

Statement of Major General (ret.) Philip K. Russell, MD

Before

The House Armed services Committee

Subcommittee on Intelligence, Emerging Threats, and Capabilities

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Mr. Chairman, members of the committee, thank you for inviting me to discuss problems with the preparedness of our armed forces to deal with the threats posed by biological weapons. It is a problem that I have been deeply concerned about for over thirty years, first as an Army Medical Corps officer and later at Department of Health and Human Services. During my government career, I have had the privilege of managing the development of several vaccines, antitoxins and other medical countermeasures for both biodefense and public health purposes.

In this testimony I would like to make two points. First, the threat that a biologic attack by terrorists or other adversaries poses to our armed forces or our nation is not fully understood or recognized by the leadership of our defensive programs. Second, the medical countermeasure development programs of the Department of Defense essential to protecting our armed forces and our nation have a long, very well documented, record of failure and will continue to fail if no corrective actions are taken.

The first point is based on three in depth studies of the achievements of U.S. offensive biowarfare program which was terminated in 1969 and on analysis of the impact of the technical progress made in recent years by the pharmaceutical industry in terms of the potential capability it provides to our adversaries. These studies, which were conducted by Mr. Joel McCleary, Dr. Keith Wells and myself over the past two years, are based on the existing unclassified documents concerning the former US program and on the oral history of one of its last surviving senior scientific leaders. We also looked at how the advances in biologic manufacturing, bioprocessing, stabilization methods, spray drying and lyophilization can be utilized by bioterrorists to produce weapons as effective as those produced by offensive programs of the US and the Soviet Union. Results of these studies have been provided in briefings to members of the intelligence community and to key personnel in the Departments of Homeland Security, Defense, and Human and Health Services.

The most significant finding of these studies was that, after years of research and testing the most effective agents chosen for use as strategic offensive weapons, were tularemia and staphylococcal enterotoxin B (SEB). Plans and equipment were made to use these agents in combination. The bacteria was chosen for its lethality and the toxin for its rapid incapacitation. Extensive field tests including "Red

Cloud," "Watch Dog," and "Speckled Start" proved that these agents used as dry powder aerosols could deliver very high doses over large areas.. Tularemia is one of the most infectious agents known; the human infectious dose determined by studies in volunteers is less than 10 bacteria. It can be grown in culture in a fermenter to concentration of 10^{11} bacteria per ml. A dry powder aerosol can deliver hundreds of thousands of organisms to exposed personnel. Recent studies in monkeys conducted by the Lovelace Institute have proven that very high doses delivered by aerosol cause a devastating pneumonia with a very short incubation period making post-attack therapeutic treatments with antibiotics problematic. Virulent strains of tularemia are readily found in nature. SEB was chosen because it is a fast acting incapacitating agent when delivered by aerosol. It causes a pneumonitis and is lethal at high doses. It is stable and relatively easy to produce in culture. High producing strains are widespread and easily found.

The offensive program created very effective strategic weapons but needed industrial level capability to manufacture the weapons they tested and stockpiled. However advances since 1969 in technology now put this capability within reach of any nation state or small number of dedicated terrorists. The pharmaceutical industry in the course of developing delivery of multiple drugs by aerosol and refining biologics manufacturing processes has created the technology and equipment to make bioweapons much more readily available. The information on the new processes is widely published in the public domain and the equipment is available for sale and resale on the internet. The obstacles that the former U.S. offensive program had to overcome such as stability and uniform particle size have been mitigated by modern technology. Our conclusions in regard to the ability of motivated terrorist group to exploit modern technology to achieve what was once only a state weapon's monopoly is accepted without reservation by the leading technical experts in our intelligence community.

The accomplishments of the offensive programs of the U.S. and the Soviet Union have largely been forgotten or ignored by policy makers and product developers. Consequently, there is no specific licensed preventive medical countermeasure available for either of the leading lethal agents of the US offensive program, tularemia or SEB. We rely on antibiotics to deal with tularemia post-exposure and on supportive medical care for SEB. This is an unaddressed national vulnerability.

The Department of Defense created a joint program for advanced development medical countermeasures in 1996. The Joint Vaccine Acquisition Program (JVAP) was a major component. A tularemia vaccine was at the top of the requirements list which included several other biodefense vaccines. It is now seventeen years later and no new licensed products have been developed. The deficiencies in our national level of preparedness have been described in detail by the Commission on the Prevention of Weapons of Mass Destruction, Proliferation and Terrorism chaired by Senators Graham and Talent and by the "Bioresponse Report Card" issued by the Bipartisan WMD Terrorism Research Center.

The Department of Defense efforts to develop vaccines have been reviewed and criticized by several independent groups. The "Top Report", a Report to the Deputy Secretary of Defense by an Independent Panel of Experts concluded in 2000 that the program is "insufficient and will fail". Reports by committees of the Institute of Medicine in 2002 and 2004 documented the program failures, criticized

the management of the program, and made recommendations for change. The National Biodefense Science Board addressed the issue of lack of countermeasures in 2010. These external independent advisory groups have had no impact on the program.

Since the origin of the DoD program billions of dollars have been spent. Yet only two vaccines, a plague vaccine and a botulism vaccine, are in advanced stages of development. The attempts to develop an early live attenuated tularemia vaccine to licensure have failed and no significant progress on a second generation product is evident. The problems with the program are detailed in multiple reports. Problems include the DoD contracting mechanisms, which are largely unsuited to working with the vaccine industry, lack of knowledge of the vaccine industry by program managers, and reliance on prime contractors with limited capability. Uncertain funding disrupts programs and, most importantly, lack of accountability by the leadership allows failure to continue.

There is some good news. The basic research programs at USAMRIID continue to be very productive and are creating the scientific basis and early prototypes for several vaccines including the hemorrhagic fever and encephalitis viruses.

In summary, lack of understanding of the threat that the strategic bioweapons produced by the U.S. program continue to pose a major threat coupled with an ineffective countermeasure development program has created a significant vulnerability for our Armed Services and our nation .