To the Editors of Newsweek,

I am writing on behalf of the more than 1300 members of the American Biological Safety Association (www.ABSA.org), an association of professionals in over 40 countries dedicated to managing risks in biological laboratories, regarding the March 13, 2014, article, “The Cure May Kill You: The Only Thing Scarier than Bio-Warfare Is the Antidote.” The Association is concerned regarding a number of statements and inaccuracies in this article and how these misleading statements could result in loss of confidence in the well-run academic, private, and government institutions which operate BSL3 and BSL4 facilities. As this needs to be brief, I would point your readers to the ABSA website for a more detailed, point-by-point rebuttal of the article which will soon be posted.

One of the key misstatements was an assertion that the passage of the BioShield Act reduced the “roadblocks that regulate how labs do their research...”. Nothing could be further from the truth. BioShield was not a program that allowed a laboratory to reduce the containment, safety, or security practices in place prior to the passage of the act. In reality, in the time since the 2003 passage of the BioShield Act, additional oversight has taken place by both the CDC and USDA over the more than 80 agents covered under the Select Agent regulations (available at http://www.selectagents.gov). For the agents considered to be the highest hazard (also called “Tier 1” agents), additional regulations have been put into place. The cumulative effect of the additional regulatory burden has been to reduce, not increase the number of laboratories performing work with Select Agents.

The other misstatement is due to a literal reading of the GAO reports. Although the article cited the two GAO reports, the two have the same complaint; that there is not a regulatory standard for construction of BSL3 and 4 labs. Although legally correct, it implies an “anything goes” philosophy and that is most incorrect. Any institution receiving funds for recombinant DNA research is required to be compliant with the NIH Guidelines for recombinant and synthetic DNA research (available at http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html). The guidelines are not optional and provide performance-based requirements for containment laboratories. Similarly, the NIH/CDC guidebook “Biosafety in Microbiological and Biomedical Laboratories” (available at http://www.cdc.gov/biosafety/publications/bmbl5/) is an internationally accepted document that also provides performance-based requirements for containment laboratories. These documents are referred to by the CDC and USDA Select Agent regulators as part of their permitting process for Select Agent laboratories. All U.S. BSL4 laboratories have been subject to the requirements of the Select Agent regulations.
The members of ABSA are skilled professionals who help ensure high risk pathogens are handled safely. The Association and the members of ABSA would have been happy to have helped to generate a more accurate picture of the work done in the BSL3 and 4 labs. It may not have made the article as sensational, but it would have been accurate.

Sincerely,

[Signature]

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President
American Biological Safety Association