



**The National Gulf War Resource Center, Inc.**

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

October 28, 1997

Re: [Docket No. 90N-0302J FDA Interim Rule, Informed Consent for Soldiers.

The National Gulf War Resource Center, which represents three dozen grassroots veterans' organizations in America and England, **believes** the FDA Interim Rule should be revoked immediately. **The** NGWRC endorses Public **Citizen** Litigation Group's comments.

**There** are **no** circumstances under which **the** Department of Defense should be allowed to use experimental drugs or vaccines or to use investigational new drugs without consent on those **in** the military (active, Reserve or National Guard). **Informed** consent **is** required under international **law**, **and** the United States must **continue** to honor **the** Nuremberg Code. Any human, regardless of military status, has the **right** to refuse to be a test subject, and they also have the right to be free from **experimentation** without their informed consent.

It is not feasible to have (or to discuss to possibility of) soldiers **signing** "anticipatory consent" forms during **so-called** "peace time." This is because the United States is currently at war **with Iraq** (a cease fire was declared, but the Gulf War continues).

According to the Senate Veterans Affairs Committee (1994), soldiers were forced to receive experimental drugs, experimental vaccines, and investigational new drugs against their will or under threat of court martial during the Gulf War (Operation Desert Storm). **In** addition, the Department of Defense failed to keep records of those who received the drugs, failed to perform agreed upon follow up studies, and the **DoD** continues to use experimental items in Bosnia (as it did in Somalia) in possible violation of the **Interim** Rule.

It is both unethical and a violation of human **rights to expose** people to biological and chemical agents, whether **this** is for the testing of those agents or for the testing of possible pre-treatment **drugs**, vaccines, **or other experimental** and investigational new drugs. Gulf War **veterans** strongly support the immediate revocation of the **Interim** Rule.

Sincerely,

**Paul** Sullivan  
Executive Director

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The National Gulf War Resource Center is an international coalition of advocates and organizations providing a resource for information support and referrals for all those concerned with the complexities of Persian Gulf War issues, especially Gulf War illnesses.

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