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A shocking biodefense editorial

To the editor:

As Assistant Secretary for Preparedness and Response at the Department of Health and Human Services, I would like to draw attention to several factual errors in the editorial entitled "US biodefense—shocking and awful" published in the June issue (*Nat. Biotechnol.* **25**, 603, 2007). There is no record of your staff contacting anyone at the US Department of Health and Human Services (HHS) to verify the information presented in your editorial, and as a service to your readers, I draw attention below to the errors in the order they appeared in the original article.

Almost six years after the anthrax attacks, the US BioShield Program has added new products to the nation's stockpile. The US Congress created BioShield in 2004—three years after the anthrax attacks. In the three years since the new program was established, a total of nine BioShield contracts have been awarded. BioShield efforts have already resulted in deliveries to the Strategic National Stockpile of anthrax vaccine, anthrax immune globulin, a new pediatric potassium iodide formulation, and Ca-DTPA (trisodium calcium diethylenetriaminepentaacetate) and Zn-DTPA (trisodium zinc diethylenetriamine pentaacetate)—two medical countermeasures for radiological or nuclear incidents. In addition, deliveries of heptavalent botulism antitoxin will begin this year.

The correct acronym for the Department of Health and Human Services is not DHSS. The department acronym is HHS.

Your article mistakenly states the US Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC) declared the Acambis (Cambridge, UK) modified vaccinia Ankara (MVA) smallpox vaccine safe and efficacious. In fact, on May 17, 2007, the VRBPAC heard presentations and made recommendations on the safety and immunogenicity of another vaccine: live vaccinia virus smallpox vaccine (ACAM2000) manufactured by Acambis. HHS, through the US Centers for Disease Control and Prevention, has already procured ACAM2000 for the Strategic National Stockpile.

Also contrary to what you indicated, The Pandemic and All-Hazards Preparedness Act as passed by the US Congress does not include an indemnity clause that would protect any company participating in BioShield from personal injury litigation. The liability protection provisions were dropped before the bill's passage.

In addition, the Pandemic and All-Hazards Preparedness Act does not allow the Biomedical Advanced Research and Development Authority (BARDA) to operate outside the Freedom of Information Act (FOIA). The law only provides an exemption from FOIA in certain instances to safeguard non-public technical information deemed to reveal significant vulnerabilities of existing public health defenses, generated during countermeasure or product advanced research and development.

Your description of the Hollis Eden situation was also erroneous. The panel of scientific experts in charge of the evaluation of proposals on radiation remedies did not revise the criteria because there was never a contract with Hollis Eden to cancel. After extensive review, the conclusion was that the Hollis Eden proposal was not acceptable for award based on evaluation factors established in the Request for Proposals, before proposal submission, regarding efficacy, treatment schedule, conditions of use and manufacturing ability. It was for these reasons, no contract was awarded.

The editorial also states that BARDA needs to articulate a clear vision for BioShield. In fact the "HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy for Chemical, Biological, Radiological and Nuclear (CBRN) Threats" was published on March 20, 2007. The strategy document, which was developed in association with federal, industry and public health stakeholders, is available online (http://www.hhs.gov/aspr/ophemc/enterprise/) and establishes the goals and objectives HHS will use to prioritize the development and acquisition of medical countermeasures for effective use against the highest-priority CBRN threats facing the nation. Furthermore, on April 23, 2007, the "HHS PHEMCE Implementation Plan for CBRN Threats" was published and is also available on the HHS website (http://www.hhs.gov/aspr/barda/phemce/enterprise/strategy/index.html). The HHS PHEMCE Implementation Plan provides near-term (fiscal year 2007–2008), mid-term (fiscal year 2009–2013) and long-term (fiscal year 2014–2023) goals for research, development and acquisition of medical countermeasures. It is consistent with the guiding principles and priority-setting criteria defined in the HHS PHEMCE strategy document.

BARDA does have an acting BARDA director; Carol Linden is serving in that position. A vacancy announcement for the BARDA director position was published on May 1, 2007 and applicants are now under consideration.

Your readers are invited to stay current with BARDA activities via the HHS web site at http://www.hhs.gov/aspr/ophemc/index.html.

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***Nature Biotechnology* responds:**

We uphold our view that an anthrax vaccine based on 1950s technology, anthrax immune globulin, a new pediatric potassium iodide formulation, Ca-DTPA and Zn-DTPA are a pitiful return for three years of effort and nearly $2 billion dollars spent; these are hardly the cutting-edge biotechnologies one would have hoped BioShield to have acquired at this stage.