Thesis: A History and Analysis of Drug Labeling Policy for Pregnant and Lactating Women and Women's Involvement in Clinical Drug Research from 1970 to 2014 [1]

By: Meek, Caroline Keywords: Drug research involving pregnant women [2] Ethics of drug research [3]

Editor's note:

Caroline Meek defended her thesis titled “A History and Analysis of Drug Labeling Policy for Pregnant and Lactating Women and Women's Involvement in Clinical Drug Research from 1970 to 2014,” in May 2018 in front of committee members Jane Maienschein, Jennifer Brian, and Carolina Abboud, earning her a Bachelor’s degree from Barrett, the Honors College. https://repository.asu.edu/items/48416 [4]

Abstract:

The inherent risk in testing drugs has been hotly debated since the government first started regulating the drug industry in the early 1900s. Who can assume the risks associated with trying new pharmaceuticals is unclear when looked at through society's lens. In the mid twentieth century, the US Food and Drug Administration [5] (FDA) published several guidance documents encouraging researchers to exclude women from early clinical drug research. The motivation to publish those documents and the subsequent guidance documents in which the FDA and other regulatory offices established their standpoints on women in drug research may have been connected to current events at the time.

The problem of whether women should be involved in drug research is a question of who can assume risk and who is responsible for disseminating what specific kinds of information. The problem tends to be framed as one that juxtaposes the health of women and fetuses and sets their health as in opposition. That opposition, coupled with the inherent uncertainty in testing drugs, provides for a complex set of issues surrounding consent and access to information.

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Subject

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