory by splicing together pieces of DNA from different species, as to create new life forms, modify existing ones, or produce useful biological chemicals.” WEBSTER’S NEW WORLD COLLEGE DICTIONARY, *supra* note 40, at 1121.

<sup>146</sup> NIH Guidelines, *supra* note 13.

<sup>147</sup> Richard R. Sharp et al., *Science & Society: Shaping Science Policy in the Age of Genomics*, 5 NATURE REVS. GENETICS 1, 1 (Apr. 2004).

<sup>148</sup> The Asilomar Conference was a meeting of scientists, policy-makers, and government officials devoted to the discussion of the potential dangers associated with rDNA research, which took place in February 1975 at the Asilomar Conference Center in Pacific Grove, California. *Id.*

<sup>149</sup> THE SUNSHINE PROJECT, MANDATE FOR FAILURE: THE STATE OF INSTITUTIONAL BIOSAFETY

NIH established a national rDNA Advisory Committee (RAC),<sup>150</sup> which released its first biosafety guidelines in June 1976.<sup>151</sup> These guidelines were designed to specify safe practices for constructing and handling rDNA molecules.<sup>152</sup> They contain provisions for public access to IBC records and meeting minutes.<sup>153</sup> The rDNA guidelines have been updated over the years and are still in place.<sup>154</sup> The rDNA guidelines are mandatory (although not always enforced) for all NIH-supported research and for all rDNA research involving testing on human subjects.<sup>155</sup>

The rDNA model could be a template for general biohazards research, if the oversight is sufficient. A national survey of IBCs found that NIH may not be using its spending power to enforce IBC compliance.<sup>156</sup> The survey reported that NIH has awarded grants to institutions and organizations without registered IBCs in direct violation of their own rules.<sup>157</sup> The problems identified by the survey indicate that the current IBC system may not be accomplishing its safety mandate under the NIH guidelines.<sup>158</sup> This research demonstrates that the regulatory licensing system successfully used for radiation research is a more comprehensive and enforceable model for ensuring safety with dangerous pathogens.

### III – BSL-4 Labs Cheered in Texas but Boomed in Boston

In the absence of federal regulations, the duty to protect the public from the risks of potential biocontainment accidents falls to state and local governments. The response in Massachusetts and Texas, where the two new NIH funded BSL-4 laboratories will be built,<sup>159</sup> is a study in contrasts. As will be discussed *infra*, in Boston, local politicians, scientists, and residents are hoping to pass new regulations to forestall development of the new laboratory, whereas in Galveston, the response has been mostly positive.

In 1981, in response to concerns about the potential dangers of unregulated rDNA research, the City of Boston passed an ordinance regulating rDNA use.<sup>160</sup> The ordinance required mandatory regulations, where federal legislators had been

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COMMITTEES IN AN AGE OF BIOLOGICAL WEAPONS RESEARCH 5 (2004), <http://www.sunshine-project.org>.

<sup>150</sup> About Recombinant DNA and Gene Therapy, <http://www4.od.nih.gov/oba/rac/aboutrdagt.htm> (last visited Oct. 11, 2006).

<sup>151</sup> Mark Cantley, *Learning From History*, 386 NATURE 642, 642 (1997).

<sup>152</sup> NIH Guidelines, *supra* note 13.

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*; THE SUNSHINE PROJECT, *supra* note 149, at 14.

<sup>156</sup> THE SUNSHINE PROJECT, *supra* note 149, at 14.

<sup>157</sup> *Id.*

<sup>158</sup> *Id.* at 21.

<sup>159</sup> The National Institute of Allergy and Infectious Diseases (NIAID) has awarded two grants to build national BSL-4 biocontainment laboratories at the Boston University Medical Center in Boston, Massachusetts and at the University of Texas Medical Branch at Galveston in Galveston, Texas. NIAID Funds Construction of Biosafety Laboratories, *supra* note 25.

<sup>160</sup> BOSTON, MASS. MUN. CODE ch. 17 § 9 (2005), available at <http://www.amlegal.com/boston%5Fma/>.

satisfied with the voluntary NIH guidelines.<sup>161</sup> The ordinance also required all institutions proposing any use of rDNA technology to obtain a use permit from the Board of Health and Hospitals before engaging in any rDNA activity, including construction or renovation of facilities for rDNA purposes.<sup>162</sup> The ordinance reinforces the NIH guidelines' requirement for an IBC by mandating that a committee be established in accordance with the NIH guidelines and that it "include at least one representative from the surrounding community, who [is] approved by the [Boston Public Health] Commissioner."<sup>163</sup> The ordinance includes a provision for reporting<sup>164</sup> and lists penalties for permit violations.<sup>165</sup> In addition, the ordinance created the Boston rDNA Advisory Committee (BRAC),<sup>166</sup> and charged it with reviewing literature on rDNA research and overseeing the regulation and permitting processes.<sup>167</sup> Because the new national BSL-4 biocontainment laboratory at Boston University will primarily focus on high-risk emerging infectious diseases,<sup>168</sup> rather than rDNA, the current ordinance will not significantly impact the new project.<sup>169</sup>

Boston University is planning to build the national biocontainment laboratory in a well populated area of south Boston, much to the dismay of residents.<sup>170</sup> Approximately 150 scientists from the Boston area released a letter on April 13, 2004, calling on city officials and Boston University Trustees to halt plans for the laboratory.<sup>171</sup> The scientists objected to the facility on "scientific, safety and political grounds, and have joined residents' groups<sup>172</sup> who claim that the laboratory is being foisted on one of Boston's poorest neighborhoods, next door to Boston Medical Center."<sup>173</sup> Penn Loh, Executive Director of Alternatives for Community and Environment (ACE) argues that the lab should not be built in Boston because the area is more densely populated than that around any comparable existing BSL-4 laboratory in the United States.<sup>174</sup> However, the university argues that researchers

<sup>161</sup> NIH Guidelines, *supra* note 13.

<sup>162</sup> BOSTON, MASS. MUN. CODE ch. 17 § 9.1(d) (2005), available at <http://www.amlegal.com/boston%5Fma/>.

<sup>163</sup> Ch. 17 § 9.1(e).

<sup>164</sup> Ch. 17 § 9.1(f).

<sup>165</sup> Ch. 17 § 9.6.

<sup>166</sup> Ch. 17 § 9.1(c).

<sup>167</sup> Ch. 17 § 9.3.

<sup>168</sup> Rex Dalton, *Infection Scare Inflames Fight Against Biodefense Network*, 433 NATURE 344 (2005) [hereinafter *Infection Scare*].

<sup>169</sup> BOSTON, MASS. MUN. CODE ch. 17 § 9 (2005), available at <http://www.amlegal.com/boston%5Fma/>.

<sup>170</sup> *Infection Scare*, *supra* note 168, at 344.

<sup>171</sup> Rex Dalton, *Boston Locals Fight Government Scheme for Bioterror Defense Lab*, 428 NATURE 785 (2004) [hereinafter *Boston Locals Fight*].

<sup>172</sup> Residents groups working to stop or regulate the development of a national biocontainment laboratory in Boston include ACE (Alternative for Community & Environment) and Boston Mobilization. ACE Alternative for Community & Environment, <http://www.ace-ej.org/BiolabWeb/biolab.html> (last visited Oct. 28, 2006); Boston Mobilization, Boston Mobilization (last visited Oct. 28, 2006).

<sup>173</sup> *Boston Locals Fight*, *supra* note 171, at 785.

<sup>174</sup> John Dudley Miller, *Sparks Fly on Boston Lab Plan*, THE SCIENTIST, May 5, 2004, <http://www.the-scientist.com/news/20040505/02>. In 2000 NIAID used the fact that the area was sparsely populated as a justification for selecting the Rocky Mountain Laboratories (RML) site for development of a new CDC BSL-4 laboratory saying that "the RML campus is located in rural western Montana, well removed from major population centers [which] reduces the possibility that an accidental release of a biosafety level-4

will be doing life saving work at the laboratory and that it will bring new jobs and tens of millions of dollars in funding to a hard-pressed corner of the city.<sup>175</sup>

Massachusetts currently has no laws or regulations restricting BSL-4 or other biocontainment research laboratories on a state-wide level.<sup>176</sup> State Representative Gloria Fox sponsored a bill, titled, An Act Protecting the Public Health and Environment from Select Toxic Biological Agents, introduced on January 5, 2005.<sup>177</sup> The proposed bill was referred to the Joint Committee on Environment, Natural Resources, and Agriculture, which held a hearing to discuss the proposed legislation on June 9, 2005.<sup>178</sup> On May 10, 2006, the Committee introduced an amended draft of the bill, titled, An Act Ensuring Safety and Security in Biomedical Laboratories and Facilities.<sup>179</sup> This new bill is presently making its way through the committee process.<sup>180</sup> The current version of the proposed legislation does not prohibit biocontainment laboratories or limit the research that can be done in BSL-4 laboratories; however, it does make compliance with the federal biosafety guidelines state law and require a formal permitting process.<sup>181</sup> The legislation also requires the creation of a community oversight board for each BSL-4 laboratory to help ensure transparency of operations and research and requires municipalities where BSL-4 laboratories are located to have emergency response plans specifically for the laboratory.<sup>182</sup> There are also provisions for inspections, whistleblower protections, and penalties for violations.<sup>183</sup> Federal preemption should not be an issue because there has been no field preemption in this area and, even if the state regulations were to overlap with the select agent or OSHA regulations, the regulations are not incompatible and thus can coexist.

Not willing to wait for the state to take action, the city of Boston developed its own laboratory safety regulations. The process began over three years ago when three Boston City Councilors proposed a new ordinance, titled, An Ordinance Regarding the Prohibition of Research Designated as Biosafety Level 4 (BSL-4).<sup>184</sup> As its title indicates, the ordinance was designed to completely prohibit BSL-4

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organism would lead to a major public health disaster.” Letter from Paul A. Marshall, Freedom of Information Coordinator, National Institute of Allergy and Infectious Diseases to James Miller, President, Friends of the Bitterroot (Jan. 9, 2003), *available at* <http://www.ace-ej.org/BiolabWeb/Biolabdocs/NIAIDmemoRMLsiting.pdf>.

<sup>175</sup> Boston Locals Fight, *supra* note 171, at 785.

<sup>176</sup> A Westlaw search of Massachusetts legislation indicates that there is no regulatory legislation on BSL-4 laboratories; this is confirmed by statements on the ACE (Alternative for Community & Environment) website. ACE, <http://www.ace-ej.org/BiolabWeb/StateLegislation.htm> (last visited Oct. 28, 2006).

<sup>177</sup> H. 1397, 184<sup>th</sup> Gen. Ct., Reg. Sess. (Mass. 2005).

<sup>178</sup> As reported on the ACE (Alternative for Community & Environment) web site. ACE, <http://www.ace-ej.org/BiolabWeb/StateLegislation.html> (last visited Oct. 28, 2006).

<sup>179</sup> H. 4937, 184<sup>th</sup> Gen. Ct., Reg. Sess. (Mass. 2005).

<sup>180</sup> LEGISLATIVE HISTORY OF THE BILL ENSURING SAFETY AND SECURITY IN BIOMEDICAL LABORATORIES AND FACILITIES, H. 4937, 184<sup>th</sup> Gen. Ct., Reg. Sess. (Mass. 2005), *available at* <http://www.mass.gov/legis/184history/h04937.htm>.

<sup>181</sup> H. 4937.

<sup>182</sup> H. 4937.

<sup>183</sup> H. 4937.

<sup>184</sup> BOSTON, MASS. MUN. CODE ch. § 16-47 (2003).

research within the Boston city limits, but it did not pass.<sup>185</sup> Next, Thomas M. Menino, Mayor of Boston, requested that the Boston Public Health Commission study the issue and develop biosafety regulations to strengthen safety oversight of all biological research laboratories in Boston.<sup>186</sup> On November 16, 2005, the Boston Public Health Commission proposed new biological laboratory regulations and published them for public review and comment through January 31, 2006.<sup>187</sup> A second draft of proposed regulations was issued on June 13, 2006,<sup>188</sup> and the final regulations were passed on September 19, 2006.<sup>189</sup> The new regulations mandate that all laboratories operating at biosafety levels two, three, and four maintain a comprehensive biosafety compliance program in order to obtain an operating permit.<sup>190</sup> Research institutions must comply with biosafety guidelines, report any incidents of disease, significant exposure, or illness, and submit to inspections.<sup>191</sup> Research institutions will be subject to fines and/or revocation or suspension of their permits for non-compliance.<sup>192</sup> In addition, the Executive Director of the Boston Public Health Commission has the power to take corrective action including closing laboratories in the case of an immediate threat to public safety.<sup>193</sup> These new regulations provide the Boston Public Health Commission with significant oversight power, including the ability to enforce compliance with safety guidelines, which will be a major step in protecting public health and safety. If the state legislature decides to implement new regulations, too, any conflicts with the Boston regulations would need to be resolved. However, based on home rule principles, laboratories would most likely have to comply with both sets of regulations.

Boston area community groups have pursued additional legal avenues to halt the development of the BSL-4 laboratory at Boston University. Members of the community action group Safety Net filed a civil suit challenging the legal adequacy of the environmental analysis used to approve the Final Environmental Impact Report (EIR) on the Boston University national BSL-4 laboratory under the Massachusetts Environmental Policy Act (MEPA).<sup>194</sup> The group alleged numerous

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<sup>185</sup> Ch. § 16-47.

<sup>186</sup> Press Release, Boston Public Health Commission, Boston Public Health Commission Releases Proposed Biological Laboratory Regulations for Public Comment (Nov. 16, 2005), [http://www.bphc.org/news/press\\_release\\_content.asp?id=299](http://www.bphc.org/news/press_release_content.asp?id=299).

<sup>187</sup> *Id.* Comments were originally required to be submitted by January 10, 2006 but the comment period was extended until January 31, 2006 to accommodate the busy holiday season and allow all interested parties ample time to comment. Press Release, Boston Public Health Commission, Boston Public Health Commission Extends Comment Period for Proposed Biological Laboratory Regulations (Dec. 14, 2005), [http://www.bphc.org/news/press\\_release\\_content.asp?id=301](http://www.bphc.org/news/press_release_content.asp?id=301).

<sup>188</sup> Press Release, Boston Public Health Commission, Boston Public Health Commission Releases 2<sup>nd</sup> Draft of Proposed Biological Laboratory Regulations for 45 Day Public Comment (Jun. 14, 2006), [http://www.bphc.org/news/press\\_release\\_content.asp?id=334](http://www.bphc.org/news/press_release_content.asp?id=334).

<sup>189</sup> Press Release, Boston Public Health Commission, Boston Public Health Commission Passes Biological Lab Regulations (Sept. 20, 2006), [http://www.bphc.org/news/press\\_release\\_content.asp?id=363](http://www.bphc.org/news/press_release_content.asp?id=363).

<sup>190</sup> Boston Public Health Commission Regulation, Biological Laboratory Regulations, §§ 2, 3 (Sept. 19, 2006), [http://www.bphc.org/board/pdfs/regs\\_LabRegFinal\\_9-19-06.pdf](http://www.bphc.org/board/pdfs/regs_LabRegFinal_9-19-06.pdf).

<sup>191</sup> §§ 2, 3.

<sup>192</sup> § 7.

<sup>193</sup> § 7.03.

<sup>194</sup> Complaint at 1, *Ten Residents of Boston v. Boston Redevel. Auth.*, 2006 WL 2440043 (Mass. Supp.

MEPA violations in their amended complaint,<sup>195</sup> and the Superior Court of Massachusetts agreed, vacating the Secretary of Environmental Affairs' approval of the EIR.<sup>196</sup> Civil litigation, attempting to enforce existing environmental impact requirements, has been successful in other areas when used to stop or slow the development of new biohazard research facilities.<sup>197</sup>

In contrast to the strong public concern and proposed regulatory legislation in Massachusetts,<sup>198</sup> the public response in Galveston, Texas has been very favorable. A significant public education and outreach campaign implemented by officials at the University of Texas contributed to the favorable public opinion in Galveston.<sup>199</sup> The only proposed legislation relating to the new national biocontainment laboratory in Galveston has been University of Texas funding appropriations requests for the national laboratory project.<sup>200</sup> In addition, a federal public hearing in Galveston on March 31, 2004, about the proposed national biocontainment laboratory, only attracted a single dissenting voice.<sup>201</sup> The media in Galveston has been very supportive.<sup>202</sup> The Galveston County Daily News reported that “[s]afety and security features at University of Texas Medical Branch infectious disease laboratories reduce to miniscule the chance of a dangerous microbe escaping into the community.”<sup>203</sup> The paper went on to quote David Walker, director of the university's Center for Biodefense and Emerging Infectious Diseases as stating “[w]e've had these BSL 3 labs for a long time. . . BSL 4 will give us more opportunities to work with more dangerous agents with more complete safety and security. It eliminates the risk.”<sup>204</sup> The University puts a similar positive spin on the development of the new national BSL-4 laboratory in their press releases, recently touting the number of dignitaries who attended the ceremonial groundbreaking for the new laboratory, including then U.S. Representative Tom Delay and Dr. Anthony

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2005) (No. 5-0109-G).

<sup>195</sup> *Id.* at 1-3.

<sup>196</sup> *Ten Residents of Boston v. Boston Redevelopment Authority*, 21 Mass. L. Rptr. 324, WL 2440043 \*19 (Mass. Supp. 2006) (holding that the Secretary's approval of the final EIR was “arbitrary and capricious”).

<sup>197</sup> *See, e.g.* Bruce Diamond, *Backyard Biodefense Rouses Extreme Reactions*, 9 NATURE MEDICINE 805 (2003) (reporting that a resident's group in Hamilton, Montana had been able to delay the development of a BSL-4 laboratory at NIAID's Rocky Mountain Laboratories by forcing NIH to complete a lengthy environmental impact statement).

<sup>198</sup> *See supra* text accompanying notes 170-175.

<sup>199</sup> Rex Dalton, *Residents Force Review of Biodefense Lab*, 419 NATURE 423 (Oct. 2003).

<sup>200</sup> A Westlaw search on biocontainment indicated that the only bills pending in the Texas state legislature relative to the new national biocontainment laboratory at the University of Texas Medical Branch in Galveston were appropriations requests. *E.g.* TEX. S.B. 12, 79<sup>th</sup> Leg. 2d Sess. (Tex. 2005) (authorizing a \$57 million appropriation for the National Biocontainment Laboratory facilities at the University of Texas Medical Branch at Galveston).

<sup>201</sup> *Boston Locals Fight*, *supra* note 171, at 785.

<sup>202</sup> An October 2006 search of google.com for media stories on the new national laboratory at the University of Texas Medical Branch in Galveston turned up only favorable stories, as did a similar search of Technorati.com.

<sup>203</sup> Carter Thompson, *Officials: Safety at Lab Top Priority*, Galveston County Daily News, Oct. 12, 2003, available at: <http://www.galvestondailynews.com>.

<sup>204</sup> *Id.*

Fauci, Director of the National Institutes of Allergy and Infectious Diseases.<sup>205</sup>

Apparently, the state of Texas is satisfied with the current federal biosafety guidelines and does not see the need for additional restrictions; the Commonwealth of Massachusetts, on the other hand, is both engaging in a robust public debate and taking definitive action toward local regulation of biohazard research.<sup>206</sup> Boston's new laboratory regulations place it well ahead of the nation in terms of protecting the public welfare from the risks of biohazard research. The rest of the nation is left to play catch-up. Regulating city-by-city and state-by-state in a piece-meal fashion is not very efficient. A federal rule making process would be more effective and would perhaps produce a better outcome through incorporation of nationwide input from experts in this complex field, in a way that cannot be accomplished on a local level.

#### IV – Federal Biohazard Regulations Critical for Public Safety

After the tragic events of September 11, 2001 and the deadly anthrax attacks, fear about the threat of bioterrorism dramatically increased.<sup>207</sup> The government has taken unprecedented steps to rapidly enhance America's biodefense capabilities by dramatically increasing investment in research,<sup>208</sup> especially after the realization that simple devices such as crop dusting airplanes or small perfume atomizers could be used to spray dangerous biological agents on an unsuspecting public.<sup>209</sup> Microbiologists are faced with a difficult situation where, even as they are being asked to help defend against the threat of bioterrorism, there is concern that they could become part of the problem.<sup>210</sup>

The proliferation of research on highly virulent pathogens in academic and commercial settings, without proper reporting and controls, poses a national public health threat. As discussed *supra*, the biocontainment aspect of research with dangerous pathogens is only covered by guidelines, not enforceable regulations. Due to the dramatic increase in funds available for biodefense research, there is a mismatch between the demand for research and the availability of experienced researchers. As a result, scientists with too little training may be handling infectious agents that are too dangerous for their level of experience.<sup>211</sup> Until recently, biodefense research on highly virulent BSL-4 pathogens was done only in high security government facilities, run by the Centers for Disease Control and Prevention (CDC) and the U.S. Army Medical Research Institute for Infectious Diseases

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<sup>205</sup> Judie L. Kinonen, *GNL Groundbreaking Attracts Large Crowd*, University of Texas Medical Branch, Galveston National Laboratory, Apr. 17, 2005, available at [http://www.utmb.edu/gnl/news/news\\_0817.shtml](http://www.utmb.edu/gnl/news/news_0817.shtml).

<sup>206</sup> See discussion *supra* Part III (explaining the different responses to the local development of a level four biocontainment laboratory in Massachusetts versus Texas).

<sup>207</sup> Ronald M. Atlas, *Bioterrorism and Biodefense Research: Changing the Focus of Microbiology*, NATURE REV. MICROBIOLOGY 1, Oct. 2003, at 70.

<sup>208</sup> *Id.*

<sup>209</sup> Committee on Environmental Health and Committee on Infectious Disease, American Academy of Pediatrics, *Chemical-Biological Terrorism and Its Impact on Children: A Subject Review*, 105 PEDIATRICS 662, 663 (2000).

<sup>210</sup> Atlas, *supra* note 207, at 70.

<sup>211</sup> THE SUNSHINE PROJECT, *supra* note 149, at 20.

(USAMRIID),<sup>212</sup> where oversight for compliance with safety guidelines is fairly strict. However, much of the proposed new biodefense research will be conducted in BSL-3 and BSL-4 laboratories in academic institutions around the country.<sup>213</sup> The expansion of this research to academic laboratories may be needed to achieve the goal of rapid development of vaccines, countermeasures, and other biodefense strategies. However, advocacy groups, such as The Sunshine Project<sup>214</sup> and the Council on Responsible Genetics,<sup>215</sup> are opposed to having high-security containment laboratories in their communities because of the potential risks of laboratory accidents.<sup>216</sup>

Questions of safety regarding high risk biohazard research and the need for regulations have split the scientific community.<sup>217</sup> The rules governing select agents have been met with resistance from scientists because they require laboratories to meet extensive security, registration, and reporting requirements.<sup>218</sup> Many microbiologists are confused and worried about complying with the select agent security regulations and fear that innocent administrative slip-ups could cause them to be dragged through the courts by overzealous federal investigators.<sup>219</sup> This grumbling may be just a natural resistance to change.<sup>220</sup> However, some researchers argue that the select agent regulations create “a climate of fear” that could potentially drive talented individuals out of select agent research, despite the attractive funding opportunities.<sup>221</sup> Others are concerned that their research will be constrained by strict new rules.<sup>222</sup> In addition, some argue that even locking laboratory doors, as required by the select agent regulations and BSL-4 guidelines, will inhibit the academic tradition of free exchange.<sup>223</sup> However, experts warn that if accidents are

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<sup>212</sup> Laura H. Kahn, *Biodefense Research: Can Secrecy and Safety Coexist?*, 2 *Biosecurity and Bioterrorism: Biodefense, Strategy, Practice, and Science* 2 (2004), available at The Science Advisory Board, Perspectives, <http://www.scienceboard.net/community/perspectives.110.html>.

<sup>213</sup> *Id.*

<sup>214</sup> THE SUNSHINE PROJECT, *supra* note 149.

<sup>215</sup> COUNCIL FOR RESPONSIBLE GENETICS, *supra* note 34.

<sup>216</sup> Kahn, *supra* note 212, at 2-3.

<sup>217</sup> Erika Check, *Heightened Security after Flu Scare Sparks Biosafety Debate*, 434 *NATURE* 943, 943 (2005) [hereinafter *Heightened Security*]. See also Miller, *Sparks Fly on Boston Lab Plan*, *THE SCIENTIST*, May 5, 2004, <http://www.the-scientist.com/news/20040505/02> (explaining that plans to build a BSL-4 research laboratory at Boston University have “split the local life sciences community, pitting hundreds of scientists against one another.”).

<sup>218</sup> *Heightened Security*, *supra* note 217, at 943.

<sup>219</sup> Apoorva Mandavilli, *Nebulous New Rules Rouse Fear and Loathing in Laboratories*, 9 *NATURE MEDICINE* 247, 247 (2003). The trial of highly respected plague researcher Thomas Butler for theft and illegally transporting plague samples overseas profoundly disturbed the scientific community, which sees him as a victim of a misguided and vindictive government prosecution. Erika Check, *Boom, or Bust?*, 426 *NATURE* 598 (2003) [hereinafter *Boom or Bust*]. Stanley Falkow, a microbiologist at Stanford University wrote to then United States Attorney General John Ashcroft arguing that “the government’s excessive zeal for biosecurity has trampled over Butler’s rights, and asking: “How could I possibly permit my students and myself to be subject to the same nightmare if we also made an inadvertent mistake?” *A Cause Célèbre*, 426 *NATURE* 598, 598 (2003).

<sup>220</sup> Mandavilli, *supra* note 219, at 247.

<sup>221</sup> *Boom or Bust*, *supra* note 219, at 601.

<sup>222</sup> Jonathan Knight, *Crackdown on Hazardous Agents Raises Concern for Bona Fide Labs*, 414 *NATURE* 3, 3 (2001) (quoting John Collier, a microbiologist at Harvard Medical School in Boston).

<sup>223</sup> Mandavilli, *supra* note 219, at 247. Texas Tech researcher Ted Reid has said that “[u]niversities need

to be avoided, scientists need to take biosafety more seriously.<sup>224</sup>

The Nuclear Regulatory Commission (NRC) regulations on research with radioactive material have not overly impeded research progress or created a dearth of talented researchers. The NRC regulatory system demonstrates how regulations can be successfully implemented in a research setting to the benefit of all.<sup>225</sup> Implementing new federal biosafety regulations that would require compliance with the current *BMBL* guidelines<sup>226</sup> would increase accountability without adding overly burdensome regulatory requirements. The guidelines reflect the consensus of what it takes to provide safe containment and, in theory, institutions are already complying with these safety guidelines.

However, the Bush administration insists that mandatory laboratory safety laws are unnecessary because the “culture of responsibility” at Institutional Biosafety Committees (IBCs) will protect Americans and the world from accidents and abuse in biodefense research.<sup>227</sup> However, according to the federal guidelines, IBCs are only tasked with oversight of rDNA research,<sup>228</sup> not other biohazard research. Additionally, concerns have been raised about whether NIH is enforcing compliance with the IBC program.<sup>229</sup> Clearly, biosafety regulations for infectious disease research are lacking and the *laissez-faire* attitude of the current administration is allowing a very risky situation to go unchecked.<sup>230</sup>

States and communities should not be left to devise their own regulations in this complex and critical area, because an infectious disease outbreak in region can quickly spread around the country and the globe causing great harm. The current IBC system needs to either be revamped or replaced with a more robust system of responsible committees with an incentive for compliance. This must be mandated by a comprehensive new system of federal regulations with enforceable, real consequences for non-compliance.

Currently, the government organizations charged with protecting the health and welfare of Americans lack the authority to create, maintain, and enforce comprehensive biosafety regulations. NIH is not a regulatory body.<sup>231</sup> NIH could take a step towards increased safety by updating and expanding the rDNA guidelines

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an open, free workspace that allows people to interact . . . [y]ou start acting like a government security lab, and it's over.” *Id.*

<sup>224</sup> Miller, *supra* note 67.

<sup>225</sup> NRC, Standards for Protection Against Radiation, 10 C.F.R. §§ 20.1-2402 (2005).

<sup>226</sup> *BMBL*, *supra* note 8.

<sup>227</sup> News Release, The Sunshine Project, NIAID Biodefense Program Funds in Violation of Federal Biosafety Rules (Aug. 2, 2004), <http://www.sunshine-project.org/publications/pr/pr020804.html>.

<sup>228</sup> NIH Guidelines, *supra* note 13.

<sup>229</sup> THE SUNSHINE PROJECT, *supra* note 149, at 4.

<sup>230</sup> A rash of laboratory accidents were reported in the United States and abroad in 2003-04, including laboratory-acquired SARS infections in Asia (*see supra* note 17), an Ebola death in Russia, an Ebola accident in the United States, accidental anthrax releases at a United States Army laboratory, and ‘dead’ anthrax that was in fact live sent to a children’s hospital in the United States. THE SUNSHINE PROJECT, *supra* note 149, at 22. “[P]roponents of the IBC system tend to overlook . . . [these accidents], even as they congratulate themselves that critics’ worst fears about an accidental release have not been realized.” *Id.*

<sup>231</sup> *See* Director of National Institutes of Health, 42 U.S.C. § 282 (2002) (specifying the duties and powers of the Director of the National Institutes of Health).

to include the *BMBL* guidelines, and by using their spending power through grant approvals to encourage compliance with the guidelines. Unfortunately, NIH does not have the power to turn the guidelines into regulations.<sup>232</sup> The CDC only has the authority to regulate agents that could “pose an immediate severe threat to public health and safety.”<sup>233</sup> Thus, the CDC is limited to expanding the list of select agents<sup>234</sup> or expanding provisions of the select agent rule to require compliance with the *BMBL* guidelines. OSHA may be able to add regulations under their workplace safety authority mandate. In particular, they could tighten up their lab acquired infections regulations. At this time, though, none of these agencies has the authority to create the broad, comprehensive regulations needed. Congress must enact new legislation authorizing one of these existing agencies to create the necessary regulations or creating a new agency, similar to the Nuclear Regulatory Commission (NRC), with broad regulatory powers over dangerous pathogens.

The high priority placed on the need to move forward quickly on biodefense research may explain the lack of biosafety regulations. Regulations are often perceived as likely to impede scientific progress. America's heightened fear over the possibility of a bioterrorist attack has greatly outweighed the concern for biohazard research safety. The government has placed a higher priority on rapidly growing the biodefense industry than on developing appropriate biosafety regulations. This shortsighted view may prove to be very costly in the long run. In the past, there were fears that radiation in research could be misused and thus its use is licensed and tightly regulated by the NRC.<sup>235</sup> The reason for the disparity between the two systems is not readily apparent; however, it is significant to note that biohazards have not had their Three Mile Island<sup>236</sup> yet. The biodefense rush should be tempered with a reasonable regulatory system so that the cure does not become more painful than the illness.

#### CONCLUSION

New federal regulations on biohazards in medical research are needed. Congress should authorize comprehensive laboratory safety regulations that require an Institutional Biosafety Committee (IBC) with supervisory powers, a biosafety officer, risk assessments, mandatory compliance with the existing *BMBL* and NIH rDNA guidelines, employee training, medical monitoring, reporting of significant exposures and regular review and assessment. These regulations should be enforced through licensing, inspections, and penalties.

A strong IBC with experienced and knowledgeable members is an essential part

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<sup>232</sup> *Id.*

<sup>233</sup> Bioterrorism Preparedness Act, 42 U.S.C. § 262a (2002).

<sup>234</sup> *See supra* note 10 (adding the 1918 influenza strain to the HHS select agent and toxins list on October 20, 2005).

<sup>235</sup> NRC, Standards for Protection Against Radiation, 10 C.F.R. §§ 20.1-2402 (2005).

<sup>236</sup> On March 28, 1979, Unit two at the nuclear power plant on Three Mile Island suffered a partial core meltdown. The situation unfolded during five tense days, during which time the various federal, state, and local government agencies considered whether or not to require a full emergency evacuation of the local population of 25,000 people. Although no identifiable injuries occurred at the time, a government report projected at least one extra cancer death due to radiation exposure. Three Mile Island Accident, Wikipedia, [http://en.wikipedia.org/wiki/Three\\_Mile\\_Island](http://en.wikipedia.org/wiki/Three_Mile_Island) (last visited on Nov. 12, 2006).

of a comprehensive institutional safety program. The regulations should specify that each research institution's IBC must review and approve the risk assessment, and specify the correct biosafety level (BSL), in compliance with the *BMBL* guidelines for each project before research begins. The regulations should require that employees, including researchers, lab technicians, and janitorial and maintenance personnel, be fully trained in the proper BSL procedures and that training be updated regularly. All laboratory personnel should also be required to be medically monitored to check for potential research related illnesses and laboratory accidents leading to significant exposures should be tracked and reported.

In addition, institutions doing BSL-3 or BSL-4 level research, or large volume work, should be required to have a Biosafety Officer tasked with making periodic inspections to ensure that the laboratories are following the required procedures, reporting any significant research-related laboratory accidents or illnesses, developing emergency plans for handling laboratory emergencies, and providing advice to lead researchers and the IBC on research safety and security procedures. All laboratories doing BSL-2, BSL-3, and BSL-4 biohazards research should be required to be licensed. Periodic inspections should be done to spot violations and enforce compliance. Violations should be punishable by fines and regulators should have the ability to shut down unsafe laboratories.

The elements described above comprise a workable and reasonable comprehensive safety program, which would protect laboratory workers and the public from the risk of serious harm from biohazard research accidents. Congress should act now, rather than wait until a major accident proves that regulations were needed.