HFH-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 26, 2001

Representative Bonnie Ladwig
63rd Assembly District
Post Office Box 8952
Madison, Wisconsin 53708-8952

Dear Ms. Ladwig:

Your September 13 letter to Secretary Tommy G. Thompson was forwarded to the Food and Drug Administration for response. In your letter, you raised concerns about a recommendation from the National Human Research Protection Advisory Committee (NHRPAC) to allow teenagers to enroll in clinical trials without parental consent.

The Federal Food, Drug, and Cosmetic (FD&C) Act consent provisions prohibit FDA from waiving informed consent (except in emergency situations), so this precludes minors from enrolling in FDA-regulated studies without parental consent; minors can only assent, they cannot consent legally. On April 24, 2001, FDA published an interim final rule to provide added safeguards for children in clinical trials of medical products the Agency regulates. The Children's Health Act of 2000 directed the Secretary to apply the safeguards for children contained in the Department of Health and Human Services regulations to research regulated by the Department; the new regulation responds to that directive.

Under the new regulation, Institutional Review Boards responsible for maintaining safeguards for clinical trial subjects now have specific standards for determining whether proposed pediatric clinical trials can be ethically conducted. A key aspect of the new rule sets standards and procedures for ensuring that children have assented to participating in clinical trials (when possible), and that their parents or guardians are able to give fully informed consent to the child's participation in a study. During the comment period for this rule, the NHRPAC recommended that we consider whether we could modify the FD&C Act (or our interpretation) to permit waiver of informed consent to—in rare instances and with IRB approval—allow the enrollment of minors without parental consent. As with all comments to an FDA docket, the Agency will consider the NHRPAC recommendation along with all of the others.

The comments are still being reviewed, and the draft interim rule is still in place. We very much appreciate you sharing your views with the Department, and I will ensure that your letter is included in those comments.

Sincerely,

Walter D. Osborne

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