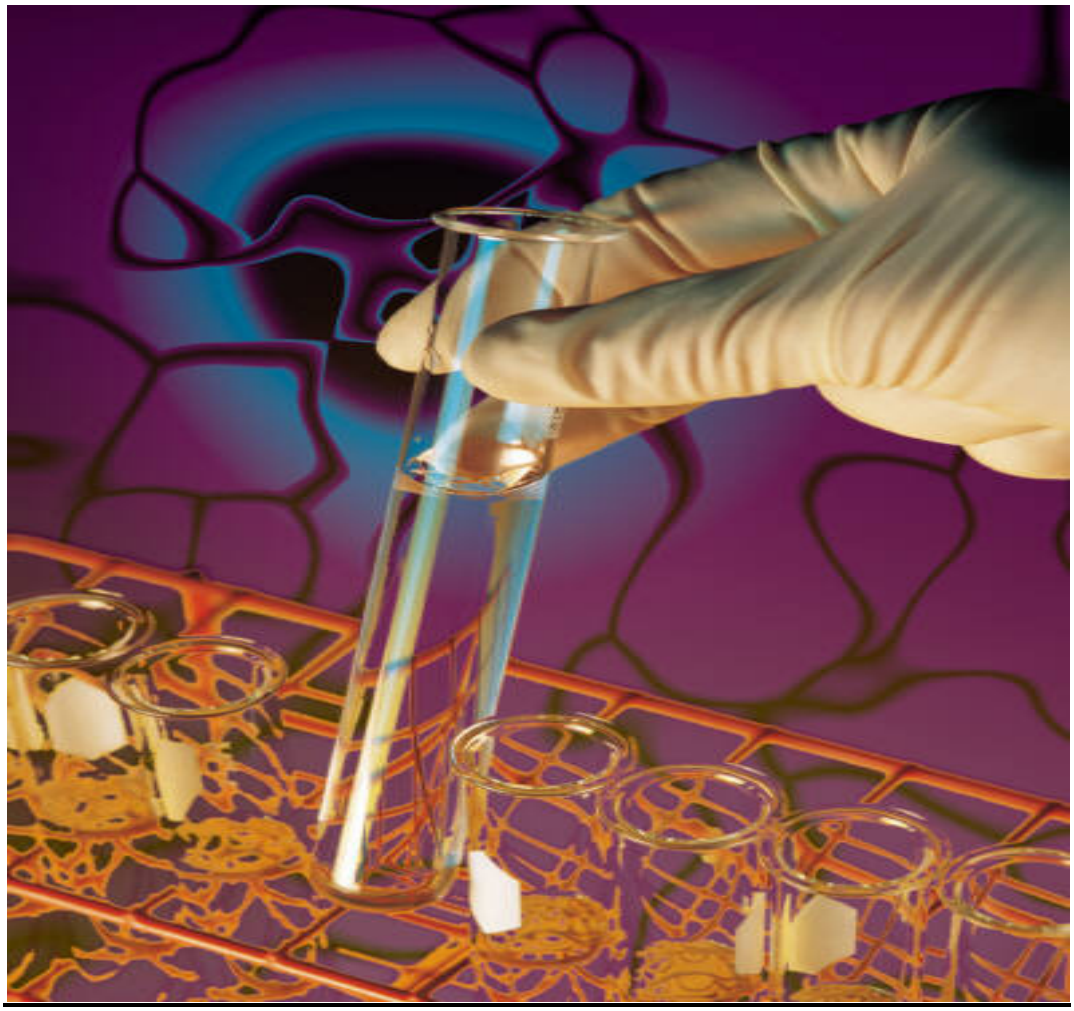
Council for Responsible Genetics

WORKER SAFETY IN BIOLOGICAL LABORATORIES

LIMITATIONS OF OSHA REGULATIONS GOVERNING BIO-LABORATORY SAFETY

SEPTEMBER 2010



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INTRODUCTION

Why would Pfizer, the world's largest drug company, so mistreat and silence one of their top molecular biologists that a federal jury in Connecticut recently awarded her $1.37 million in damages? The answer promises to tear open the curtain covering hazards confronting tens of thousands of scientists and assistants in corporate, government and university labs. Becky McClain's lawsuit against Pfizer claimed that the company's sloppiness exposed her to an engineered form of the lentivirus, a virus related to one that could lead to immune deficiencies. It documented the absence of any available risk assessments and exposed the cruel refusal to give afflicted employees their own exposure records on the grounds that they are company trade secrets. Pfizer denied connections between its lab practices and Ms. McClain's reoccurring paralysis and other illnesses. Becky McClain is not alone. As a revolution in genetic and other biological sciences has greatly expanded the number of laboratories in the past twenty years, workers in the biological industries have suffered from health and safety regulations that have fallen well behind the times. David Michaels, the head of OSHA, has admitted that there are "many gaps" in his agency's standards. "New biological materials, nanomaterials, there are many things where we don't have adequate information" (NY Times interview).

The Council for Responsible Genetics is mobilizing an effort to ensure that worker health and safety are once again protected in the United States by identifying hazards, educating the public and policy makers and working towards the creation of enforceable and openly accessible standards and practices for biological laboratories. The following report represents an important step in this process as it lays out the current regulatory framework for commercial and academic biotechnology laboratories in the United States, identifies specific gaps in these regulations and offers some initial recommendations for improvements.

QUESTIONS EXPLORED

(1) What federal regulations currently govern worker safety in commercial and academic biotechnology laboratories?

The main federal agencies overseeing safety in biological laboratories are OSHA and NIH. OSHA's regulations on chemical and blood borne pathogen hazards govern both academic and commercial labs. The NIH issues two sets of guidelines describing safety practices for biological

laboratories. Along with the CDC, it issues a manual on Microbiological and Biomedical Laboratories (BMBL). The Office of Biotechnology Activities (OBA) at the NIH also publishes a set of safety requirements for experiments dealing with recombinant DNA (rDNA), entitled the NIH Guidelines for Research Involving Recombinant DNA Molecules. While the guidelines on rDNA are mandatory for institutions receiving NIH funds, largely universities and academic laboratories, the BMBL is entirely advisory for all institutions.

(2) What gaps exist in these regulations?

While comprehensive and frequently updated, the NIH guidelines are largely advisory for many institutions. Even the NIH guidelines on rDNA research, which are mandatory for academic institutions, remain largely unenforced. This is primarily because the NIH is not an inspection or enforcement agency. OSHA regulations on the other hand, while mandatory, do not address a broad range of potential safety issues encountered in biological laboratories. OSHA has specific regulations governing chemical substances and blood borne pathogens, which focus on HIV and HBV. However, most of the potentially infectious agents studied and engineered in biolabs are covered by neither of those two provisions in the OSHA regulations.

(3) How can oversight of laboratory safety be improved?

At minimum, OSHA should make both the BMBL and the NIH guidelines on rDNA research mandatory for all laboratories. This reform, however, is still insufficient given the high level of expertise required in order to assess and enforce compliance with NIH guidelines. Rather, safety rules that are conducive to fast and easy inspections that can be conducted by regulators lacking in specific expertise on biological and rDNA hazards should also be implemented. Therefore, OSHA should also enact specific rules that govern safety generally, not unlike some of the regulations research laboratories dealing with blood borne pathogens or chemical hazards must comply with, including requirements for restricted access, air filters, personal protective equipment, and food and drink prohibitions. However, because many biohazards are not only blood borne but also perhaps airborne, provisions requiring the employer to assess specific hazards and to protect against other routes of infection are also necessary.

DISCUSSION

I. OVERVIEW OF REGULATORY REGIME

1. OSHA

a. General Duty Clause.

Under what is known as the "General Duty Clause" in Section 5 of the Occupational Safety and Hazard Act, an employer is required to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees."[1] This provision is rarely enforced, however, due to the difficulty of proving that a hazard not specifically addressed in OSHA regulations is "known" to the employer.

b. Bloodborne Pathogens (29 C.F.R. §1910.1030 (2009)).

The section on bloodborne pathogens primarily addresses risks to employees working with human blood. It spells out specific requirements for personal protective equipment (PPE) and engineering controls to prevent contact with human blood or "other potentially infectious materials" (OPIM) that might contain human blood in order to protect employees from infection. It also requires that employers implement and annually update an "Exposure Control Plan."

Under this provision, "bloodborne pathogens" is defined as any pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).[2] This section also regulates "Other Potentially Infectious Materials" (OPIM), meaning (1) 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; (2) any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ

[1] 29 U.S.C. § 654(5)(a)(1) (2004).
[2] 29 C.F.R. §1910.1030(b) (2009).

cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.[3]

The bloodborne pathogens standard seeks to regulate occupational exposure to pathogens transmitted through the blood or OPIM, where "occupational exposure is defined as any reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties."[4] Work practice protocols specified in the regulation include mandatory hand washing, personal protective equipment such as latex gloves, engineering controls such as sterilizing surfaces, disposing of needles and containers, and the prohibition of food, drink, etc. in the space where body fluids are handled. These and other controls must be outlined by every employer in an annually updated Exposure Control Plan.[5] The Exposure Control Plan must include (1) a schedule and method of implementation for avoiding incidents as described in regulations and (2) "The procedure of the evaluation of circumstances surrounding exposure incidents . . ."[6] The Plan must be updated at least annually and must "solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps. . ." [7]

Methods of compliance detailed in the regulations include "Engineering and Work Practices Controls" and "Personal Protective Equipment" (PPE) – including specifications for hand washing facilities, antiseptic hand cleanser, gloves, protocols for handling sharps, laundry, equipment disinfection, disposal of waste or infected material, labeling of containers, etc.[8] The regulations also prohibit "eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure."[9] PPE is required only when there is occupational exposure not alleviated by engineering and work practice controls, the determination of which is highly discretional to the determination of the employer.[10]

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[3] *Id.*
[4] *Id.*
[5] Rebecca Emerson, *Biosafety Regulations: Who's Watching the Lab? Safety in High Risk Infectious Diseases Research,* 25 TEMP. J. SCI. TECH. & ENVTL. L. 213, 218–21 (2006).
[6] 29 C.F.R. §1910.1030(c)(1) (2009).
[7] *Id.*
[8] 29 C.F.R. §1910.1030(d) (2009).
[9] *Id.*
[10] *Id.*

In the event of an "exposure incident," meaning "specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties," this section requires that the employer make available to the employee information such as the documentation of the route of exposure, identification and documentation of the source individual of the infection, and provide access to medical care including testing of the source individual, testing for the employee, prophylactic measures, etc.[11] Employers are also required to maintain a sharps injury log documenting exposure incidents relating to the use of needles or other sharps in the handling of human blood.[12]

While the above-mentioned regulations are intended for workers dealing with blood and OPIM generally, OSHA regulations also include specific, more restrictive provisions for "research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV."[13] These regulations do not apply, however, to "clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs."[14] The rules governing these research laboratories specify requirements such as automatic doors, restricted entry, and airflow requirements, etc. They also include specific forms and protocols in the event of exposure, including post-exposure follow up. Generally, these regulations closely mirror the NIH guidelines. The bloodborne pathogens standard further mandates additional training along the guidelines of the BMBL for employees of HIV and HBV laboratories and production facilities.[15]

OSHA has also issued policy statements regarding animal research, advising that the bloodborne pathogens standard covers animal blood only for those animals purposely infected with HIV or HBV. The bloodborne pathogens standard does not apply to animal blood unless the animal has been purposely infected with HIV or HBV. Nevertheless, OSHA *recommends* that persons handling animals or animal blood follow general precautions as recommended by the

[11] 29 C.F.R. § 1910.1030(f)(3) (2009).
[12] 29 C.F.R. § 1910.1030(h)(5) (2009).
[13] 29 C.F.R. § 1910.1030(e) (2009).
[14] *Id.*
[15] 29 C.F.R. § 1910.1030(g)(2) (2009).

Centers for Disease Control/National Institutes of Health Publication, Biosafety in Microbiological and Biomedical Laboratories.[16]

c. Regulation of Laboratories Generally

OSHA's website groups regulations by "Safety and Health Topics,"[17] which cite multiple regulatory provisions that might apply to specific worksites or types of hazards. One of these topics is "Laboratories," which cites the specific regulations discussed below. Interestingly, while there is some reference to the BMBL, there is no reference to the bloodborne pathogens standard. Furthermore, the regulations cited as a part of this topic almost exclusively deal with chemical hazards.

i. Occupational Exposure to Hazardous Chemicals in Laboratories (29 C.F.R. §1910.1450 (2009)).

These regulations outline the rules for working with hazardous chemicals in laboratories. They generally set fairly stringent guidelines describing how employers must assess known hazards and create a workplace environment that protects workers from these hazards. However, these regulations are explicitly excluded from applying to biohazards.

For the purposes of this section, a "hazardous chemical" is defined as "a chemical for which there is statistically significant evidence based on at least one study conducted in accordance with established scientific principles that acute or chronic health effects may occur in exposed employees."[18] The term "health hazard" includes chemicals which are carcinogens, toxic or high toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic systems, and agents which damage the lungs, skin, eyes or mucous membranes.[19] The rules set permissible exposure limits of chemicals and non-biological substances that are explicitly listed as regulated agents by the

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[16] *See* OSHA, *Q49. Is animal blood used in research covered under the laboratory section of the standard?*, Most Frequently Asked Questions Concerning the Bloodborne Pathogens Standard. OSHA website, February 1, 1993. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21010 (accessed on 9/1/10).

[17] OSHA's website groups sets of regulations by "topic," one of which is "Laboratories." Interestingly, this "topic,: accessed at http://www.osha.gov/SLTC/index.html,does not include links to the bloodborne pathogens standard, indicating the degree to which OSHA has failed to address laboratories dealing with biotechnology, where both chemical hazards and biohazards are present.

[18] 29 C.F.R. § 1910.1450(b) (2009).

[19] *Id.*

OSHA rules, as well as maximum atmospheric concentrations for these chemicals in the workplace.[20]

This section also outlines the protocol for determining whether an employee has been exposed to a hazardous chemical where an exposure incident is suspected. Required protocol includes initial monitoring, where the employer must measure the employee's exposure to any substance regulated by OSHA if there is reason to believe that exposure levels for that substance routinely exceed the maximum level permitted under law.[21] Furthermore, the regulation requires the employer to undertake additional periodic monitoring of exposure levels when initial monitoring discloses employee exposure over the maximum level.[22]

In order to ensure that employers comply with exposure limits and regulations, OSHA requires employers to institute a Chemical Hygiene Plan, which is similar to the Exposure Control Plan required under the bloodborne pathogens standard.[23] The Chemical Hygiene Plan requirements are similarly deferential to the assessments of the employer. Furthermore, the requirements for hazard prevention are restricted to known hazards or those agents specifically regulated by OSHA standards only, and thus the chemical hazard regulations do not comprehensively cover novel agents.

As part of the Chemical Hygiene Plan, employers are required to disseminate information regarding hazards, safety protocol, etc. to employees working with known hazards.[24] Employers must also determine the hazardous characteristics of any novel chemical developed in the lab, which includes treating all unknown byproducts as hazardous.[25] When there is reason to suspect that an employee has developed a medical condition as a result of hazardous chemical exposure, including situations such as when an employee develops signs or symptoms associated with a hazardous chemical to which he may have been exposed in the laboratory, when exposure monitoring levels show that an employee may have been exposed at levels above the maximum, or whenever an event takes place in the work area such as a spill, leak, explosion or other occurrence resulting in the likelihood of a hazardous exposure, the employer must provide

[20] 29 C.F.R. § 1910.1450(c) (2009).
[21] 29 C.F.R. § 1910.1450(d) (2009).
[22] *Id.*
[23] 29 C.F.R. § 1910.1450(e) (2009).
[24] 29 C.F.R. § 1910.1450(f) (2009).
[25] 29 C.F.R. § 1910.1450(h) (2009).

medical attention, including any follow-up examinations which the examining physician determines to be necessary.[26]

The chemical hazards standard also requires the designation of personnel responsible for the implementation of the Chemical Hygiene Plan, including the assignment of a Chemical Hygiene Officer, and, if appropriate, the establishment of Chemical Hygiene Committee.

ii. Personal Protective Equipment (29 C.F.R. §§ 1910.132–1910.134 (2009)).

These sections outline requirements for employers to provide protective equipment and clothing for their workers. However, there are very few specific rules or requirements; for the most part, these regulations are highly deferential to employers and rely on the employer to provide the equipment he evaluates as necessary within the specific context of each workplace environment.

Under §1910.132, employers are required to determine whether protective equipment for the "eyes, face, head, and extremities, protective clothing, respiratory devices, and protective shields and barriers" is necessary, and if so, to provide it at no cost to employees.[27] Under more specific provisions dealing with eye and face protection, employers are required to "ensure that each affected employee uses appropriate eye or face protection when exposed to eye or face hazards from flying particles, molten metal, liquid chemicals, acids or caustic liquids, chemical gases or vapors, or potentially injurious light radiation."[28] This regulation also incorporates an external set of standards, the American National Standard Practice for Occupational and Educational Eye and Face Protection, by reference through this section, thereby making those guidelines mandatory.[29]

Additionally, OSHA regulations provide specifically for respiratory protection from the hazards of "harmful dusts, fogs, fumes, mists, gases, smokes, sprays, or vapors," where preventing "atmospheric contamination" by "accepted engineering control measures (for example, enclosure or confinement of the operation, general and local ventilation, and

[26] 29 C.F.R. § 1910.1450(g) (2009).
[27] 29 C.F.R. § 1910.132(a) (2009).
[28] *Id.*
[29] 29 C.F.R. §1910.133 (2009).

substitution of less toxic materials)" is not feasible.[30] The section outlines the kinds of respirators necessary when working with various hazardous substances at different concentrations.

Similar to the Chemical Hygiene Plan and the Exposure Control Plan discussed previously, the respiratory protection rules require the employer to develop and implement a written Respiratory Protection Program, including mandatory worksite-specific procedures and mandatory respirator use. The regulations also require that the program be administered by a suitably trained program administrator. In addition, the program must address potential hazards to employees that may result from respirator use, therefore requiring that employees be evaluated for health and fitness to wear and carry these devices. This regulation also references the Small Entity Compliance Guide, which contains criteria for the selection of a program administrator and a sample program that meets these requirements.[31]

iii. Air Contaminants (29 C.F.R. §1910.1000 (2009)).

OSHA issues specific regulations that set the limits for the ceiling concentration limits of various chemical and solid air contaminants. Limits are set for specific chemical and solid agents; these do not include any potentially airborne biohazards.

iv. Hazard communication (29 C.F.R. §1910.1200 (2009)).

This section aims to "ensure that the hazards of all chemicals produced or imported are evaluated, and that information concerning their hazards is transmitted to employers and employees."[32] The rule includes provisions on what information regarding health hazards and safety precautions must be gathered by employers and disseminated to employees. The regulation requires chemical manufacturers or importers to assess the hazards of chemicals which they produce or import, and lists a series of resources as establishing certain well-studied or well-known chemicals as hazardous. The regulation further requires that all employers provide information to their employees about the hazardous chemicals to which they are exposed. This is to be accomplished by means of a Hazard Communication Program, container labeling and other forms of warning, including material safety data sheets, and information and training.[33] In addition, this section requires distributors to transmit the required safety

[30] 29 C.F.R. §1910.134(a) (2009).
[31] 29 C.F.R. §1910.134(c) (2009).
[32] 29 C.F.R. § 1910.1200(a) (2009).
[33] *Id.*

information to employers.[34] This rule further includes provisions on the required protocol for assessing various hazards and risks. However, the rule explicitly excludes these regulations from applying to biological hazards.[35] Therefore, there are no regulations requiring employers to disclose the detailed risks of working with infectious agents to their workers.

Many of the disclosure requirements mandated under this section hinge on OSHA's interpretation of chemical "identity," which is defined as any chemical or common name which is indicated on the material safety data sheet (MSDS) for the chemical. The name serving as the "identity," which employers use to refer to specific chemical substances, is intended to permit cross-references to be made among the required list of hazardous chemicals, the label and the MSDS.

Importantly, while these regulations are intended to ensure that employers inform workers of the hazards associated with chemical substances they are working with, the regulation specifically allows employers to withhold the "identity" of hazardous chemical if it is a trade secret.[36] In order to qualify for trade secret protection, employers must show that (1) the claim that the information constitutes a trade secret can be supported; (2) information contained in the MSDS concerning the properties and effects of the hazardous chemical is disclosed; (3) the MSDS indicates that the specific chemical identity being withheld as a trade secret; and (4) the specific chemical identity is made available to health professionals, employees, and designated representatives.[37] Nevertheless, trade secret protection does not apply in emergency situations where knowledge of the chemical identity is necessary to provide treatment to an injured or exposed employee. There are also some non-emergency situations where the employer is required to disclose the chemical identity to a health professional (i.e. physician, industrial hygienist, toxicologist, epidemiologist, or occupational health nurse) providing medical or other occupational health services to exposed employee(s), and to employees or designated representatives.[38] In order to receive this information, employees or medical professionals must (1) issue a written request that (2) describes with reasonable detail one or more designated occupational health needs for the information, including to assess the hazards of the chemicals to which employees will be exposed, to conduct or assess a sampling of the workplace atmosphere

[34] 29 C.F.R. § 1910.1200(b) (2009).
[35] *Id.*
[36] 29 C.F.R. § 1910.1200(i) (2009).
[37] *Id.*
[38] *Id.*

to determine employee exposure levels, to conduct pre-assignment or periodic medical surveillance of exposed employees, to provide medical treatment to exposed employees, to select or assess appropriate person personal protective equipment for exposed employees, to design or assess engineering controls or other protective measures, or to conduct studies to determine the health effects of exposure. Furthermore, the regulation requires that (3) the request explain in detail why the chemical identity is essential, and why information such as the properties and effects of the chemical, measures for controlling workers' exposure to the chemical, and methods of diagnosing and treating harmful exposures to that chemical are insufficient to achieve the purpose at hand. Finally, the regulation requires that (4) the request include a description of the procedures to be used to maintain the confidentiality of the disclosed information and (5) that a written confidentiality agreement be created.[39] If the request is denied, the chemical manufacturer, importer or employer must explain in detail how the alternative information described above may satisfy the specific medical or occupational health need without revealing the specific chemical identity."[40]

d. American Biological Safety Association Alliance

The American Biological Safety Association (ABSA) formed an alliance with OSHA to produce information and guidelines for biological laboratory safety. [41] All guidelines produced by the Alliance are advisory only, and for the most part consist of "fact sheets" giving a cursory outline of a limited set of known biohazards. They do not address novel biotechnological products but pre-existing or "natural" bio-hazardous organisms.

One guideline issued by the Alliance is the Select Agent Diseases Fact Sheet,[42] a "reference tool" that includes the symptoms, transmission and treatment for some of the most commonly encountered pathogens or biological toxins that are federally regulated and have the potential to pose a severe threat to public health and safety. The pathogens listed on this fact sheet include anthrax, brucellosis, bubonic plague, glanders, melioidosis, Q fever, tularemia, Rocky Mountain spotted fever, African hemorrhagic fever, Marburg disease, Japanese encephalitis, eastern equine encephalitis, Venezuelan encephalitis, South American hemorrhagic

[39] *Id.*
[40] *Id.*
[41] *American Biological Safety Association (ABSA)*, ALLIANCE: an OSHA Cooperative Program, September 23, 2002. http://www.osha.gov/dcsp/alliances/absa/absa.html (accessed on 9/1/10).
[42] *Select Agent Diseases Fact Sheet*, ALLIANCE: an OSHA Cooperative Program, July 2008. http://absa.org/pdf/SelectAgentsFactSheet.pdf (accessed on 9/1/10).

fever, vesicular disease, Simian B disease, smallpox, and sub-viral related diseases (i.e. Mad Cow Disease).[43] The ABSA Alliance has also issued a "Zoonotic Diseases Fact Sheet,"[44] which includes the symptoms, transmission and treatment for some of the most commonly encountered diseases that are generally found in animals but can be spread to humans.

More generally, ABSA has issued a Principles of Biosafety Fact Sheet,[45] which is comprised of twelve very general rules stressing the importance of employees' being careful and treating experimental materials with caution, as well as other basic, common sense principles for dealing with potentially hazardous biological materials. Finally, ABSA has posted a "BioSafety Levels" [46] fact sheet briefly outlining the safety characteristics requisite of labs at each of the four designated biosecurity levels created by the BMBL. The fact sheet does not describe any guidelines for what kinds of experiments should be relegated to labs at any of these biosafety levels.

2. NIH

The NIH issues two sets of guidelines that govern biological laboratory safety. Along with the CDC, it issues a manual on Microbiological and Biomedical Laboratories (BMBL).[47] However, the safety provisions contained within the BMBL are entirely advisory. The Office of Biotechnology Activities at the NIH also publishes a set of safety requirements for experiments dealing with recombinant DNA (rDNA), entitled the NIH Guidelines for Research Involving Recombinant DNA Molecules (hereinafter, "NIH Guidelines on rDNA Research").[48] Compliance with these guidelines is mandatory only for those institutions that receive NIH funds, and therefore these guidelines are not binding on private industry.

a. NIH/CDC Guidelines for Microbiological and Biomedical Laboratories

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[43] *Id.*
[44] *Zoonotic Diseases Fact Sheet*, ALLIANCE: an OSHA Cooperative Program, July 2008. http://absa.org/pdf/ZoonoticFactSheet.pdf (accessed on 9/1/10).
[45] *Principles of Biosafety Fact Sheet*, ALLIANCE: an OSHA Cooperative Program, April 2008. http://www.absa.org/pdf/OSHAPrincOfBS.pdf (accessed on 9/1/10).
[46] *BioSafety Levels*, ALLIANCE: an OSHA Cooperative Program, April 2008. http://www.absa.org/pdf/OSHABSLFactSheet.pdf (accessed on 9/1/10).
[47] *Biosafety in Microbial and Microbiological Laboratories (BMBL)*, Centers for Disease Control & National Institutes of Health, (5th Ed., December 2009). http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf (accessed on 9/1/10).
[48] *NIH Guidelines for Research Involving Recombinant DNA Molecules*, National Institutes of Health Office of Biotechnology Activities, September 2009. http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Gdlnes_lnk_2002z.pdf (accessed on 9/1/10).

The NIH, in conjunction with the CDC, issues a manual called the Biosafety in Microbiological and Biomedical Laboratories intended to provide guidance on safety protocol in biological laboratories.[49] It is frequently updated, with the most recent edition issued in December of 2009. However, the BMBL is entirely advisory for all institutions.

The BMBL describes practices, safety equipment and facilities that constitute the four Biosafety Levels (BSL), where BSL 1 is appropriate for the least dangerous experiments and where BSL 4 is reserved for the most dangerous biological agents. The BMBL advises that institutions set up Institutional Biosafety Committees (IBCs) to conduct risk assessments on specific experiments and assign them to the appropriate BSL based on the degree of safety risk to researchers, the community and the environment. Factors to be considered in BSL assignment include the biological agent's pathogenicity, route of spread, biological stability, origin and communicability of the agent, the type of testing or procedures to be done with the agent, and the availability of effective vaccines or therapeutic measures. The BMBL also includes Agent Summary Statements for known pathogens outlining laboratory hazards and recommended precautions for IBC's to consider in the risk assessment.[50]

b. NIH Guidelines for Research Involving Recombinant DNA Molecules[51]

These guidelines are issued by the Recombinant DNA Advisory Committee (RAC), within Office of Biotechnology Activities (OBA) at the NIH. Frequently updated, these guidelines constitute the most comprehensive and updated set of best practices for any research involving rDNA. Compliance with these guidelines is mandatory for institutions receiving any NIH funding. Importantly, this mandate extends to all experiments and research within institutions receiving NIH funding, even individual experiments not directly funded by NIH. Like the BMBL, the NIH Guidelines on rDNA Research require that an IBC execute a risk assessment for the rDNA agents used in any experiment, and to implement safety protocols similar to those outlined for BSL equipment and facility requirements under the BMBL. The NIH Guidelines on rDNA Research also provide for public access to IBC records and meeting minutes.

3. Select Agents Regulations

[49] BMBL, *supra* n.47.
[50] *See* Emerson, *supra* n.5 at 218–21.
[51] NIH Guidelines, s*upra* n.48.

The U.S. Department of Health and Human Services (HHS) promulgates a list of "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.[52] The U.S.A. Patriot Act criminalizes unjustified possession or use of "select agents" by "restricted persons."[53] Select agent regulations, therefore, primarily focus on physical security aspects of safety, such as controlling access, rather than biocontainment safety.[54]

II. GAPS IN THE CURRENT REGULATORY FRAMEWORK

1. SCOPE AND FOCUS OF ANALYSIS

This analysis of the gaps in regulations over laboratory safety will focus on the OSHA regulations. This is primarily because the NIH guidelines are largely advisory, and, where mandatory, largely unenforced. Second, a rigorous analysis of gaps in the NIH guidelines would require expertise, experience and technical training in laboratory safety beyond the scope of this report. Nevertheless, this report concludes that the major limitation of the NIH guidelines is the agency's lack of enforcement power. As NIH is not en enforcement agency, it is therefore not equipped to perform the rigorous oversight necessary to ensure IBC compliance. For example, the Sunshine Project found in 2004 that many IBCs do not comply with NIH mandates for disclosure, and that some commercial institutions receiving NIH funding had not yet even set up IBCs; nevertheless, these institutions continued to receive NIH funds.[55] The findings reported by The Sunshine Project suggest that the IBC system may be highly noncompliant with NIH guidelines, but any record of regulatory violation is hidden by nondisclosure and lack of federal oversight.[56] Furthermore, the NIH guidelines are also limited because they are largely deferential to IBC's risk assessments over specific experiments. Therefore, compliance protocol is largely

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[52] 42 C.F.R. §§73.3, 73.4 (2005).
[53] 18 U.S.C. §175(b) (2005).
[54] *See* Emerson, *supra* n.5 at 226. "The safety section requires institutions working with select agents to develop a written biosafety plan "sufficient to contain the select agent or toxin" that takes into consideration the CDC/NIH BMBL guidelines, the NIH rDNA guidelines, and the OSHA regulations. The regulations do not require a BSL risk assessment or safety officer charged with ensuring biosafety. They allow great flexibility and discretion as to biocontainment procedures for select agents."
[55] The Sunshine Project, *Mandate for Failure: The State of Institutional Biosafety Committees in an Age of Biological Weapons Research* 5 (2004). http://www.sunshine-project.org/biodefense/tspibc.pdf (accessed on 9/1/10).
[56] *See* Emerson, *supra* n.5 at 229.

individualized, making it difficult for any inspector to evaluate its sufficiency for any particular experiment.

This analysis also will not focus in detail on Select Agent Regulations. First, select agents are only a small subset of the potential biological hazards – those that might potentially serve as bioweapons – found in commercial and academic biological laboratories. These safety regulations have been criticized as focusing "more on the physical security aspects of safety (such as controlling access), rather than biocontainment safety," and are therefore deemed largely insufficient for protecting worker safety and health. [57]

Finally, this analysis will not explore in-depth on the risk of biohazard release into the environments or communities where research or production laboratories are located. While the Environmental Protection Agency (EPA) has issued regulations governing "intergeneric," or recombinant, organisms, research institutions are clearly exempt from complying with these regulations because they are considered "contained institutions." However, this exemption neglects the real possibility that "contained institutions" often leak or spill the genetically engineered viruses they contain into the environment.

2. GAPS IN OSHA REGULATIONS

There are many specific areas where the OSHA regulations fail to account for the nuanced safety issues that arise in the biological laboratory context. Two overarching concerns, however, prevail across the agency's current regulatory oversight.

First, the majority of OSHA's standards address only known hazards from well-studied or well-known chemical or biological agents. However, as rDNA viruses and microbes have become integral to biological research, the specific risks faced by laboratory workers have become increasingly particularized to individual experiments and workplaces. Therefore, OSHA's framework for regulating only well-identified risks posed by known agents will leave a large portion of workers unprotected.

Second, OSHA regulations, like the NIH guidelines, defer a great deal of the safety decisions to employers' own determinations of the hazards and appropriate safety measures in their individual workplaces. While this in some ways counters the concerns expressed above

[57] *See id.* at 226. "The safety section requires institutions working with select agents to develop a written biosafety plan "sufficient to contain the select agent or toxin" that takes intoconsideration the CDC/NIH BMBL guidelines, the NIH rDNA guidelines, and the OSHA regulations. The regulations do not require a BSL risk assessment or safety officer charged with ensuring biosafety. They allow great flexibility and discretion as to biocontainment procedures for select agents."

regarding the regulation of only well-known risks, this level of deference to employers is a major issue when it comes to inspection and enforcement. OSHA's resources are limited with respect to how many labs it can inspect and how thoroughly it can oversee those inspections. This is especially poignant when the safety risks are posed by microscopic agents that cannot easily be tested for "identity," or where identity is largely meaningless because the infectious agents have been engineered in the same laboratory whose safety they threaten. Therefore, deferring to employer discretion may create incentives for providing employees incomplete information regarding the risks posed by the agents they are working with – deception that will largely evade any oversight and increase the risks posed to employees.[58] This problem is further exacerbated by the currently broad trade secret protection offered to manufacturers. OSHA has regrettably interpreted its trade secret provisions to exempt employers from having to disclose the genetic makeup of microbes engineered in privately owned laboratories to potentially infected employees. Therefore, the health risks associated with working on experiments involving rDNA research remain largely unknown, and potentially infected persons have no way to obtain adequate testing or medical treatment upon infection.

Apart from these overarching problems with the OSHA framework for regulating laboratories, which are exacerbated in situations involving novel or not well-studied biological entities, a second major gap exists between the subject matters covered under the two major standards governing laboratories – OSHA's bloodborne pathogens standard and its chemical hazards standard. Chemical hazard rules only apply to chemicals, and bloodborne pathogens guidelines only narrowly apply to human blood and "Other Potentially Infectious Materials." In between these two categories of potential hazards exists a broad swath of biological agents that are infectious through means other than blood contact and that can exist or be created without using any human-derived materials, let alone human blood. While by definition these hazards do not fall under the scope of the bloodborne pathogens standard, they are also explicitly excluded from the chemical hazard regulations. Therefore, these hazards are not at all regulated by OSHA except under the General Rule, which carries little enforcement power.[59] Therefore, one major recommendation proposed in this report is for OSHA to explicitly incorporate human-infectious

[58] This is largely what happened to Becky McClain, a worker infected with a genetically engineered virus at one of Pfizer's Connecticut labs. *See* Andrew Pollack and Duff Wilson, *Former Pfizer Whistle-Blower is Awarded $1.4 Million,* The New York Times, April 2, 2010. http://www.nytimes.com/2010/04/03/business/03pfizer.html (accessed on 9/1/10).

[59] *See supra* n.1 and accompanying text.

agents, broadly defined, into its regulations and provide general safety guidelines for dealing with such agents, including such measures as air filters, restricted access, personal protective equipment, etc. Below is a more detailed analysis of specific regulations that exemplify the gaps in OSHA's current framework for regulating laboratory workplaces.

a. Bloodborne Pathogens

OSHA's definition of bloodborne pathogens is extremely narrow – limited only to agents infectious through blood contact. In practice, this rule is narrowed further by standard's focus on HIV and HBV, to the exclusion of the numerous other deadly and dangerous pathogens encountered in biological laboratories, including those that are airborne or infectious through skin or mucous membrane contact. While the regulations governing safety in research laboratories and production facilities handling with HIV and HBV mandate a higher, more appropriate level of biosafety than those applicable to clinical laboratories, these regulations only apply to laboratories specifically studying HIV and HBV. Therefore, most of the provisions in the bloodborne pathogens standard exclude the majority of biotechnology laboratories, where organic products such as stem cells are less directly derived from humans, likely are not contaminated with blood as required to bring them under the purview of this section, and where the potentially hazardous pathogens are often engineered and thus less closely related to naturally occurring bloodborne pathogens such as HIV. Perhaps a very liberal interpretation of the rules on "Other Potentially Infectious Materials" (OPIM), which are regulated by this section, would include some rDNA research; however, the definition of OPIM is limited to "Any unfixed tissue or organ … *from a human,"* or "*HIV-containing* cell or tissue cultures, organ cultures, and *HIV- or HBV-containing* culture medium or other solutions, and blood, organs, or other tissues from experimental animals infected with *HIV or HBV*" (emphasis added).[60] Thus, any experiment dealing with animal tissues infected with other diseases or any non-human derived tissues containing potentially infectious agents is not at all covered by the standard.

Furthermore, many vectors used in biotechnology and biological research, while often derived from bloodborne viruses like HIV, have been modified to be airborne and/or to infect a broader array of cells than just blood. Therefore, limiting safeguard regulations to contamination from body fluids is unlikely to be effective in eliminating laboratory dangers.

[60] *See supra* n. 2.

Another limitation of the bloodborne pathogens standard comes from the narrow definition of "exposure incident." An exposure incident must first occur in order to trigger mandatory, employer-funded screening and medical attention for exposed employees, but it is defined as limited to only those instances where there is actual contact with infectious materials. However, where researchers are dealing with agents that are transmitted not only through blood contact, but possibly through skin, eye, and mouth contact or are even possibly airborne, access to medical attention should to be triggered under a broader definition of "exposure incident." Furthermore, the focus of the regulations on appropriate medical attention is clearly tailored to HIV and HBV prophylaxis, which are largely irrelevant for other types of infections.

Thus, while the procedures outlined in the bloodborne pathogens standard are a good template for the kinds of rules that should be implemented in biological laboratories, the new rules should be modified to afford employers a lesser degree of discretion in assessing necessary safety equipment and protocols and should be written so as to apply to a wide range of potential biological hazards.

b. Chemical Hazards Regulations

The most important limitation of these regulations is that they explicitly do not apply to biological hazards. While an easy fix would be to remove this exemption, and thus to require OSHA officials to attempt to apply the chemical hazard regulations to biological hazards as well, a better option would be to use chemical hazard regulations as a template for a separate provision regulating biological hazards. Therefore, this analysis will proceed assuming that chemical hazards regulations *do* in fact apply to biohazards, in order to identify the gaps in these regulations as a template for further rulemaking.

First, the definition of a "health hazard" under the regulations governing chemicals in laboratories under-inclusive, especially if applied to biological hazards, which frequently involve novel or poorly studied agents. The regulations define health hazards as "a chemical for which there is *statistically significant evidence based on at least one study conducted in accordance with established scientific principles* that acute or chronic health effects may occur in exposed employees."[61] When novel organisms are genetically engineered in the same laboratories or institutions where workers are exposed to them, however, it is impossible that studies will have been undertaken to demonstrate those agents as hazardous. Furthermore, the focus on "toxins" in

[61] *See supra* n.18.

this definition, which includes "carcinogens, toxic or high toxic agents, reproductive toxins, irritants, corrosives, sensitizers, hepatotoxins, nephrotoxins, neurotoxins, agents which act on the hematopoietic systems, and agents which damage the lungs, skin, eyes or mucous membranes,"[62] excludes a range of hazards posed by infectious agents that may produce disorders that do not fall into these categories or that affect a range of organ systems. Finally, the constant references to specified lists of select carcinogens and hazardous chemicals distributed by government or independent organisms cannot be applied to biological hazards; rather, this language must be broadened to include less clearly defined or studied hazards from biological agents.

These regulations also focus largely on permissible exposure limits, which are difficult to apply to biological hazards. For example, it would be nearly impossible to set atmospheric concentration limits for certain rDNA molecules or viral agents. Nevertheless, similar regulations governing periodic monitoring of possible contamination events where infectious agents are used or studied might be necessary.

Furthermore, the definitions of "exposure" and "exposure incident" are too narrow, especially where they address leaks, spills and explosions and rely on monitoring. Dealing with microscopic agents that have no taste or smell and that are not easily monitored requires a broader definition of exposure and exposure incident in order to trigger the employer's duty to provide medical attention in more situations where a real risk of exposure may exist.

Finally, the trade secret protections offered to companies are far too broad, especially where poorly understood infectious agents are concerned and/or when those agents have been genetically engineered specifically for a particular laboratory or experiment. The definition of chemical identity under the trade secret provisions is impossible to apply in a meaningful sense to biological agents or rDNA microbes, and thus a new set of terminologies must be developed for these hazards. Furthermore, the focus of the MSDS regulations is specific to chemicals; an analog to this type of fact sheet should be developed for communicating information regarding the hazards of biological agents to employees.

Thus, while the regulations governing chemical hazards serve as a good template for implementing rules that require hazard assessments for dangerous and novel biological agents by employers, certain terms and provisions should be broadly framed and construed in order to include all potentially hazardous workplace situations.

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[62] *See supra* n.19.

III. RECOMMENDATIONS FOR REGULATORY REFORM

1. Recommended Reforms

(1) Incorporate the NIH Guidelines on rDNA research and the BMBL into OSHA regulations, mandating compliance with these guidelines and attaching penalties for breach.

(2) Create a separate set of regulatory standards specifically addressing biological agents, regardless of their route of infection, with general safety rules governing laboratories working with these agents.

(3) Broaden the definition of an "exposure incident" to include situations such as the discovery of an improperly functioning filter, etc. whereby one could have been exposed to airborne agents.

(4) Expand the applicability of the rules governing HIV and HBV research laboratories to laboratories studying a broader range of infectious biological agents and diseases.

(5) Loosen requirements for statistically significant evidence that would qualify a biological agent as "hazardous" as required under the Hazardous Chemicals regulations. This is necessary when novel organisms are genetically engineered in the same laboratories or institutions where workers are exposed to them, therefore precluding the possibility that studies would have been undertaken to demonstrate those agents as hazardous.

(6) Expand hazard identification regulations, which currently apply only to chemicals, to include novel biological entities, including both biological agents engineered in the laboratory and those that have been found in the wild but have not yet been well studied.

(7) Mandate personal protective equipment standards for any experiment dealing with agents that may be human-infectious.

(8) Mandate respiratory protection programs for any laboratories or experiments involving airborne biological agents.

(9) Implement requirements for an analog to the chemical material safety data sheets for biological agents and require that they be made available to exposed employees.

(10) Create rules restricting eating, drinking and personal hygiene-related activities in all biological laboratories similar to those included under the bloodborne pathogens standard.

(11) Require that institutions housing biological laboratories, or the laboratories themselves, designate safety officers and, where more than a threshold number of employees are exposed, designate bio-lab safety committees to oversee and ensure adequate risk assessments, compliance with safety provisions, education, training and to promote a culture of safety.

(12) Broaden definition of "health hazard" to include a presumption of hazard where agents may potentially be human-infectious, putting the burden on the employer to document and prove that biological agents present in the laboratory are not human-infectious.

(13) Ensure that trade secret protection for biological agents is limited where worker health is compromised to ensure access to records that could assist in the diagnosis and treatment of infected workers.

(14) Require employers to keep all records pertaining to the genetic code and surface receptors of biological agents.

(15) Expand EPA regulation of novel intergeneric organisms to include those contained within laboratories. Although a different process of regulation may be necessary, some oversight of the risks posed to communities and the environment of novel, genetically engineered organisms is necessary.

(16) Expand tort liability for biological infections resulting from lack of biological laboratory safety (see discussion).

2. Discussion

Making NIH guidelines mandatory is a start, but it is insufficient. This is primarily because these guidelines depend on risk assessments that are highly technical and complex and cannot quickly and easily be reviewed by an inspector. Therefore it would be better to institute more specific regulations, similar to the bloodborne pathogens and chemical hazards standards, to bridge the regulatory gap between those two sets of regulations. Nevertheless, as an additional safeguard and a source of concrete statutory authority for imposition of General Rule liability

and fines, OSHA should also incorporate by reference the BMBL and the NIH Guidelines on rDNA Research, making them mandatory and permitting recovery or penalty if investigations following an incident reveal breaches of these standards. This can be accomplished much the same way that the "American National Standard Practice for Occupational and Educational Eye and Face Protection" is incorporated into OSHA regulations through a clause in the rules.[63]

Ultimately, the best outcomes may result if more stringent tort liability is imposed on employers responsible for worker infections. While workers compensation is the sole legal recourse for injured employees under most state and federal regimes, laboratory-acquired infections are a unique class of workplace injuries and should be treated differently. Unlike industrial accidents, the safety protocols necessary are extremely difficult to ascertain and must inherently be left to a great deal of employer discretion. This is because workplaces dealing with microscopic hazards and entities, especially novel infectious agents engineered by the laboratory under inspection, make it impossible for an inspector to (1) know with certainty that lab workers are handling the agents employers claim they are, (2) determine what the appropriate safeguards must be, and (3) ascertain the potential risks to human health and safety arising from work with those agents. Furthermore, the difficulty of proving causation between on-site infection and an illness, where symptoms are latent and overlap with many externally-acquired infections or genetic conditions, renders it impossible to appropriately sanction employers under the General Rule. Finally, unlike industrial accidents, laboratory-acquired infections are simply rarer and are more often due to negligence or recklessness rather than the inherently dangerous nature of the work. Therefore, expanded employer liability paired with liberal discovery rules that can penetrate trade secret protection would best create incentives for employers to protect the health of their employees and encourage a culture of safety and compliance.

CONCLUSION

The current regulatory framework governing laboratory safety largely excludes biological hazards, especially novel, poorly studied or genetically engineered biological agents that can infect humans. This poses a major threat not only to worker safety, but to the communities housing research institutions and those individuals who come into contact with potentially

[63] 29 C.F.R. §1910.133(b)(1)(i) (2009).

infected workers outside of the lab. Although the NIH has issued fairly comprehensive guidelines on biological laboratory safety, these guidelines are not mandatory for many employers. OSHA, the agency mandated with regulating workplace hazards, has failed to issue any rules on the safety of workers in the growing biotechnology industry. The current framework leaves too many safety decisions to the discretion of the employer and is not conducive to easy inspections ensuring compliance and workplace safety. As a result, it is recommended that OSHA explicitly expand its current laboratory safety regulations to include biological hazards, that OSHA implement specific safety protocols where human infectious agents are handled, that it loosen trade secret protections for firms whose employees may have been infected, and that the agency loosen its requirements for determining and classifying hazardous agents. Finally, given the difficulty of inspecting and enforcing rules in such a highly technical industry, we recommend expanded employer liability for worker infections and loosening evidentiary requirements in order to create incentives for employer investment in safety and in order to ensure adequate compensation for employees who have been injured. We must move forward quickly with improved worker safety standards in this area. In the absence of any action, business as usual will continue to be cruel and unusual punishment for innocent scientists, lab technicians and other workers.