APPENDIX BB

OCTOBER 30, 1990

LETTER FROM ENRIQUE MENDEZ, JR., M.D., ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS, TO JAMES O. MASON, M.D., DEPARTMENT OF HEALTH AND HUMAN SERVICES

THE ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301-1200

HEALTH AFFAIRS

30 OCT 1990

Honorable James O. Mason, M.D.
Assistant Secretary for Health
Department of Health and Human Services
Washington, D.C. 20201

Dear Doctor Mason:

This is to follow up on discussions of DoD and HHS personnel over the past weeks. As you know, the memorandum of understanding between DoD and the Food and Drug Administration recognizes "special DoD requirements to meet national defense considerations." Operation Desert Shield presents such special DoD requirements.

Our contingency planning in Desert Shield has had to take into account endemic diseases in the area and the well-publicized capabilities of the Iraqi military with respect to chemical and biological weapons. For some of these risks, we have determined that the best preventive or therapeutic treatment calls for the use of products now under "investigational new drug" (IND) protocols of the FDA.

These are not exotic new drugs; these drugs have well-established uses (although in contexts somewhat different from our requirements) and are believed by medical personnel in both DoD and FDA to be safe. For example, one product consists of a very commonly used drug packaged in a special intramuscular injector to make it readily useable by soldiers on the battlefield. Another example involves a vaccine long recognized by the Centers for Disease Control as the primary preventive treatment available for a particular disease, but the relative infrequency of its use has slowed the accumulation of sufficient immunogenicity data to yet support full licensing of the product. Still another example involves a drug in common use at a particular dosage level, but to preserve alertness of the soldiers, we prefer a lower-dosage tablet, which is not an FDA approved product. FDA personnel have been extremely cooperative and supportive in reviewing our proposed protocols for these products, quickly providing favorable responses to all of our submissions to date.

FDA assistance is also needed on the issue of informed consent. Under the Federal Food, Drug and Cosmetic Act, the general rule is that, regardless of the character of the medical evidence, any use of an IND, whether primarily for investigational purposes or primarily for treatment purposes, must be preceded by obtaining informed consent from the patient. The statute authorizes exceptions, however, when the medical professionals administering the product "deem it not feasible" to obtain informed consent.

Our planning for Desert Shield contingencies has convinced us that another circumstance should be recognized in the FDA regulation in which it would be consistent with the statute and ethically appropriate for medical professionals to "deem it not feasible" to obtain informed consent of the patient -- that circumstance being the existence of military combat exigencies, coupled with a determination that the use of the product is in the best interest of the individual. By the term "military combat exigencies", we mean military combat (actual or threatened) circumstances in which the health of the individual, the safety of other personnel and the accomplishment of the military mission require that a particular treatment be provided to a specified group of military personnel, without regard to what might be any individual's personal preference for no treatment or for some alternative treatment.

In all peacetime applications, we believe strongly in informed consent and its ethical foundations. In peacetime applications, we readily agree to tell military personnel, as provided in FDA's regulations, that research is involved, that there may be risks or discomforts, that participation is voluntary and that refusal to participate will involve no penalty. But military combat is different. If a soldier's life will be endangered by nerve gas, for example, it is not acceptable from a military standpoint to defer to whatever might be the soldier's personal preference concerning a preventive or therapeutic treatment that might save his life, avoid endangerment of the other personnel in his unit and accomplish the combat mission. Based on unalterable requirements of the military field commander, it is not an option to excuse a non-consenting soldier from the military mission, nor would it be defensible militarily -- or ethically -- to send the soldier unprotected into danger.

To those familiar with military command requirements, this is, of course, elementary. It is also very solidly established in law through a number of Supreme Court cases establishing that

special military exigencies sometimes must supersede normal rights and procedures that apply in the civilian community. Consistent with this, long-standing military regulations state that military members may be required to submit to medical care determined necessary to preserve life, alleviate suffering or protect the health of others.

Such special military authority carries with it special responsibility for the well-being of the military personnel involved. Thus, we propose specific procedural limitations on the "not feasible" waiver of informed consent based on military combat exigencies. We propose that decisions on waiving informed consent be made on a case-by-case basis by the Commissioner, assuring an objective review outside of military channels of all pertinent information and an independent validation of the special circumstances presented. Further, we propose the following specific limitations: 1) that drug-by-drug requests for waiver be accompanied by written justification based on the intended uses and the military circumstances involved; 2) that no satisfactory alternative treatment is available; 3) that available safety and efficacy data support the proposed use of the drug or biologic product; 4) that each such request be approved by the applicable DoD Institutional Review Board; and 5) that the waivers be time-limited.

To recap, we have nothing exotic in the works. We are methodically planning for a range of medical treatment contingencies in Operation Desert Shield corresponding to the predictable medical problems that might arise. Some of these contingencies require the availability of products now under IND protocols. For products that will be in the best interests of the patients, military combat exigencies may justify deeming it not feasible to obtain informed consent. FDA's regulation should provide the mechanism, subject to appropriate limitations, for DoD to request on a drug-by-drug basis, and the Commissioner to decide, that a waiver be granted in cases in which it is established that military combat exigencies make that necessary.

Your cooperation and assistance in this regard is appreciated.

Sincerely,

Enrique Mendez, Jr., M.D.