

USAWC STRATEGY RESEARCH PROJECT

**VACCINE ACQUISITION STRATEGIES  
THE FORCE PROTECTION GAMBLE**

by

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The views expressed in this academic research paper are those of the author and do not necessarily reflect the official policy or position of the U.S. Government, the Department of Defense, or any of its agencies.

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## ABSTRACT

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The advances in the weapons technology of the 20<sup>th</sup> century ensure the United States will achieve military dominance on the battlefields of today and tomorrow. Victories require people on the ground facing the enemy wherever the threat is present. These warriors must be protected from the endemic infectious disease threats as well as from the possibility of an intention release of a biological agent. The Department of Defense has a unique role in conducting research and development to produce vaccines against those threats that could serious hamper the global role of the military to defend this nation. The military vaccine program is facing untenable odds at maintaining its momentum while faced with severely unfunded programs and a lack of commitment from the Department of Defense to recognize this force protection imperative.

When the United States was attacked on September 11, 2001, the focus of this nation changed forever. Homeland security became the number one priority. There was unprecedented national support directed at improving public health emergency preparedness specifically vaccines to protect this nation from a biological attack. Congress has allocated billions of dollars to pursue immediate advances in medical countermeasures, vaccine development, and drug availability. This has not translated into increasing the military research programs. The purpose of this paper is to examine the unique role of the Department of Defense in vaccine research and development and how the current emphasis on homeland security and public health emergency preparedness threatens the viability of this program. This paper will highlight the importance of the military vaccine program; identify its weaknesses and vulnerabilities and make recommendations to secure its vital role in protecting the U.S. military personnel both at home and abroad.



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## VACCINE ACQUISITION STRATEGIES THE FORCE PROTECTION GAMBLE

The causes of the origin and spread of pestilences during a war are clear. Every aggregation of people, even in times of peace, at celebrations and annual fairs, in barracks and so forth, is necessarily exposed to the danger of pestilence; but this danger is ten times as great in large assemblages of troops during a war. The soldiers are then subjected to all possible kinds of hardships and suffering--lack of food, or food which is inferior and badly cooked; sleeping out in the cold and rain, fatiguing marches, constant excitement, and homesickness--all of these things greatly lessen their power of resistance. If an infectious disease reveals its presence in such an aggregation of people, energetic and stringent measures must be adopted, even in time of peace to prevent it from spreading. In war times it is often impossible to take the necessary precautions, since the attention of the commander is directed toward very definite objects, to which all other considerations are subordinate. Whether the germ of the disease is already in the place or whether the soldiers bring it with them, in either case there is danger that the fighting armies will cause the disease to spread over the entire scene of the war, and thus seriously endanger thousands of lives.

? Dr Freidrich Prinzing, 1916

The United States is preparing for war. It is deploying the largest military force since 1990 to an area where the risks for infectious disease and bio-warfare are high. The military has experience in this region and knows the capabilities of the enemy. The Department of Defense has invested new weapons systems, new communications systems, new command and control systems, and new transportation systems to increase the survivability of its forces. However, has the Department of Defense invested as much time, energy and resources into the military medical preventive measures to protect its personnel, military and civilian, from the threats in this region? The purpose of this paper is to examine the unique role of the Department of Defense in vaccine research and development and how the current emphasis on homeland security and public health emergency preparedness threatens the viability of the military vaccine program. The paper highlights the importance of the military vaccine program, identifies its weaknesses and vulnerabilities, and makes recommendations to secure its vital role in protecting our military both at home and abroad.

The United States Department of Defense has a unique mission that is different from the other federal agencies or private industry. It must prepare to fight and win wars to preserve the security and freedoms of this nation. Military leaders must protect its personnel from the threats that will confront them on foreign soil in order to be victorious in battle.

The military is undergoing a transformation that will change the way America fights the battles of tomorrow. With a defense budget proposal of \$380 billion aimed at financing the



weapons systems of the 21<sup>st</sup> century,<sup>1</sup> there is still the undeniable fact that to be victorious requires putting forces on the ground. As stated in the U.S Army Objective Force White Paper, “we must protect the soldier from disease and other biological threats.”<sup>2</sup> As the demographics of the force changes to a more diverse mix of military, contractor and civilian personnel, providing that protection becomes even more complicated. The threats are not only from conventional weapons but also from an austere, deteriorating infrastructure, endemic disease and from the possibility of chemical, biological, nuclear, radiological, and explosive weapons. It is the responsibility of the Department of Defense to protect the entire force against these threats.

## **THE FEDERAL ROLE**

Protection against biological threats took on a new dimension after September 11, 2001. Historically, only the military focused on protecting its personnel against biological threats. The military focused its research efforts to develop medical countermeasures to protect against those threats. Now the threat has emerged on the domestic front, and homeland security is the nation’s top priority.<sup>3</sup> The battlefield dynamics are forever changed; those once distant threats are now within U.S. borders. The military medical research and development programs are now even more important than ever. However, these programs appear dwarfed in comparison to the federally funded programs now earmarked for homeland security and public health preparedness.<sup>4,5</sup>

Today’s American society is mostly naïve concerning highly infectious disease threats. Vaccine developments in the 20<sup>th</sup> century led to the disappearance of the many of the dreaded childhood diseases such as polio, neonatal tetanus, and measles. At least 29 previously unknown diseases have appeared globally since 1973; many of them incurable, including HIV/AIDS, Ebola Hemorrhagic Fever, and Hepatitis C.<sup>6</sup> Despite significant progress in the development and distribution of vaccines, infectious diseases remain the second leading cause of death and the leading cause of disability worldwide. Infectious diseases and non-battle injuries still accounted for the largest percentage of combat-related hospitalizations in U.S. deployed troops in the 20<sup>th</sup> century.<sup>7</sup> Vaccines are more effective and have fewer adverse effects than antibiotics or other treatments.<sup>8</sup> There are a number of government agencies that have a role in vaccine research, (Figure 1). The need for close interagency coordination and parallel collaboration among these agencies is obvious but each has a distinct role and mission in vaccine research development. DOD’s focus on the threats to U.S. military personnel separates the DOD role from that of the other agencies.

- **CDC** has a myriad of roles related to vaccines, the most important being to conduct the epidemiological studies and surveillance needed to define health priorities and to develop recommendations for vaccine use
- **DOD** supports research into vaccines to protect against pathogens likely to be encountered by military personnel.
- **USAID** supports research on vaccines of particular relevance to young children in developing countries.
- **FDA** establishes standards for the processes, facilities, and pre-and post-licensure activities needed to insure the safety and efficacy of vaccines.
- **NIH** supports, through its extramural and intramural programs, much of the basic research in microbiology and immunology that underpins vaccine development. NIH also provides research resources such as reagent repositories, genomic databases, and clinical trials support to identify vaccine targets and move candidates along the pathway to licensure.

FIGURE 1. GOVERNMENT PLAYERS IN VACCINE RESEARCH<sup>9</sup>

Congress allocated billions of dollars since September 2001 to public health emergency preparedness, with specific attention given to biological threat vaccine research. Though once considered the research leaders in this field, the defense biological vaccine programs did not receive additional funding from these allotments. The DOD's vaccine programs are in jeopardy due to infusion of funding into other federally funded vaccine programs that compete with the existing military research agenda. The Department of Defense must recognize the relevancy of its vaccine research and development program and transform it to better address the military significant threats or face the prospect of losing this vital capability to other government agencies that focus and resource these programs. If DOD loses its vaccine program or loses the ability to direct the research against the militarily significant threats then the inherent result is an increased risk to the military forces.

## **MILITARY VACCINE RESEARCH**

Military medicine has always focused on the prevention of disease. General George Sternberg, U.S. Army Surgeon General (1893-1902), founded the Army Medical School in 1893. It is widely recognized as the oldest school of public health and preventive medicine in the United States. In 1898, 50,000 American troops occupied Cuba after the ratification of the Treaty of Paris. Yellow Fever was a significant threat to the American soldiers and civilians in Cuba that also threaten the success of the mission of restoring political stability to the Island. General Sternberg (Surgeon General) and Leonard Wood (Governor of Cuba and former Army Surgeon) shared the belief that this was a tremendous opportunity to study the disease. As a bacteriologist, General Sternberg conducted extensive studies and his research indicated the filthy living conditions contributed to Yellow Fever. He thought good hygiene and discipline could control the disease. Wood and Sternberg assigned sanitation officers to clean private residences and clear garbage and sewage from the American camps and from the streets of Havana. The sanitation effort did not eliminate the disease but it did reduce the severity of the outbreak. Sternberg and Wood understood the ramification of controlling this disease and dedicated the first Army medical research team to study the cause and spread of Yellow Fever in Cuba. This team, led by Major Walter Reed discovered that the mosquito transmitted Yellow Fever,<sup>10</sup> a discovery that led to the development of the Yellow Fever vaccine in 1937, which still controls outbreaks today around the world.

The Army Medical School became the Walter Reed Army Institute of Research in 1953. Its medical research focus has continued to expand as the U.S. military presence has emerged as a global force. The distinguished researchers of the Institute discovered the cause of Dengue Fever, Dysentery, Typhoid, Syphilis, and Japanese Encephalitis. They have made significant advancements in military medicine through their investigations on malaria, combat stress, wound treatment and chemical and biological weapons.

Because of the military medical discoveries and scientific advances, the U.S military is better prepared to face the challenges of the global deployments. The military conducts medical research around the world to continue the advancement of scientific discoveries directed at protecting the military and civilian populations serving this country. Force health protection is a military imperative dedicated to protecting the military's most valuable resource, its people. Force health protection involves not only the enforcement of the most basic personal protection measures but also the ability to recognize those threats to the combat effectiveness of the forces and neutralize them through effective vaccines and countermeasures.<sup>11</sup>

## **EMERGING PUBLIC HEALTH THREATS**

During the past century, the control of infectious diseases and advances in preventive medicine made tremendous strides in the public health of this country. Nevertheless, infectious disease agents remain a substantial threat to the operational capacity of the United States military. There are three distinct reasons for this: (1) recruits continue to train in groups under crowded conditions, increasing the risk of spread of infectious agents; (2) deployed warfighters, whether on combat or peacekeeping missions, continue to come into contact with pathogens with which they have no prior experience and therefore no immunity; and (3) warfighters along with others, face an increasing risk of the intentional use of weaponized infectious agents.<sup>12</sup> The intelligence community recognizes the national security dimension of a non-traditional threat.

The growing threat of global infectious disease is a concern to senior U.S. leaders as it threatens the health, economy, and national security of this nation. New and reemerging infectious diseases pose a rising global health threat and will complicate U.S. and global security over the next 20 years.<sup>13</sup> These diseases endanger U.S. citizens at home and abroad, threaten U.S. armed forces deployed overseas and exacerbate social and political instability in key countries and regions in which the U.S. has significant interest.<sup>14</sup> The implications for U.S. national security are clear. As a major hub of global travel, immigration, and commerce with wider ranging interest and a large civilian and military presence overseas, the United States and its personnel abroad remain at risk.

## **INFECTIOUS DISEASE THREATS**

Emerging and reemerging infectious diseases, many of which originate overseas, kill at least 170,000 Americans annually.<sup>15</sup> The current West Nile Virus (WNV) outbreak is a textbook scenario for studying emerging infectious disease outbreaks in the United States. Since its initial identification in the United States in August 1999, West Nile Virus has killed 254 Americans and infected 3,893.<sup>16</sup> First identified in New York, it has spread to 40 of the contiguous states. The identification of this pathogen shocked the medical community for the West Nile Virus was never identified as an emerging disease threat for this country. Discovered in Uganda in 1937, the West Nile Virus now appears in Africa, the Middle East, and Western Asia. Until 1999, it had not appeared in the Western Hemisphere. The epidemiology of West Nile Virus serves as a valuable template to study how a more deadly disease could spread through a virgin population. It makes experts question whether it arrived naturally or intentional planted by a bioterrorist.

Other vector-borne pathogens if introduced into the United States could cause human epidemics and devastation to the livestock industry. With today's international trade market, mosquitoes or mosquito eggs from Asia or elsewhere in the Middle East could easily carry the viruses of Japanese Encephalitis (JE) or Rift Valley Fever (RVF). Once confined to Asia, JE has now appeared New Guinea, Australia, and elsewhere in the Western Pacific. If JE arrived in the U.S., as many as 30 different vectors could tote it around--and eradication would be impossible.<sup>17</sup> Rift Valley Fever (RVF) is another mosquito-borne infectious disease, which causes fever, shock, and encephalitis. It too, could travel to the United States on an infected mosquito from Africa or the Middle East and would almost surely cause human death as well as epidemics among cattle and sheep. In 1977, the RVF virus jumped from southern and eastern Africa to Egypt causing 200,000 human deaths. In 2000, Rift Valley Fever appeared for the first time outside Africa: in Saudi Arabia and Yemen, and now it threatens the Arabian Peninsula. The legendary virus hunter, C.J. Peters, predicts that RVF or similarly dangerous viruses will come to the United States.<sup>18</sup>

Some virus experts think that the leap of WNV into North America is one of the most important biological events to occur in the world in the 20<sup>th</sup> century. There are two reasons for this: (1) the virus had generally not been fatal to its avian hosts and (2) the outbreak reveals the mobility and the propensity of the virus to cross-continent.<sup>19</sup>

Another example of an infectious disease that is experiencing a reemergence is malaria, eradicated from this country in the 1970s. The 2002 report of two unrelated cases in Virginia illustrate the susceptibility of this country to induction of foreign infectious agents. These recent outbreaks represent the first probable mosquito-borne malaria transmissions since 1999 and, interestingly, these cases share common features: 1) an initial case without known risk factors, 2) probable proximity to a person with malaria parasitemia, 3) presence of competent mosquito vectors, and 4) environmental conditions conducive to the maturation of the parasite in the mosquito.<sup>20</sup>

The underlying message regarding emerging infection diseases is they are impossible to predict.<sup>21</sup> WNV, JE, Malaria, and RVF are infectious diseases that pose significant threats to military personnel and therefore have had extensive research dedicated toward developing vaccines and effective countermeasures to ensure adequate force protection. In fact, a military vaccine developed by the United States Army Medical Research Institute for Infectious Disease (USAMRIID) controlled the RVF epidemics in Egypt and Saudi Arabia.<sup>22</sup> These contributions by military medical research reinforce not only its relevance to protecting the nation security interests around the world but also to the overall public health of this nation.

Infectious diseases pose considerable threats not only to the U.S. population but also to the agriculture industry as well.<sup>23</sup> Research efforts must continue towards developing effective vaccines to protect the deployed forces as well as U.S. citizens from outbreaks in this country. An intervening ocean and strong animal quarantine laws have kept this country relatively safe so far.<sup>24</sup> However, this country cannot rely on hope or luck to keep it safe. As President Bush said at the West Point Commencement Ceremony on 3 June 2002, "If we wait for threats to fully materialize, we have waited to long."<sup>25</sup>

#### **BIOTERRORISM THREAT**

The military had for decades focused on the possibility of a biological attack during the conduct of military operations. However, once thought only a military threat, "Al Qaeda and anthrax made domestic terrorism a reality."<sup>26</sup> The spotlight turned to civilians, not involved in a military operation, with the 1995 attack on the Tokyo subway with the nerve gas Sarin.<sup>27</sup> The 1993 bombing of the World Trade Center, the 1995 bombing of the Alfred P. Murrah Federal Building in Oklahoma, the 2001 attacks on the World Trade Center and the anthrax letters finally changed America from a nation of skeptics to a nation of believers concerning biological threat.<sup>28</sup> This has created unprecedented support for civilian research and development programs to advance medical treatments, vaccines, and antidotes against bioterrorism.

With the ever-rising threat of an intentional release of a biological weapon, the United States must protect its citizens at home and abroad. The probability of a bioterrorist attack within the United States or against civilian and military personnel overseas is likely to grow as more states and groups develop biological warfare capability. This has sparked an impetus among the federal agencies involved in vaccine research to capitalize and enhance upon the DOD developed strategies, products, procedures, and training for medical defense against biological warfare agents. The DOD programs cannot compete on the same level as these other federal programs due to the disparity of the funding programs. If the distinction between the military and civilian programs is to remain then DOD must transform its vaccine strategy to address more precisely the force protection imperatives, otherwise the DOD program is vulnerable and the force is at risk.

#### **VACCINE ACQUISITION IN THE DEPARTMENT OF DEFENSE**

Vaccines within the Department of Defense (DOD) fall into two categories; vaccines to protect against biological warfare agents (BD), funded by Office of the Secretary of Defense (OSD); and vaccines to protect against infectious diseases (ID), funded by the Operations and

Maintenance budgets of each Service. In accordance with public law, a single office within the Office of the Secretary of Defense oversees the chemical and biological defense programs within the Department of Defense.<sup>29</sup> DOD established a Joint Service Chemical and Biological Defense Program Office in 1994. The vision of the program is to ensure U.S. military personnel are equipped and prepared for operating in battlespaces that feature chemical or biological contamination.<sup>30</sup> Vaccines to protect against biological agents provide one critical capability to protect against the threat. This consolidation and integration of the chemical and biological defense requirements caused the administrative separation of the vaccine acquisition process. It created separate funding and approval authorities for the BD and ID vaccines.<sup>31</sup> This separation severely challenged vaccine research and development for the Department of Defense by defining a difference between naturally occurring and weaponized sources of infectious agents that has led to a severe lapse in defense vaccine acquisitions.

The Army is the lead agent for the infectious disease program and executes the program through the U.S. Army Medical Research and Materiel Command (MRMC), a subordinate command of the U.S. Army Medical Command. As part of its lead agent responsibilities, MRMC conducts research and product development for vaccines and therapeutic agents aimed at preventing and controlling infectious diseases and biological warfare threats. The medical products developed to protect military personnel against biological attack include drugs, vaccines, diagnostics, and various medical management procedures to eliminate or minimize the effects of biological hazards on the fighting force. Since many potential biological weapons are weaponized agents of naturally occurring infectious diseases, it is the basic research of the infectious disease threats that serve as the foundation of the bioterror investigations. This is the cornerstone of military vaccine research: to protect the operational effectiveness of the U.S. forces from the threats of endemic diseases or biological agents.<sup>32</sup>

Since George Washington ordered the systematic variolation of the Continental Army to protect the nation's soldiers from smallpox, vaccines serve as a significant method of preventing infectious disease among America's military forces.<sup>33</sup> Protecting the health of military personnel is essential to national security, and vaccines are often the most cost-effective way to protect individuals from infectious diseases. However, DOD often overlooks their value since the vaccine programs are fragmented. This organizational structure adversely affects DOD's ability to deliver vaccines to the military, which results in the force health protection gamble. DOD needs a single authority to represent the value of the vaccines, both BD and ID, in order for force health protection to remain the priority. Conversely, this lack of a DOD commitment toward a comprehensive vaccine program can have only disastrous outcomes. The review of

the Adenovirus Vaccine Strategy illustrates how a poorly conceived vaccine decision can adversely affect the health of the force.

#### ADENOVIRUS VACCINE DEBACLE

The Adenovirus Vaccine illustrates the disastrous outcome that occurs when the lack of a long-term DOD commitment coincides with the profitability index of the vaccine-manufacturing industry. The result is loss of capability and increased risk to the military force. Wyeth, a major vaccine manufacturer, licensed vaccines against Adenovirus 4 and 7 over two decades ago to halt epidemic levels of infection among military recruits--large populations living in close quarters.<sup>34</sup> Wyeth was the sole producer of the vaccine. Faced with costly regulatory compliance upgrades to its production facility Wyeth requested DOD to invest in the vaccine infrastructure. DOD determined it would not make the investment that prompted Wyeth to announce in 1995 permanent cessation of production. The news of this announcement prompted an immediate recommendation to DOD to continue funding this significant force health protection vaccine. "It is a matter of priorities," advised one official. "There is not enough money to do everything."<sup>35</sup> The existing supplies of vaccine ran out in 1999. It did not take long for large outbreaks of Adenovirus to reappear among recruits. Army, Navy and Air Force Basic Training Centers started reported large outbreaks of the virus. Some outbreaks persisted for several months and accounted for a 20% increase in the number of Air Force recruits being recycled for medical reasons due to Adenovirus-Associated FRI illnesses.<sup>36</sup> However, it took the deaths of two navy recruits at the Great Lakes Training Center in 2000 for DOD to reconsider its decision to eliminate the vaccine and initiate action to find a new manufacturer. It will take a manufacturer up to five years to produce a new vaccine.<sup>37</sup>

The Adenovirus Vaccine is a perfect example of a militarily significant vaccine that has limited commercial marketability and therefore needs DOD protection (commitment) to ensure continued production and availability. It illustrates how an ineffective DOD vaccine acquisition strategy, competing priorities, and lack of a single vaccine authority can adversely affect the force health protection of the military.

One of the most obvious methods to measure DOD commitment to vaccine research and development is through an examination of the funding levels, including infrastructure and plant modernization. The regulatory compliance requirements on vaccine manufacturing cannot be underestimated and DOD must consider them in the development of an overall DOD vaccine strategy. DOD budgeted an estimated \$14 million for finding a new Adenovirus manufacturer. That compares negatively to the industry standard of \$400 to \$500 million to bring a new drug to



market. DOD cannot independently entice commercial interest without offering some financial incentive, long-term commitment, and partnership to allow for stability.

#### UNFUNDED VACCINES

Other examples that illustrate DOD's unwillingness to invest in vaccine research are evidenced by the establishment of a joint working group to review DOD Unfunded Vaccine Projects. In September 2002, The Office of the Assistant Secretary of Defense for Health Affairs sent a memorandum to the Office of the Assistant Secretary of Health and Human Services, Public Health Emergency Preparedness offering the research materiel and vaccine lots for the following military vaccine projects:

- Rift Valley Fever Vaccine, Formalin Inactivated
- Rift Valley Fever Vaccine, Attenuated
- Argentine Hemorrhagic Fever (Junin) Vaccine, Attenuated
- Chikungunya Vaccine, Attenuated
- Hantavirus Vaccine, Vaccinia Vectored
- West Nile Vaccine Inactivated, Seed Lots<sup>38</sup>

DOD sponsored research on these products during the height of the Cold War, 1960-1995, at the following facilities developed these products: the U.S. Army Medical Research Institute of Infectious Diseases; the Walter Reed Army Institute of Research (WRAIR); or at the Salk Institute (Government Services Division, Swiftwater, Pennsylvania.) The Salk Institute closed resulting in the termination of the manufacturing process for these products. All of these products, with the exception of the West Nile Virus Vaccine, carried the Investigational New Drug (IND) Label from the Food and Drug Administration. Following the closure of the Salk Laboratory in 1998, DOD moved the actual materials and production records to various storage locations.<sup>39</sup> Further advancement of these products was the responsibility of the U.S. Army Medical Materiel Developmental Activity (USAMMDA) another subordinate command of the MRMC. Dwindling budgets and higher priorities for militarily significant products caused further development of all of these projects to halt, thereby leaving these products to atrophy on the shelf.

The requirement for these products was to develop vaccines to protect military personnel against threats either from naturally occurring infectious diseases endemic throughout the operational area or from highly infectious agents that through aerosol delivery,

have the potential use as a biological warfare weapon.<sup>40</sup> The threats remain, and the outcomes could be catastrophic to U.S. forces or to the U.S. Hemorrhagic fever or the diseases caused by members of the arenavirus and bunyavirus families,<sup>41</sup> the Chikungunya Vaccine, a mosquito-borne disease endemic throughout most of Africa, Southeast Asia, India and the Western Pacific,<sup>42</sup> and Rift Valley Fever a mosquito-borne or aerosol-transmitted viral infection of man, could reduce the operational effectiveness of U.S. forces. In addition, forces returning home could introduce this disease creating catastrophic impact on the domestic livestock industry.<sup>43</sup>

The significance of these products is the value of basic research that went into the vaccine developments. It is clear; particularly as the U.S. witnesses the spread of WNV in the United States that diseases once thought to circulate in localized areas abroad could enter the United States leaving death and destruction in their wakes. Though not committing any additional resources and after failing to compile usable product assessment, DOD is finally realizing the potential scientific value of the unfunded vaccine projects and is offering the material to DHHS in an effort to preserve the intellectual properties.

There are two interesting discoveries in reviewing the vaccine decision documents mentioned above. First, in 1994, the Milestone Decision Authority at MRMC approved the advancement of the Argentina Hemorrhagic Fever (AHF) for a Product License Application (PLA) for the vaccine. After more than 15 years of research, the military and contract scientists of the USMRIID and the SALK Laboratories produced a vaccine that demonstrated a 95.5 percent efficacy in preventing AHF.<sup>44</sup> Sadly, DOD never submitted the PLA therefore never licensing the vaccine. This loss is again an illustration of the lack of commitment on the part of DOD to invest in its vaccine research progress. The arenavirus and bunyavirus families may not be the agents of choice for biological warfare weapons but they are highly infectious diseases that have the potential to become effective BW weapons. One would think that the seriousness of their threat would seemingly justify preserving the research.

Second, the Rift Valley Fever Vaccine (RVF) is a prime example of how divergent funding streams for infectious disease vaccines and the biological warfare vaccines led to the vaccine's ultimate demise. Rift Valley Fever, as discussed earlier, was a disease of the sub-Saharan desert in Africa. It appeared in Egypt in 1977 causing extensive human sickness and more than 600 fatalities. This illustrates that the disease is capable of spreading to other regions, particularly the Middle East.<sup>45</sup> The USAMRIID received an Investigational New Drug (IND) license for the Inactivated RVF virus vaccine in June 1969. The United States provided this vaccine to Egypt and the United Nations peacekeeping force stationed in the Sinai

Peninsula during the 1977 epidemic that controlled the epidemic. The vaccine induced a protective antibody in 95 percent of those vaccinated. An improved inactivated RVF virus vaccine was prepared in FY 78. The Department of Defense transitioned the vaccine from a development vaccine to a contingency vaccine in 1989 to have it available for military operational requirements. Other contingency vaccines included Venezuelan Equine Encephalitis (VEE), Eastern Equine Encephalitis (EEE), and Western Equine Encephalitis (WEE).<sup>46</sup> IND protocols exist for these vaccines, which in order to use, require informed consent and voluntary participation.

Rift Valley Fever remained under the contingency vaccine umbrella until November 1998 when an Acquisition Memorandum terminated the program based on its reclassification from a perceived biological warfare threat to an infectious disease threat. In the decision memorandum, the requirement for a vaccine to protect against RVF remains and will be supported by existing supplies of the inactivated RVF vaccine under its IND status.<sup>47</sup> RVF remains a viable threat for U.S. forces deployed to Southwest Asia. A new contingency protocol was prepared for potential use in the current operational conflict in Southwest Asia. If vaccinated today, personnel would be under the 1978 IND protocol for the RVF vaccine. A foreign military sales program to Saudi Arabia in 2000 has sustained current lot testing and maintenance of this vaccine. The program is in jeopardy because the current storage contract will expire at the end of 2003 with no additional sustainment dollars earmarked for its renewal.<sup>48</sup> The Rift Valley Fever Vaccine could be a significant force multiplier for military operations in Southwest Asia. The loss of this critical force health protection vaccine highlights the strategic impact that the competing vaccine programs within DOD have on each other.

These vaccines are important to the Department of Defense for two reasons: 1) they are primarily, infectious diseases that are endemic in operational areas of interest to U.S. national security and 2) they are potential biological warfare agents through their propensity for aerosol delivery. The status of these particular vaccines is at this time unresolved, though DOD has made it clear that the programs are dead. The Department of Health and Human Services has an interest in the products for their scientific merit but is unwilling to accept the products without a detailed assessment of each program. As the debate over these products languishes between action officers, and budget officers, and scientists, the more fundamental issue in the debate is the lack of a single authority within DOD to make vaccine decisions. It is impossible for the Department of Defense to have an effective vaccine acquisition program when there is not a single authority responsible for vaccine research and development. The DOD must

consider the threats, risks, and costs when making decisions that could ultimately jeopardize the health of the U.S. forces.

## **VACCINES, INDUSTRY AND THE DEPARTMENT OF DEFENSE**

The reason these products remained in active IND status for 20 years is the inability to rapidly produce a vaccine for which there is no commercial market. The American people, military or civilian, do not want products labeled Investigational New Drugs (IND). The stigma associated with IND is that of an experimental guinea pig. This perception, coupled with the unfavorable publicity from the Gulf War Syndrome, resulted in the publication of DOD Directive 6200.2, Use of Investigational New Drugs for Force Health Protection.<sup>49</sup> The Secretary of Defense is the approval authority to use IND products for force health protection and only after documented confirmation of a high threat, and the risks and benefits of the use of the IND are fully justified to the Secretary. The preferable product for force health protection is one approved by the Food and Drug Administration. However, since the ability to license medical products is not within the purview of the DOD, it must continue to conduct research to develop effective countermeasures against chemical, biological, and radiological warfare and endemic disease threats with an ultimate end state of licensure. The Food and Drug Administration, internationally recognized for its high standards, is the compliance arm of industry comprises a successful vaccine strategy is the defense needs, industry wants, and regulatory standards. A fragmented approach to this triad represents a vaccine strategy at risk. The current DOD policy of separate vaccine programs fails to capture the total vaccine requirements and therefore reduces industry's interest to participate. This inhibits the ability to produce the required vaccines and thereby fails to protect U.S. forces against the identified threats, endemic or intentional.

There are only four major vaccine manufacturers licensed in the United States: Wyeth-Ayerst International, SmithKline Beecham, Pasteur Merieux Connaught, and Merck & Company, Inc. The primary drivers behind the industry's investment decisions are public health (i.e., medical need), potential profitability (i.e. return on investment), and technological feasibility (i.e., access to technology). High-priority public health needs can fulfill humanitarian concerns and in turn ensure sufficient profits through annual sales and potential long-term investments. The important distinction between industry and the military is the process of determining the needs. For civilian use, industry selects a need for which there will be high acceptability for the vaccine within the medical community. By contrast, the military determines its needs based on the

global threats and force protection needs. Industry can choose the need it wishes to address; DOD must address the threat.<sup>50</sup>

DOD has identified 15 threats from biological weapons and endemic diseases that require vaccines. By comparison, the entire vaccine program for the United States includes only 20 licensed vaccines.<sup>51</sup> The size and scope of the DOD program is too large for DOD to handle independent of industry, yet its production requirement is too small to entice industry to enter into this market alone. Industry will not enter into vaccine production unless guaranteed a profit. The difference between the 20 licensed vaccines for U.S. public health and the 15 military significant vaccines is the demand. The U.S. public health demand is constant and long term where as the militarily significant vaccines are contingent on mobilization requirements. The military stockpile vaccines in anticipation of need, which requires a manufacturing commitment to ensure continued availability without constant demands. This is not a profitable venture for industry unless there are substantial federal guarantees and investment initiatives for long-term investment potential.

DOD cannot adequately address the total vaccine requirement when there is neither a single authority responsible for the vaccine acquisition program nor adequate up-front multi-year funding commitment to allow for rapid transition from discovery to production and licensure. The problems associated with militarily significant vaccine acquisition are widely acknowledged within the military and congressional committees. However, vaccine acquisition did not receive national attention until the anthrax attacks of October 2001. With Americans heightened awareness of bioterrorism and its focused attention on the nation's public health system, the responsibility of the government to protect the citizens of the United States from an intentional release of a biological agent gained national attention.<sup>52</sup> This attention translated into a federal response called Project BioShield, "\$6 billion over a 10 years."<sup>53</sup> Project BioShield is a comprehensive effort to develop and make available modern, effective drugs and to protect against biological and chemical weapons. It has three major focuses:

- To ensure that resources are available to pay for the "next generation" of medical countermeasures. Project BioShield will allow the government to buy improved vaccines or drugs,
- To strengthen the National Institute of Health development capabilities by speeding research and development on medical countermeasures based on the most promising recent scientific discoveries,

- To give the FDA the ability to make promising treatments quickly available in emergencies. This tightly controlled new authority can make the newest treatments widely available to patients who need it in a crisis.<sup>54</sup>

Project BioShield will focus on accelerating the process of research, development, purchase, and availability of drugs and vaccines to counter bioterror attacks. The National Institute of Allergy and Infectious Diseases at the National Institute of Health (NIH) would execute the program as currently configured. Under this plan, the government could guarantee drug companies a buyer for their product. Without such a guarantee, the pharmaceutical companies are reluctant to develop, produce, and sustain the needed products. The lack of such a guarantee is the reason that military significant vaccines remain as IND products and that the manufacturer stopped production of Adenovirus.

BioShield a victory for the homeland security could severely undermine and distract from the vaccine research efforts of the military. BioShield will focus its efforts against the identified agents of bioterrorism and not on the infectious disease agents that threaten U.S. forces. It also has the propensity to severely undermine the BD vaccine research programs since industry will follow the money. The military medical research community has long-standing relationships with the NIH but now NIH will be the lead in this arena with DOD in a supporting role. This is clearly illustrated in a current DOD proposal to transfer a major biological defense vaccine program, Tularemia, to NIH in order to be accelerated under the BioShield umbrella.<sup>55</sup> Additional efforts such as this could have serious consequences on the force health protection research role of the DOD. Other federal programs will jeopardize the military vaccine program if the DOD does not streamline its decision-making matrix (responsibility, authority, and accountability) over vaccine development and maximize its ability to focus on the “force” health protection priorities.

## **RECOMMENDATIONS**

The Department of Defense has a unique role in conducting vaccine research and development on disease threats, either naturally occurring or intentionally released, in order to defend the nation on multiple fronts. For the Department of Defense to maintain its vital role in this process it must consolidate all vaccine research and development under one authority and establish clear lines of authority, responsibility and accountability for program management. With a consolidation of the decision-making authority, the DOD would gain total visibility over vaccine requirements. It could better utilize the experts within this research field and provide a

focused effort toward vaccines against the highest threats. Considerable advancements can be gained by partnering with the other federally funded programs but only in instances where similarly addressed threats areas have market support for vaccine production, i.e., public health need. The focus of the public health sector is on total populations, whereas the focus on the military sector is on a specific segment of the population that is already healthy, well equipped, and trained. These characteristics define the difference in the research approach and threat assessment. If the DOD does not address the “threats” to the U.S. forces, no other organization will.

After the consolidation of the vaccine decisions authority, the Department of Defense must change its acquisition strategy for vaccine development. The Department of Defense has clearly demonstrated its ineffective approach to vaccine development and lack of commitment to vaccine acquisition. The Department of Defense must commit throughout the vaccine life cycle in order to secure industry support for vaccine production. DOD must demonstrate a long-term commitment to invest with industry to promote the advancement of military significant vaccines. For never let it never be said that the military did not provide its future warriors with the best capability to win the nations' wars.<sup>56</sup>

## **CONCLUSION**

Homeland security is foremost in the minds of all Americans. The Department of Defense has a responsibility to the 230,000 soldiers, sailors, airmen and marines poised for battle in Southwest Asia, as well as to the 120,000 military routinely deployed around the world protecting our national interests and promoting peace to keep them healthy and safe. Vaccines are the most effective and practical way of protecting the military forces from a biological warfare or infectious disease threat. The Department of Defense will lose its edge in the area of infectious disease and biological threat research if it does not consolidate its approach to addressing the threats. We cannot relinquish our responsibility to invest in the frontline protection of our forces. The Department of Defense cannot gamble with the force health protection of the U.S. forces because regardless of the mode of transmission, natural or intention, disease threats can have catastrophic impact on military operations and threaten the national security interests of the United States.

WORD COUNT = 6,588

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