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Contact: HHS Press Office
(202) 690-6343

STATEMENT BY TOMMY G.THOMPSON
Secretary of Health and Human Services
Regarding Protections for Pregnant Women and Fetuses in Research

Today, I am announcing that the administration is taking steps to ensure that federally funded research on pregnant women, fetuses, and newborn infants continues to conform to the very high standards that are needed to guide scientists who work in these areas. The Department has carefully considered the rule that was published last January, which was aimed at updating the special protections for pregnant women and fetuses that have been in place since 1975. We believe that it is appropriate to let the January rule take effect, subject to three limited modifications on which the Department will seek public comment very shortly.

First, the Department will propose adding to the regulations the term "neonate" to describe an infant that has been delivered, but for which a viability determination has not yet been made. Previously, such infants were covered under the regulatory definition of "fetus." The Department believes that using the term "fetus" only for those infants that have not been delivered is more consistent with the ordinary understanding of that word. This modification will not change the regulatory framework that has been established to guide federal research funding decisions, but will simply make the regulatory definitions easier to understand.

Second, the Department will propose to require a father's consent (if the father is readily available) for participation in research that is directed solely at a fetus and that does not affect a mother's health. We believe that this approach is most respectful of the parents' joint interests in their fetus's health. In keeping with the January rule, a father's consent would not be needed for a woman to participate in a research activity that would benefit her health.

Third, the Department will propose a clarification to the language that governs funding decisions for research on infants of uncertain viability. Some minor changes in wording introduced in the January rule may inadvertently have created confusion on this issue. We wish to make clear that these infants may be subjected to added risk only if the research is intended to enhance the particular infant's probability of survival to the point of viability.

To give the Department an opportunity to consider these refinements to the January rule and gather additional comment, I am today delaying for 180 days the effective date of the January 18 regulation. My goal is to ensure that we give thorough consideration to the complex questions raised by these types of research, so that all pregnant women, fetuses, and newborn infants will be able to receive the best possible medical treatment.

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