




# Homeland Security

September 23, 2008

MEMORANDUM FOR: Michael O. Leavitt  
Secretary of Health and Human Services

FROM: Michael Chertoff 

SUBJECT: Determination Pursuant to § 564 of the Federal Food, Drug, and  
Cosmetic Act

You have asked whether, with regard to a potential attack involving *Bacillus anthracis*, a biological agent that causes anthrax, the conditions in § 564(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act, as amended by Pub. L. 108-276, 21 U.S.C. § 360bbb-3(b)(1)(A), have been met.

That statute authorizes the Secretary of Health and Human Services to declare an emergency on the basis of, among other things,

A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents.

There is not currently a domestic emergency involving anthrax. Additionally, there is not currently a heightened risk of an anthrax attack. We have no credible information indicating an imminent threat of an attack involving *Bacillus anthracis*.

But these findings are not necessary to make a determination under § 564(b)(1)(A). Rather, a significant potential for a future domestic emergency involving a heightened risk of attack with anthrax is a sufficient basis for such a determination.

I have made the requested determination on the following basis. First, our Department has already found that an anthrax attack poses a material threat to the United States population sufficient to affect national security<sup>1</sup>—which allows me to conclude that there is a non-negligible possibility that a heightened risk of attack will arise. Second, were the government to determine in the future that there is a heightened risk of an anthrax attack—if, for example, there were

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<sup>1</sup> On January 20, 2004, Secretary Ridge made a determination, under § 3(a) of the Project Bioshield Act of 2004, Pub. L. 108-276, that anthrax presents a material threat against the United States population sufficient to affect national security. On September 22, 2006, I made a determination under the same statutory provision that “multi-drug resistant *Bacillus anthracis*” presents such a threat.

credible information about an imminent threat of such an attack—that determination would almost certainly result in a domestic emergency. This is so, among other important reasons, because those exposed to *Bacillus anthracis* need to take appropriate antimicrobials rapidly after exposure to avoid contracting anthrax and because of the significant challenges to rapidly delivering such antimicrobials to those at risk in an anthrax emergency.

On this basis, I determine that there is a significant potential for a domestic emergency, involving a heightened risk of attack with a specified biological, chemical, radiological, or nuclear agent or agents – in this case, *Bacillus anthracis*.

Given this determination, I urge you to employ all relevant emergency powers under 21 U.S.C. § 360bbb-3 to ensure distribution of pre-need countermeasures that may be effective in preventing the contracting of anthrax by people in the delivery chain, such as U.S. Postal Service workers; to first responders, including law enforcement; to essential government and non-government workers; and to the general public.