

Title: Clear Warning in Labeling of Home Pregnancy Tests

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Referred to: Reference Committee D

House Action:

Whereas, the use of self-administered over-the-counter pregnancy tests is widely utilized by women prior to obtaining medical advice, and

Whereas, said tests claim a 99 percent sensitivity within one day from the missing menstrual period, and

Whereas, the presence of a positive pregnancy test does not guarantee a normal ongoing uncomplicated early pregnancy, and

Whereas, recent data from the Michigan Maternal Mortality Surveillance Committee demonstrates that 75 percent of pregnant women that carry an undetected ectopic pregnancy die before any effective medical assistance could be rendered, and

Whereas, a review of the patient labeling in home pregnancy testing kits show that said kits contain only a generic statement for patients to seek medical advice immediately whether the test is negative or positive without reference to potentially serious early pregnancy complications to the unaware, uninformed or non-compliant woman, and

Whereas, one third of ectopic pregnancies rupture in an average of seven days from the starting of vague symptoms not frequently recognized by the woman, her family and/or unaware health care professionals, and

Whereas, it is almost impossible to clinically ascertain the natural history of ectopic pregnancies; therefore be it

RESOLVED: That MSMS work closely with the AMA, the appropriate specialty societies, pregnancy kit manufacturers and the Federal Drug Administration to obtain the placement of a clear and emphatic “warning box” with the following suggested text: “Whether a positive or negative result, this test does not guarantee the presence of a normal early pregnancy, nor its absence. Serious complications including death may occur if a confirmation is not obtained from a health care professional immediately.”

WAYS AND MEANS COMMITTEE FISCAL NOTE: NONE