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To  
FDA  
Dockets Management Branch

Re: My public comment on :

**INFORMED CONSENT WAIVER RULE IN COMBAT SITUATIONS**

(1) The interim rule should be amended. Reasonable efforts should be made to inform combatants and or civilians in advance that such compounds are going to be used . The extent and appropriateness of the information is to be determined by the commissioner. All combatants and or civilians exposed must be informed not later than a year after the use of such compounds. A publicly accessible site for the most updated scientific information on these products must be made available at that time.

(2) It is never ethical to expose volunteers to toxic chemicals and or biological agents to test the effectiveness of products that may be used to provide potential protection against those agents.

(3) Efficacy studies in animals and human phase I studies ( pharmacokinetic/antibody response ) should have resulted in plausible evidence that a protective product will have a reasonable risk/benefit ratio in a combat situation or during an attack on civilians. The phase one studies should include the generation of data in children and take into account anticipated combination(s) with other products and immunization schedules.

Sincerely,

  
Juan N. Walterspiel MD

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