

Food and Drug Administration,
Dockets Management Branch, HFA-305,
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857.

RE: Informed Consent Rules In Combat Situations.

I understand that the FDA has asked for comment on the following:

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*whether it should revoke or amend rule of December 1990 and if the latter, whether and how it could be amended;

--> I urge FDA to revoke this rule, as the Dept of Defense has proven itself incapable of providing the necessary oversight and record-keeping.

*when is it ethical to expose volunteers to toxic chemical and biological agents to test the effectiveness of products that may be used to provide potential protection against those agents;

--> Testing the efficacy of anything is NEVER ethical unless the subjects truly volunteer with full informed consent; one way to insure this is to require that DOD and VA recruit only non-DOD and non-VA volunteers who are not otherwise beholden to these agencies for their employment or pensions. Given the risks, of course, it is unlikely that anyone will volunteer, so I think FDA must simply accept that efficacy testing is not always possible.

*if products that may be used for protection against toxic substances cannot be ethically tested in humans, what evidence would be needed to adequately demonstrate their safety and effectiveness.

--> While some products may not be ethically tested to demonstrate their EFFECTIVENESS against toxic substances, this should NOT preclude testing designed to demonstrate their SAFETY in the absence of any toxic exposures. Dr. Kessler once admitted to me personally that the FDA granted the waiver allowing DOD to use PB in the Gulf without ever asking for any data from DOD or the manufacturer documenting that PB could be safely used in healthy males or females when taken at a 30mg dose every 8 hours for up to 21 days, as the DOD was proposing.

Apparently, FDA simply assumed the safety data it had already collected from the original licensing of PB were sufficient, especially since PB's safety had been established at a much higher dose in MG patients. But this critical assumption that PB would be safe for healthy adults if given at a lower doses turned out to be wrong, judging from what even the DOD acknowledged (at the NIH Symposium on Gulf War Veterans' illnesses in 1994) was a 50% adverse reaction rate when PB started being used in the field (compared to the 5% to 10% expected).

FDA should not ever again approve or grant a waiver for any use of any drug without at least establishing its safety in the specific population at issue and at the proposed dosage levels. When synergistic exposures or stresses are likely in real world use, these should be incorporated into the safety testing as much as possible. So while FDA may have to concede that the efficacy of PB against chemical warfare agents can't be tested, its safety can and should be studied under high heat conditions and in combination with personal OP pesticide use.

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Anyone want to volunteer? How about the DOD officials who're currently asking FDA to drop the experimental drug warning on the PB label? Would they be willing to take 30mg every 8 hours for 21 days to prove its safety? And how about doing this while also turning the heat up to 100 Jegreees and spraying themselves and their living quarters on a daily basis with DEET, Permethrin, Malathion and/or Dursban?

C145

Sincerely,

Mark A. Langenkamp
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