

Written Public Testimony
Energy & Commerce Subcommittee on Health
“Examining Legislation to Improve Health Care and Treatment”
Submitted by Mary E. Norton, MD
Ph: 415-353-7865 Email: Mary.Norton@ucsf.edu

Re: H.R. 3441, the Accurate Education for Prenatal Screenings Act

My name is Dr. Mary Norton, and I currently serve as President of the Perinatal Quality Foundation (PQF). I am Professor of Obstetrics, Gynecology and Reproductive Sciences at the University of California, San Francisco, and the Vice Chair of Clinical and Translational Genetics and Genomics in my Department. I appreciate the opportunity to offer written public testimony on the Energy & Commerce Subcommittee on Health’s hearing “Examining Legislation to Improve Health Care and Treatment.” Specifically I would like to comment on H.R. 3441, the Accurate Education for Prenatal Screenings Act.

The Perinatal Quality Foundation is an independent non-profit foundation incorporated in 2004. The mission of the Perinatal Quality Foundation is to improve the quality of obstetrical medical services by providing state of the art educational programs, and evidence-based, statistically valid monitoring systems to evaluate current practices and facilitate the transition of emerging technologies into clinical care.

I have a great interest in H.R. 3441, which I feel attempts to address an important current issue in perinatal care. We strongly agree that prenatal screening is important, and that current advances have made the area so complex that appropriate implementation into obstetrical care has been challenging. This very complex medical arena requires detailed expertise and on-going training and education. Moreover, the field is changing and evolving at a very rapid pace, making it very difficult to keep up with ongoing developments, including those directly impacting clinical care. Professional societies, including the Society for Maternal-Fetal Medicine (SMFM) and American College of Obstetricians and Gynecologists (ACOG), have generally guided care in this area, and most recently issued a joint Committee Opinion in June of 2015 related to Cell-free DNA Screening for Fetal Aneuploidy. In this document, the professional societies indicated that “Patients should be counseled that cell-free DNA screening does not replace the precision obtained with diagnostic tests. . . and therefore, is limited in its ability to identify all chromosomal abnormalities.” It goes on to say that these new technologies should not replace conventional screening methods, particularly in the low-risk obstetric population, wherein conventional screening methods remain the most appropriate choice for first-line screening.

With the ever evolving and improving technology, we strongly agree that materials such as those described in this bill are urgently needed. I would like to tell you about an initiative that the PQF is currently developing, and is exactly what is described in this bill. With representation and support from genetic counseling (NSGC), obstetrics and gynecology (ACOG), maternal fetal medicine (SMFM), and genetics (ASHG) we are working to create a state-of-the-art, unbiased, patient and provider education program. We are working in partnership with four of the commercial genetics laboratories (including those that provide cell free DNA screening –Quest Diagnostics, Illumina, LabCorp, and Sequenom); these laboratories have provided some funding for the project. We are working on a very aggressive timeline to complete these materials, and are planning to have a demonstration pilot available by early February (to coincide with the SMFM annual meeting), and the final product ready to demonstrate at the ACOG

annual meeting in early May.

The PQF's Genetic Education Module (GEM) will include information regarding all the prenatal genetic tests that are currently routinely available; this includes but is not limited to cfDNA screening. We would suggest that legislation should not be so specific as to include only cell-free DNA screening for fetal aneuploidy, but that materials for prenatal screening broadly would be more appropriate as women making decisions about cfDNA screening need to do this in the context of the alternative options available to them.

The PQF program is aimed at exactly the activities included in this legislation – a national campaign to improve the understanding of “the advantages, limitations and clinical appropriate interpretation of results in noninvasive prenatal screening and other diagnostic tests for pregnant women and their healthcare providers.” The program will also create an online patient registry through which women who receive prenatal screening during pregnancy may report results of confirmatory diagnostic tests as well as post-partum outcomes. This information is key to allow scientists to use this de-identified information to determine the positive and negative predictive value for noninvasive prenatal screens.

The campaign will also educate health care providers to be alert to circumstances under which women should be referred for consultation with a genetic counselor to better understand their risks or test results. To promote quality assurance, PQF also expects to track clinicians and other healthcare providers who complete the online and other educational programs.

Given this project's current status, H.R. 3441 would create duplicative activities related to this space. We would encourage the committee to consider providing funding for projects such as these, which include input by professional societies and national leaders in this clinical space. The PQF project has been developed in the spirit on the bill, which discusses the importance of how: “... the federal government works with private organizations through public-private partnerships on these issues.” I appreciate the opportunity to provide this testimony. We greatly appreciate the Subcommittee's attention to maternal health and hope that we can continue to work together to improve care and outcomes for women and their children. Please do not hesitate to contact me with any additional questions you may have.