



Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

418 6 SEP 15 19:13

P.O. Box 1350
Stafford, VA 22555
phone: 540-659-4171
fax: 540-659-2586
e-mail: JBrown@ALL.org
web: www.ALL.org

To whom it may concern:

Having completed a review of the 30-page "Guidance for Institutional Review Boards, Clinical investigators and Sponsors Exception from informed Consent Requirements for Emergency Research," we are left with a single overriding concern.

Board of Directors

Judie Brown
Founder and President
Scarlett G. Clark
Secretary
Catherine M. Daub
Mildred F. Jefferson, M.D.
President, Right to Life Crusade
Patrick J. Murphy
Robert L. Sassone, Esq.
Director, World Life League
Philippe Schepens, M.D.
General Secretary, World Federation of Doctors Who Respect Human Life

Board of Advisors

Patrick J. Murphy, Chairman
Fritz Baumgartner, M.D.
Hugh R. Brown
John and Gail Cady
Paul R. Fransway
David Grabosky
Nicholas J. Healy, Jr., J.D.
Joanne Meurer
Andrew Mislser
Mickey O'Hare
Barbara Sanders
Germaine Wensley
Cliff Zarsky, Esq.
Harold Ziegler, Jr.

Catholic Medical Ethics Advisory Council

C. Ward Kischer, Ph.D.
Donald T. DeMarco, Ph.D.
Robert L. Fastiggi, Ph.D.
David Hargroder, M.D.
Nicoleta E. Manciu, M.D.
Bernard N. Nathanson, M.D.
Charles E. Rice, Esq.
Philippe Schepens, M.D.

Projects

Associates Program
Crusade for the Defense of Our Catholic Church
Rock for Life
STOPP International
Youth Outreach

Publications

ALL News
Celebrate Life
Communiqué
RFL Report
STOPP Report

The proposal appears to place an inordinate emphasis on the role of third parties in the decision making process for those patients who, for whatever reason, are unable to provide the appropriate required consent prior to becoming a guinea pig in a trial involving an unapproved drug.

Clearly there could be abuses of this proposal. For example, if the patient was facing certain death and was unable to defend his right to live out the balance of his life naturally, there could be callous disregard for his dignity. The patient could even be subjected to trials that could be considered unthinkable if the subject was a laboratory chimpanzee rather than a human being.

The same could be true of the comatose patient whose family or physicians look upon him as less than human because he can no longer communicate with them. One can also envision problems for those severely disabled patients whose caregivers may see the value of the emergency research as being more beneficial to society as a whole than to the one who will become the research subject.

In a nation of almost 300 million people, we find it terribly hard to understand how there could ever be a situation in which a patient would be exposed to "emergency research" without being permitted to give his properly informed consent.

The best way to resolve these potential abuses of the human person would be for the FDA to make a hard and fast rule that no human subject will be exposed to clinical trials for any reason unless he or she has personally given informed consent. Anything short of that borders on inhumane abuse of the most vulnerable in our midst.

Sincerely yours in the Lord who is life,


Judie Brown, President
American Life League, Inc.
JAB/krw

2006D-0331

C1