



U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

<http://finance.senate.gov>

For Immediate Release

Tuesday, April 5, 2005

Grassley questions HHS Secretary about short supply of anthrax vaccine

WASHINGTON — Sen. Chuck Grassley is asking for more information about the government's preparation for an anthrax attack.

In a second letter to the Secretary of Health and Human Services, Grassley expresses concern about the inadequate stockpile of the anthrax vaccine and questions a promotional claim by the Department about the effectiveness of the particular anthrax vaccine just selected for a government contract. Under the contract, VaxGen is tasked with developing the new anthrax vaccine. Once developed, the government intends to purchase 75 million doses for the Strategic National Stockpile.

Grassley is chairman of the Senate Committee on Finance. The text of his letters to Secretary Leavitt follows here.

April 4, 2005

The Honorable Michael O. Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Leavitt:

By letter dated January 28, 2005, I requested that the Department of Health and Human Services (Department) respond to allegations and concerns regarding a Project BioShield contract awarded to VaxGen, Inc. (VaxGen). Under the contract, VaxGen would manufacture and deliver 75 million doses of a new anthrax vaccine to the Strategic National Stockpile (SNS). The first 25 million doses of this experimental vaccine are not expected to be delivered to the SNS until late 2006. On February 23, 2005, representatives of the Food and Drug Administration (FDA) met with my Committee on Finance (Committee) staff to address questions and issues related to VaxGen's experimental recombinant protective antigen (rPA) anthrax vaccine. My Committee staff also met with representatives of the Department's Office of the Assistant Secretary for Public Health Emergency Preparedness (OASPHEP) on March 3, 2005. Thank you for the Department's cooperation with the Committee's inquiries to date.

Last month's anthrax scare provided us all with another sobering wake-up call. I remain greatly concerned that the Department is not prepared to protect the American people from an anthrax attack. My staff have been informed that the Department has not stockpiled one additional dose of anthrax vaccine for the SNS since the anthrax incidents of October 2001. Apparently, for close to two years now the Department has been negotiating the procurement of millions of doses of existing anthrax vaccine. However, the Department has not taken necessary action to address the SNS. Accordingly, please advise me about the status of the Department's contract negotiations to purchase doses of anthrax vaccine for the SNS until an rPA vaccine becomes available. In addition, as Chairman of the Committee, I request that the Department provide the Committee with the number of doses of anthrax vaccine currently in the SNS and whether the stockpiles are presently sufficient to protect the American people.

In addition, the accuracy of a Department press release dated March 12, 2004, has been called into question. The press release states, "The new rPA anthrax vaccine has already been shown to be stronger and more effective than the vaccine being used today." During the aforementioned meetings both OASPH and FDA staff stated to my staff that there is no scientific basis to support the Department's statement. As of April 4, 2005, this press release is still posted on the Department's web site. Unless the Department has scientific information or evidence to the contrary, the Department's press release appears to have no basis in science. Please confirm whether the Department's press release is scientifically inaccurate and, if so, state what actions the Department will take to correct this situation.

In closing, I look forward to hearing from you regarding the issues and concerns set forth in this letter, and I would appreciate a timely response to my inquiries no later than April 18, 2005. Please do not hesitate to contact me if you have any concerns.

Sincerely,

Charles E. Grassley
Chairman

January 28, 2005

The Honorable Michael Leavitt
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Leavitt:

In November 2004, the Department of Health and Human Services (Department/HHS) announced that it awarded the first contract under Project BioShield to VaxGen, Inc. (VaxGen). Under the terms of the \$877.5 million contract, VaxGen will manufacture and deliver 75 million doses of a new recombinant anthrax vaccine to the Strategic National Stockpile. A number of troubling allegations have been brought to the attention of the Senate Committee on Finance (Committee) related to the Department's contract with VaxGen.

Among other allegations, questions have been raised as to whether HHS acted prematurely and relied on insufficient data to support the VaxGen contract for a recombinant vaccine. Some have questioned the effectiveness of this vaccine, arguing that it has not been proven in people and that an existing FDA-approved vaccine has been available for use in this country for several decades. On December 11, 2004, the New York Times reported that VaxGen does not intend to submit a license application to the Food and Drug Administration (FDA) until 2007, the year in which the company expects to deliver the vaccine to HHS. Further, it is alleged that shipments from VaxGen may expire by the time the vaccine is approved by the FDA.

Aside from these allegations, the Department's decision to procure a vaccine from a single manufacturer is highly suspect, especially in light of the recent flu vaccine shortage in the United States. This country lost half of its flu vaccine supply when the Chiron facility in England was shut down due to contamination problems. Yet HHS did not have plans in place to adequately respond to the shortage. It appears that HHS may not have learned a lesson from the recent flu vaccine shortage.

Accordingly, as Chairman of the Committee, I request that HHS provide information, documents and access to documents related to the VaxGen contract to the Committee. First, it is my understanding that Dr. Philip Russell, Senior Advisor to the Assistant Secretary for Public Health Emergency Preparedness, was involved in both the development of the recombinant anthrax vaccine while he was with the United States Army Medical Research Institute of Infectious Diseases, as well as in the decision to award the contract to VaxGen. Please make Dr. Russell available for an interview with my Committee staff at his earliest scheduling opportunity. My Committee staff will make themselves available to meet with Dr. Russell at the Department to expedite this meeting.

Second, I request all records and /or access to all records related to the Department's decision to stockpile a recombinant anthrax vaccine and award the contract to VaxGen including but not limited to the administrative file for all Department actions, all copies of the VaxGen contract, inter-Department email, and communications and email between the Department and VaxGen.

Thank you in advance for having your staff coordinate with my staff about this letter by no later than February 4, 2005. Please do not hesitate to contact me if you have any concerns.

Sincerely,

Charles E. Grassley
Chairman