Whereas, each year 3.6 million individuals give birth in the United States and 3 million people are lactating; and

Whereas, 70% of pregnant and lactating people take some kind of medication when they are pregnant or lactating; and

Whereas, pregnant and lactating people are generally excluded in clinical research, there is a dearth of data about the appropriate safety, dosage, and efficacy of most medical interventions in pregnant and lactating individuals; and

Whereas, the lack of data results in patients and clinicians choosing to (a) forego an intervention which may result in harm from an un(der) treated condition or (b) use an intervention which may carry an uncertain risk of harm for an unknown potential benefit; and

Whereas, lack of access to research exacerbates health inequities in pregnant and lactating individuals; and

Whereas, the harm from excluding pregnant individuals from clinical research was very apparent during the COVID-19 pandemic and contributed to vaccine hesitancy and resulted in unnecessary and avoidable maternal and infant mortality and morbidity, and

Whereas, recent initiatives from the White House, National Institutes of Health, and the National Academies of Science, Engineering, and Medicine have emphasized the need for further research in pregnant and lactating individuals; and

Whereas, the American College of Obstetricians and Gynecologists, National Academies of Science, Engineering, and Medicine, and the U.S. Department of Health and Human Services have moved from an overly protectionist ethic that prioritizes minimization of fetal risk to one that recognizes the scientific, legal, and ethical complexities of research including the risks to the pregnant/lactating individual, fetus, and/or neonate of NOT doing research; and

Whereas, the HHS Task Force on Research Specific to Pregnant Women and Lactating Women released detailed recommendations, along with an implementation plan, to protect pregnant and lactating individuals through research, rather than from research; and

Whereas, as this national policy discussion unfolds, the ethical guidance of our profession must undergird this discussion; and
Whereas, the existing Code of Medical Ethics Opinion 7.3.4 Maternal-Fetal Research extracts content from both the Code modernization process of 2016 with foundational original material stemming from the “Medical applications of fetal tissue transplantation” opinion passed in 1989; and

Whereas, much in women’s health, research infrastructure, ethical frameworks, and liability landscape has changed since 1989 and the ethics of research in lactation is not discussed in the Code; therefore be it

RESOLVED, that our American Medical Association Council on Ethical and Judicial Affairs update its ethical guidance on research in pregnant and lactating individuals. (Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000

Received: 4/24/2024

REFERENCES
RELEVANT AMA POLICY

7.3.4 Maternal-Fetal Research

Maternal-fetal research, i.e., research intended to benefit pregnant women and/or their fetuses, must balance the health and safety of the woman who participates and the well-being of the fetus with the desire to develop new and innovative therapies. One challenge in such research is that pregnant women may face external pressure or expectations to enroll from partners, family members, or others that may compromise their ability to make a fully voluntary decision about whether to participate.

Physicians engaged in maternal-fetal research should demonstrate the same care and concern for the pregnant woman and fetus that they would in providing clinical care.

In addition to adhering to general guidelines for the ethical conduct of research and applicable law, physicians who are involved in maternal-fetal research should:

(a) Base studies on scientifically sound clinical research with animals and nongravid human participants that has been carried out prior to conducting maternal-fetal research whenever possible.

(b) Enroll a pregnant woman in maternal-fetal research only when there is no simpler, safer intervention available to promote the well-being of the woman or fetus.

(c) Obtain the informed, voluntary consent of the pregnant woman.

(d) Minimize risks to the fetus to the greatest extent possible, especially when the intervention under study is intended primarily to benefit the pregnant woman.