PREFACE

Stringent protocols and engineering are used to contain the most dangerous pathogens, therefore these facilities are often referred to as high-containment laboratories. High-containment laboratories play a critical role in the biodefense effort, offering the hope of better responses to a biological attack and a better understanding of the bioterrorism threat. However, they could also increase the risk of a biological attack by being a source of materials or training. This book examines the biosafety and biosecurity issues in high-containment laboratories across the United States.

Chapter 1 - Biosafety laboratories are primarily regulated by either the Department of Health and Human Services (HHS) or the U.S. Department of Agriculture (USDA), depending on whether the substances they handle pose a threat to the health of humans or plants, animals, and related products, respectively. Currently, all operational biosafety level 4 (BSL-4) labs are overseen by HHS's Centers for Disease Control and Prevention (CDC). BSL-4 labs handle the world's most dangerous agents and toxins that cause incurable and deadly diseases.

This testimony summarizes GAO's previously issued reports on perimeter security at the nation's BSL-4 laboratories that were issued in September 2008 (**GAO-08-1092**) and July 2009 (**GAO-09-851**). Specifically, this testimony describes (1) the findings and recommendation on key perimeter security controls at five of the nation's operational BSL-4 labs, (2) CDC efforts to address our recommendation, (3) improvements that have been made to the perimeter security controls at the two labs found to be deficient, and (4) other observations about the BSL-4 labs GAO assessed.

View GAO-09-1038T or key components. For more information, contact Gregory D. Kutz at (202) 512-6722 or kutzg@gao.gov.

Chapter 2- This chapter is edited and excerpted testimony by Nancy Kingsbury before the Subcommittee on Terrorism and Homeland Security, Committee on Judiciary on September 22, 2009.

Chapter 3 - U.S. laboratories working with dangerous biological pathogens (commonly referred to as high- containment laboratories) have proliferated in recent years. As a result, the public is concerned about the oversight of these laboratories. The deliberate or accidental release of biological pathogens can have disastrous consequences.

GAO was asked to determine (1) to what extent, and in what areas, the number of high-containment laboratories has increased in the United States, (2) which federal agency is responsible for tracking this expansion and determining the associated aggregate risks, and

(3) lessons learned from highly publicized incidents at these laboratories and actions taken by the regulatory agencies.

To carry out its work, GAO surveyed and interviewed federal agency officials, (including relevant intelligence community officials), consulted with experts in microbiology, reviewed literature, conducted site visits, and analyzed incidents at high-containment laboratories.

Chapter 4 - The federal government responded to the September 11, 2001, terrorist attacks and the subsequent anthrax attacks with increased focus on and funding for biodefense. A key consideration in this response was addressing shortages in diagnostic, clinical, and research laboratory capacity. Several departments and agencies have increased or are in the process of increasing their laboratory capacity. High-containment laboratories play a critical role in the biodefense effort, offering the hope of better responses to an attack and a better understanding of the threat posed by bioterrorism. However, they also could increase the risk of a biological attack by serving as a potential source of materials or training. Indeed, the Commission on the Prevention of Weapons of Mass Destruction Proliferation and Terrorism recommends tightening government oversight of high-containment laboratories.

Policymakers have become increasingly interested in the oversight of these facilities following reports of accidents, regulatory noncompliance, and community resistance. The increase in high-containment laboratory capacity has raised new policy questions and emphasized existing ones. How much laboratory capacity is enough? What is the necessary federal investment? Should laboratories be consolidated or dispersed? What plans exist to coordinate multiple agency efforts to expand high-containment laboratory capacity? Does increasing laboratory capacity increase the risk of accidents and the opportunity for purposeful misuse? What is an acceptable balance between the benefits these laboratories provide and the risks they pose?

Interested Members of Congress might take action to address some or all of these concerns. Alternatively, they might defer action until efforts currently under way assess and make recommendations regarding the existing regulatory structure. If Congress chooses to enhance oversight, it might require a survey of existing facilities and their use and a national needs assessment, perhaps barring further construction until these are complete. Stakeholders could focus on enhancing self-regulatory activities such as improving or standardizing laboratory worker training or building a mechanism for sharing lessons learned. Rather than relying on self- regulation, policymakers might enhance oversight through additional regulation of high-containment facilities, requiring laboratory or personnel certification, or by broadening the Select Agent Program. Which agencies should implement any new mandates remains an open question.

Biocontainment technologies are widely used by scientists around the world. Efforts to increase control of U.S. high-containment laboratories may put domestic industry at a competitive disadvantage and inhibit international academic collaboration. Absent international harmonization, the United States can only partially address the threat of a high-containment laboratory being the source of a bioterror weapon.

A key task for policymakers is to define their goals for enhancing oversight of high-containment laboratories. The focus of the oversight effort may affect which policy issues are addressed. For example, focusing on a registry of existing high-containment laboratory capacity may improve planning, coordination, and efficiency of use but provide relatively limited security benefits. Similarly, a rigorous oversight program including facility and personnel licensure, mandatory training, and restricted construction of new facilities may

provide security benefits at the cost of regulatory burden, increased federal expenditures, and impeded scientific progress in countermeasure research, bioforensics, and public health. When weighing options to address these complex policy issues, policymakers may have to reconcile many competing and potentially conflicting national needs.

Chapter 5 - New scientific tools and understanding have created unprecedented opportunities for progress in life sciences research, medicine, and agriculture. Coincident with this era of opportunity have been elevated concerns about emerging infectious diseases, bioterrorism, and criminal acts involving the use of hazardous biological agents, prompting the rapid development of diagnostics, vaccines, and other medical countermeasures. Research on hazardous biological agents that could threaten human health or agriculture has become a national priority, with increased Federal support for programs to promote scientific investigation in academic and commercial settings, as well as in Federal research facilities. Essential to continued progress in these areas of research are the high and maximum containment[1] facilities in which to study these agents.

Effective biosafety and biocontainment practices and oversight of research activities at individual high and maximum containment facilities are critical components of the research enterprise. The Federal Government is committed to the highest quality design and construction of biocontainment facilities, the rigorous training of personnel who work in these laboratories, and the safe conduct of research and research-related activities that occur within these facilities. However, there are areas of concern, which include lapses in biosafety, lack of timely reporting of incidents, and lack of Federal oversight for research involving pathogens that are neither select agents nor recombinant DNA agents. Press reports, articles in scientific publications, Government Accountability Office reports, a report by the Commission on the Prevention of WMD Proliferation and Terrorism,[2] as well as congressional hearings have focused attention on these issues. At the October 4, 2007, House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations hearing entitled "Germs, Viruses, and Secrets: The Silent Proliferation of Bio-Laboratories in the United States," the Department of Health and Human Services (HHS) announced the formation of the Trans-Federal Task Force on Optimizing Biosafety and Biocontainment Oversight (the "Task Force").