Statement of Senator Susan M. Collins

"Six Years After Anthrax: Are We Better Prepared to Respond to Bioterrorism?"

Committee on Homeland Security and Governmental Affairs October 23, 2007

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Six years ago, anthrax-laced letters resulted in the deaths of five people, widespread concern about the safety of postal workers and the U.S. mail, the treatment of thousands of people with antibiotics, and the evacuation of the Hart Senate Office Building.

Today's hearing concerns two matters of great importance for this Committee and for all Americans: our preparedness for bioterrorism and efficiency in government operations.

Unfortunately, the report that Senator Lieberman and I requested from the Government Accountability Office makes clear that the federal attempt to procure an improved anthrax vaccine has yielded not a new, improved vaccine, but instead a textbook example of prodigious waste.

As the GAO also discovered, taxpayers stand to lose \$128 million in 2008 as stocks of the current vaccine expire. The Department of Health and Human Services has no system to transfer them for use by the Department of Defense, the only large-scale user of anthrax vaccine.

In 1996, former Army Chief of Staff Gordon
Sullivan wrote a wise book on a systematic approach
to management in settings of uncertainty and

change. Its title alone was a kernel of wisdom: *Hope*Is Not a Method.

The story of the now-cancelled 877-million dollar procurement contract between HHS and VaxGen demonstrates the danger of relying on hope for progress. The Department *hoped* that a small company could not only develop an effective vaccine, but also obtain approval for it and manufacture 75 million doses, all on an unrealistically fast track. VaxGen officials hoped that they could meet terms and deadlines of a contract that lacked specific requirements and was critically vulnerable to future decisions by the Food and Drug Administration.

VaxGen also *hoped* that their small staff, lack of expertise in vaccine formulation, and limited access

to additional capital would not impede the required rapid progress to contract fulfillment.

Not one of these hopes survived the collision with reality.

The reality is that HHS is contracting practices for Project BioShield have displayed many of the same defects that this Committee has observed in procurements related to Hurricane Katrina and to reconstruction work in Iraq and Afghanistan – flaws that several colleagues and I are attempting to correct through contracting reform legislation.

HHS was responding to a crisis in the wake of the 9/11 terrorist attacks and the anthrax mailings. No one knew how soon or in what number follow-on attacks might appear. But the risks, uncertainties, and vulnerabilities revealed by the anthrax attacks

made a methodical approach to vaccine procurement *more*, not less, important.

A methodical rather than a hopeful approach to the Project BioShield contract might have included a more realistic evaluation of the suitability of using a small vendor of limited experience – a vendor that had been delisted from the NASDAQ securities market *three months* before the November 2004 contract signing.

A methodical approach would have included a fact-driven assessment of vaccine-development prospects and production capabilities – an assessment that GAO interviews with industry experts suggest would have been bleak indeed.

And perhaps most important, a methodical approach would have identified and specified contract requirements up front.

I have no doubt that many lessons could be drawn from this appalling story. But as the GAO report notes, HHS has not yet conducted a formal lessons-learned study.

We will spend additional time today discussing two disturbing issues outside the immediate ambit of the VaxGen contracts – the lack of a process to move stocks of the current anthrax vaccine to the military before they expire, and the reported willingness of HHS to deploy the vaccine even if it *has* expired.

I look forward to hearing our witnesses'
testimony today on the procurement and other
challenges we must address to ensure that our

Strategic National Stockpile fulfills its purpose of maintaining readily available stocks of vital medical supplies for victims of major disasters. I am particularly interested in hearing Admiral Cohen's thoughts on how the findings in the GAO report could be applied to the work of the DHS Science and Technology Directorate.

The only good news in the GAO report was the observation that we have suffered no new anthrax attacks since 2001. If we had, our hearing could have unfolded in the wake of another tragedy. We must apply the lessons learned from the failures documented by the GAO to improve our preparations for a possible terrorist attack using biological weapons before it is too late.