ABC News: The Blotter

Government to Review Rules Allowing Human Testing Without Consent

September 05, 2006 3:07 PM

The federal government said it will now reconsider a controversial loophole that allows human medical experiments without the subjects' consent.

The decision comes in the wake of a highly-criticized experiment involving a blood substitute product, Polyheme, which was given to trauma patients in 27 U.S. cities without their knowledge. Our 20/20 report on the Polyheme trials detailed how the FDA had come under fire for allowing the experiment to proceed despite heavy criticism from many in the medical community.

The regulation, approved in 1996, allows experimental testing without consent in the field of emergency medicine research. The first trial under the new rules involved another experimental blood substitute product called HemAssist, which was also tested on trauma patients without consent. That trial was halted after far more patients died who were given HemAssist than those who received standard care. Development of the product was ultimately discontinued.

On the 10-year anniversary of the regulation, the FDA says it will take "a close look" at how it is being used. According to Dr. Janet Woodcock, FDA Deputy Commissioner for Operations, "It is appropriate that we review the regulation and get the perspectives of those who participated in such studies to make sure that emergency research is being carried out in a scientifically sound and ethical manner."

The FDA has released a draft of revised guidelines on non-consent trials that "broaden the discussion of community consultation and public disclosure" and "clarify terminology used in regulations that have been difficult to interpret." A public hearing on the issue is scheduled for Oct. 11, at the University of Maryland Shady Grove Center.

Click here to read ABC News report on Polyheme trials.

Read Brian Ross' 20/20 script on the Polyheme trials.

Click here to read FDA regulation allowing testing without consent. (Enter 21 CFR 50.24)