

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**

COMMITTEE ON ENERGY AND COMMERCE

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WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

May 7, 2015

The Honorable Gene L. Dodaro  
Comptroller General  
U.S. Government Accountability Office  
441 G. Street, NW  
Washington, DC 20548

Dear Comptroller Dodaro:

Last July, the Committee on Energy and Commerce held an oversight hearing examining recent incidents at the Centers for Disease Control and Prevention (CDC) and other federal high containment laboratories involving the potential release of anthrax and H5N1 avian influenza. For example, numerous CDC personnel in Atlanta were unintentionally exposed to anthrax because inactivation safety practices were not followed. These incidents raised lab safety concerns about the sufficiency of inactivation protocols and procedures for studying dangerous pathogens. At our hearing the Government Accountability Office (GAO) testified on findings from past reports about the risks associated with proliferation of the high-containment laboratories.

Inactivation and attenuation is a technique that renders pathogens non-viable and is used in laboratories around the world in scientific research. However, in certain circumstances, a balance may need to be struck between maintaining sample integrity and using a sufficiently robust inactivation treatment by strictly following inactivation and attenuation protocols. In such cases, appropriate empirical studies, scientific judgment, and the proper safety assessments will be required to establish a sufficient balance between the preservation of sample integrity and adherence to safety protocols. However, safety should be the overriding priority, despite any logistical inconvenience of sample handling. Consequently, it will be important to find out how such decisions and judgments about adherence to inactivation and attenuation protocols are currently made in the U.S. and abroad.

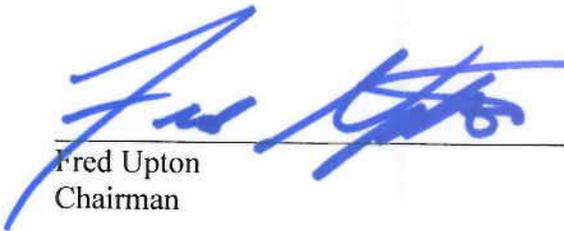
Therefore, we are asking GAO to address the following questions:

1. What are the different types and methods of biosafety inactivation and attenuation protocols and what are their relative strengths and weaknesses?

2. What, if any, are the current scientific issues involving inactivation and attenuation protocols? Do scientifically-established kill curves exist for major pathogens, and if so, do clearly defined conditions exist for each method?
3. What characteristics, if any, of select agents/major pathogens (i.e., viability, infectivity, pathogenesis, resistant to treatment, or transmissibility) require modification, and to what extent is validation required to ensure the modification criteria have been met?
4. What is the incidence of potential exposure to select agents/major pathogens due to insufficient inactivation or attenuation protocols in the U.S., Canada, the European Union, and Australia? How do regulators in these countries address this issue?

We believe that it is essential for Congress to have answers to these questions if we are to be able to fulfill our oversight responsibilities in this matter. If you have any questions regarding this request, please contact Alan Slobodin of the majority committee staff at (202) 225-2927 and Una Lee of the minority committee staff at (202) 225-3641.

Sincerely,



Fred Upton  
Chairman



Frank Pallone, Jr.  
Ranking Member



Tim Murphy  
Chairman  
Subcommittee on Oversight  
and Investigations



Diana DeGette  
Ranking Member  
Subcommittee on Oversight  
and Investigations

Attachment