The Ethical Issue of Using Investigative Drugs on Soldiers to Defend Against Biological Warfare

By

MSG Teddy C. Robinson
Student No. 208

Instructor:

SGM Jose A. Madera

16 November 2005

Thesis Statement: *It is ethically justifiable to administer drugs and vaccines that have not undergone the complete research or approval process in accordance with Food and Drug Administration (FDA) guidelines to Soldiers facing a possible attack from biological agents.*

The threat of biological or chemical warfare raises urgent questions about how best to protect both civilian populations and military personnel from biological attacks. My ethics brief will focus on the moral and ethical issues that arise specifically in the military, with regard to the administering of investigational drugs and vaccines to Soldiers that have not been approved by the Food and Drug Administration (FDA) for that particular use. I believe that it is ethically justifiable to administer drugs and vaccines that have not undergone the complete research or approval process in accordance with Food and Drug Administration (FDA) guidelines to Soldiers facing a possible attack from biological agents.

The use or the threat of use biological agents has been apart of warfare since the American Revolution. GEN George Washington had his troops vaccinated at Valley Forge against smallpox in opposition to an outcry by the press and a frightened public. Captured Hessian Soldiers were held in Frederick, Maryland and vaccinated as "test Soldiers" against their will. There were biologic weapons fears in WWII, the military threat of biological weapons use during the Cold War, and Desert Shield and Desert Storm and the current day threat of terrorist using biological weapons against a civilian population. It is because of the current threat of bioterrorism that I believe it is ethically justifiable to administer drugs and vaccines that have not undergone the complete research cycle and approval process in accordance with Food and Drug Administration (FDA) guidelines to Soldiers facing a possible attack from biological weapons.

Many people passionately believe that forced injections of vaccines with unknown short term and long term affects are highly immoral and unethical without the approval of "informed consent." The Department of Defense requested to the FDA that it be allowed to waive informed consent in certain combat-related situations. As a result, the FDA issued the Interim Rule, which said that informed consent is not feasible and the Commissioner of Food and Drugs could waive it under certain military emergencies.

In March of 2003, while assigned as First Sergeant of the Joint Service Whole Blood Processing Laboratory at McGuire Air Force Base, New Jersey, I received a permanent change of station (PCS) notification from the Army's Human Resource Command. The PCS orders included a special instruction memorandum that stated, "Due to work requirements of bio-safety levels 3 and 4 service member will enter into the Special Immunization Program (SIPS) which includes but is not limited to, the following vaccinations; Anthrax, Yellow Fever, Hepatitis, Rabies, Plague, Smallpox, Western Equine Encephalitis, Venezuelan Equine Encephalitis, Q-fever, Botulinum Toxin and Rift Valley Fever. A final statement at the bottom said, "If Soldier is not willing to comply he must contact his losing command immediately. I complied and in July of 2003, I in processed into the United States Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, MD to serve as the NCOIC of the Diagnostic Systems Division (DSD). This division included Applied Diagnostics, Systems Development, Clinical Pathology and Field Operations and Training branches. It was DSD that was given the task of performing the DNA identification of anthrax laced letters mailed to the Hart Senate Office building and other locations. During this time, I had an opportunity to see first hand the bioterrorist threat that threatens American society.

This strengthen my belief that the biological threat was possible and had to be addressed through safe yet aggressive research.

To help support my position that it is ethically justifiable to administer not fully approved FDA drugs and vaccines to Soldiers without informed consent, one must understand the approval process. Ever year a new vaccine is marketed for the upcoming influenza season. The same vaccine from the previous year is not used because of virus and cell mutations that could render the previous vaccines ineffective. Drug manufactures and research personnel simply change the genetic makeup of a previous version of the vaccine and add different anti-virulent. The drug is then resubmitted to the FDA for approval but does not go through the entire research, testing and licensing process that would take months or years but instead is introduced into the FDAs Accelerated Approval Process. The FDA may have licensed some drugs for one particular illness but have enough research and testing data to strongly support using it to combat a different illness that it was not originally licensed for.

In July 2004, I was selected to serve as USAMRIIDs' First Sergeant, an Army organization that had conducted biological defense research using humans since the early 1950s. Between 1954 and 1973 under "Operation Whitecoat" over 2,300 Seventh Day Adventist served as test subjects in 137 different protocols who's goals were directed at developing and testing vaccines and therapeutic drugs against Q fever, Tularemia, various viral encephalitides, Rift Valley Fever Virus, sand fly fever and Plague. USAMRIID conducted human subjects research for more than 50 years with only one claim of disability and no deaths. The early involuntary inoculation of Soldiers with the anthrax vaccine, which deployed to Southwest Asia, again brought the debate of unapproved FDA vaccines without informed consent to forefront of the

ethical debate. Some Soldiers experienced illness, disabilities and even death. The debate is still on going in the medical community on whether or not these medical problems were caused by underlying undiagnosed medical conditions or were a direct result of the anthrax vaccines.

The threat of biological or chemical warfare raises urgent questions about how best to protect both civilian populations and military personnel from biological attacks. My ethics brief will focus ~~on~~ discussed the moral and ethical issues that arise specifically in the military, with regard to the administering of investigational drugs and vaccines to Soldiers that have not been approved by the Food and Drug Administration (FDA) for that particular use.* I believe that it is ethically justifiable to administer drugs and vaccines that have not undergone the complete research or approval process in accordance with Food and Drug Administration (FDA) guidelines to Soldiers facing a possible attack from biological agents.