

Statement of Philip K. Russell

Biological threats, whether man-made or naturally occurring, pose a critical threat to our nation's citizens. My career, both in the military and as a civilian, has been dedicated to the development of vaccines to combat infectious diseases. I have a long-standing interest in ensuring vulnerable populations are protected. A career in infectious disease research taught me how devastating biological pathogens can be to individuals and to populations. As Director of the Walter Reed Army Institute of Research and Commander of the U.S. Army Medical Research and Development Command, I worked hard to develop products to protect the armed forces from infectious diseases.

In 2001, soon after the anthrax mail attacks, I was honored to be chosen by then Secretary of Health and Human Services, Tommy Thompson, to advise the Department on biodefense preparedness and response. We understood that the government was embarking upon a new and important mission – stockpiling promising, but in some cases unlicensed investigational products, to protect the American public in the event of an emergency. Success would mean prioritizing the threats, sharing the risk with industry, and procuring promising products.

Anthrax was the highest priority biological threat then and remains so today. Taking anthrax off the table as a potential threat was a critical priority. During my tenure at HHS, I saw many promising products that I believe could be vital components of our strategy to achieve this goal. I worry, however, that in the years since the anthrax mail attacks, the sense of urgency has waned and we have fallen short of our goal. Are we better prepared than we were six years ago? Yes, we are. Are we as prepared as we could be and should be? Sadly no.

The Monograph – *Spores: The Threat of a Catastrophic Anthrax Attack on America* is a provocative document that credibly lays out the anthrax threat while using fictional scenarios to demonstrate the economic and social consequences of an anthrax attack. I encourage you to read it and make your own assessment.

Rich Russell retired as Major General from the military after a career focused on researching a variety of infectious diseases and managing several vaccine development programs. After retiring, he was appointed Professor in the Department of International Health at Johns Hopkins University School of Hygiene and Public Health and serves as Chairman of the Board of the Sabin Vaccine Institute and consultant to The Bill Gates & Melinda Gates Foundation.

Statement of Former HHS Secretary Tommy Thompson

In late January 2003, President Bush announced Project BioShield during his State of the Union address. At the time, I served as Secretary of Health and Human Services. When we developed the Project BioShield initiative, there was great urgency to prevent, prepare for, and respond to potential terrorist attacks involving chemical, biological, and radiological weapons. Congress shared the Administration's concerns about bioterrorism and passed legislation to establish Project BioShield. It was signed into law by the President in July of 2004.

Much has been accomplished as a result of Project BioShield and the Administration's other public health preparedness initiatives. A major goal of BioShield was the creation of a private industry market for the development of medical countermeasures. Under BioShield, funding authority was created to allow the government to procure medical products without going through the annual appropriations process. Knowing that funds are available, private industry, especially small biotechnology companies, responded. Today the United States has a growing biodefense industry developing promising medical products to counter the bioterrorism threat.

When I was HHS secretary we prioritized CBRN threats. Having recently experienced the anthrax mail attack, in which five people died, anthrax was at the top of the list. Our first goal was to stockpile antibiotics to respond to an attack that is detected early. This has been accomplished. Antibiotics are positioned around the United States and can be deployed in short order once an attack has been detected. There can be no doubt that enormous progress has been made in preparing America to respond to a chemical, biological, and radiological terrorist attack. But much remains to be done. In addition to an anthrax vaccine made with 21st century technology, we still need a larger and more sophisticated capacity to treat anthrax. Antibiotics are necessary but are not solely sufficient, and additional measures are needed to counteract the bacterial toxins. Anthrax therapeutics are an important and needed next step.

Time is of the essence, as explained in the monograph, *Spores: The Threat of a Catastrophic Anthrax Attack on America*. We face potentially devastating consequences from an anthrax attack if we are unprepared. I hope this monograph will encourage policymakers to examine the issues, commit to adequate funding commensurate with the threat, and find a way to speed up our preparedness for a potential anthrax attack.

Statement by Kay Goss

I congratulate Dr. Neil Livingstone and his company, ExecutiveAction, for devoting their enormous talents and commitments to focusing our attention on our nation's vulnerabilities to an anthrax attack, documenting the intense planning that is going on around the globe to bring this potential catastrophe to bear, and highlighting the dramatic need for drastically escalated emergency preparedness for this illusive and pervasive threat.

Dr. Livingstone has made our jobs as emergency preparedness professionals easier by painting the most holistic picture I have seen of the explicit nature of the potential anthrax attacks, including the economic and psychological impacts of such an incident.

We tend to prepare for the last catastrophic disaster. Dr. Livingstone and Mr. Wright have stepped out smartly and in a timely manner to point us toward this future catastrophic event. The 9/11 Commission concluded that our greatest weakness in emergency preparedness for that event was "lack of imagination." This paper shows the necessary thought process to in fact prepare for the future!

Kay Goss is former Associate FEMA Director in charge of National Preparedness, Training, and Exercises, Chair of the Training and Education Committee, International Association of Emergency Managers, Co-Chair ASTM Work Group on School Emergency Preparedness Guidelines, and Adjunct Faculty in Emergency Planning and Preparedness, George Mason University

Statement by Rick Rest, Ph.D.

There are countries where *Bacillus anthracis* is commonly found in the soil, and where anthrax in cattle occurs sporadically. Farmers in these countries generally recognize that their animals have symptoms of anthrax only a few hours before the animals die. It is routinely lethal. Inhalation anthrax kills infected humans in a few days, as opposed to a few hours, after symptoms arise. In one respect, this is a good thing, since it allows for a window of opportunity for infected people to be treated, whether or not they yet show signs of disease.

However, this 'window' is not crystal clear. By the time we realize that we have been attacked ... that we have been exposed to anthrax spores ... the spores have already morphed into rapidly growing anthrax bacteria and have begun to grow and multiply in our blood stream and in our tissues; they are already secreting their deadly anthrax toxins that, left unchecked, will rapidly kill. So what can we do to save people's lives? People exposed to spores would best be treated with a combination therapy, which optimally would comprise (i) an antibiotic to kill the growing anthrax bacilli, (ii) a vaccine to protect against a future attack or lingering spores, and (iii) a therapeutic, such as an antitoxin, i.e. a molecule or medicine that will quickly stop the anthrax toxins from doing their damage to cells and host, thus protecting us from death.

The US has antibiotics that are effective against all known natural strains of *B. anthracis*. Such antibiotics surely saved lives after the anthrax attacks in the Fall of 2001. There are anthrax vaccines, but they are not optimal. More efficacious vaccines are needed and are being developed. Finally, we do not have adequate stocks or choices of therapeutics for anthrax. Thus, there is a need to continue to fund promising and innovative projects across the research spectrum – industry, government and academia.

Just like other bacterial diseases, not everyone exposed to anthrax spores will get anthrax. However, everyone will want to be protected ... everyone will want to receive the best available combination therapy. Everyone will hear from the news media that they have to be treated ... now! Being treated a week from now will not work. There are many challenges and consequences to this. One is that medical facilities and medical care givers (doctors, nurses, aids, practitioners, EMTs, medical students, etc) will be completely overwhelmed. Not only for the first few days after an anthrax attack, but for several weeks – there would be an unprecedented demand for medical attention by people concerned that they and their family members have contracted anthrax. Thus, not only do successful therapies need to be further developed, but, once developed, enough of them need to be produced to treat large numbers of affected individuals, in a short period of time.

There are many virulence factors that come in to play during anthrax. That is to say, *B. anthracis* has evolved numerous methods, mechanisms and structures to outsmart and evade our innate and adaptive immune defenses. No bacterial pathogen uses a single 'silver bullet' to kill its host. There are always multiple virulence factors; they are always redundant. Although vaccines against the major anthrax toxin are protective, and therapeutics aimed at this major toxin are meeting with success, there are many additional avenues of research that might lead to successful protective therapies. There is no shortage of ideas or lack of will to find protective therapies.

One thing is almost certain. We won't know that we have been attacked with anthrax spores until after we have been attacked. The Spores monograph demonstrates the tremendous toll an anthrax attack could have on our nation. Since we won't be warned, we must be prepared.

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