ONE HUNDRED EIGHTH CONGRESS

# Congress of the United States

## House of Representatives

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December 16, 2004

The Honorable Tommy Thompson
Secretary of Health and Human Services
Hubert Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20001

Dear Secretary Thompson:

This is in reference to the December 10 request by the Deputy Secretary of Defense for emergency use authorization, pursuant to Section 4 of the Project BioShield Act of 2004, for administration of the anthrax vaccine to certain military personnel. The Department of Defense (DOD) request presents a number of unique, potentially troubling, legal and procedural issues; and the Subcommittee requests information on how the Department of Health and Human Services will approach this precedent-setting matter.

It is not clear whether the letter from the DOD Deputy Secretary constitutes the determination required by Section 564(b)(1)(B) of the Federal Food, Drug and Cosmetic Act (FFDCA) as the basis for an emergency use authorization. The law explicitly requires a determination "by the Secretary of Defense" and further requires publication of such a determination in the Federal Register. Is it the position of the Department of Health and Human Services (HHS) that the December 10 letter satisfies the statutory requirements for a determination upon which the Secretary may base an emergency use authorization?

With regard to the process of consultations and deliberations necessitated by the DOD request, it is vital that so important a public health matter be conducted deliberately and openly. It is essential that HHS consider this first request for Project BioShield Act authority carefully and with maximum public input to avoid even the implication HHS will rubber stamp or give unquestioning, and undeserved, deference to DOD determinations on medical matters. Such deference has not served our military personnel well in the past, when DOD failed to meet conditions and commitments on the use of experimental products like pyridostigmine bromide. How will the Department ensure the rigor and transparency of its deliberations regarding this matter?

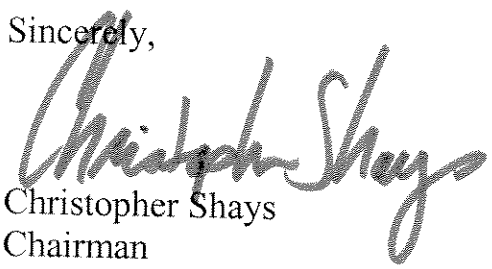
The threat of biological terrorism is not uniquely military. Only U.S. civilians have died or been infected due to exposure to weaponized anthrax, but hundreds of military service personnel have suffered adverse reactions to the vaccine. With regard to the basis for the DOD determination of a military emergency, will HHS have access to the "classified November 2004 Intelligence Community assessment of the anthrax threat" cited by DOD? How will HHS determine the potential benefits of the product "outweigh the known and potential risks" of the anthrax vaccine, as required by FFDCA Sec. 564(c)(2)(B)? What evidence will the Department consider in attempting to make the required finding "there is no adequate, approved and available alternative" to the anthrax vaccine? Will the Department consider recent studies regarding the efficacy of antibiotics, in combination with post-exposure vaccination, in treating anthrax infection? Will HHS require information from DOD regarding the adequacy of non-medical force protection measures i.e. detectors, masks, collective shelters and decontamination suites against the threat of anthrax infection?

If the emergency use authorization is granted, how will the Department monitor DOD compliance with legal requirements to inform health care practitioners and recipients of the emergency use determination, the benefits and risks of the vaccine, alternatives to inoculation, and the option to refuse. In the event the Department of Defense also seeks a presidential waiver of informed consent requirements under 10 U.S.C. 1107 and applicable Executive Order(s), will HHS undertake that process concurrently or only after emergency use authorization?

Finally, assuming the DOD request is for authorization for an unapproved use of an approved product, pursuant to FFDCA Sec. 564(a)(2)(B), what impact would HHS approval have on efforts by the Food and Drug Administration (FDA) to correct the procedural infirmities in anthrax vaccine classification noted by the U.S. District Court in John Doe #1 et al. v. Rumsfeld (Civil Action No. 03-707, Memorandum Opinion issued October 27, 2004, Emmett Sullivan, J.)? Given the court decision, and the DOD request, does HHS now consider the current anthrax vaccine product labeling incomplete or misleading in that it fails to differentiate between approved use for cutaneous exposure and as yet unapproved use for inhalantional exposure?

The Subcommittee shares your commitment to the proper implementation of the Project BioShield Act and looks forward to your reply.

Sincerely,



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