

September 25, 2015

The Honorable Jaime Herrera Beutler  
United States House of Representatives  
1130 Longworth House Office Building  
Washington, DC 20515-4703

The Honorable Lucille Roybal-Allard  
United States House of Representatives  
2330 Rayburn House Office Building  
Washington, DC 20515-0540

Re: HR 3441

Dear Representatives Herrera Beutler and Roybal-Allard:

The American College of Medical Genetics and Genomics (ACMG) writes in support of HR 3441, the “Accurate Education for Prenatal Screenings Act”. As the specialty society representing U.S. clinical and laboratory Medical Geneticists (ACMG Fellows), ACMG — with its more than 1800 members, including non-Fellow genetic counselors, genetics nurses, and public health geneticists — *is the only nationally recognized medical organization dedicated to improving health through the practice of medical genetics and genomics.*

ACMG has a long tradition of positioning itself at the forefront of health professional and public education due, in large measure, to the rapid pace in which new technologies are being translated into clinical practice, with their attendant complexities and nuances, and their unfamiliarity to the healthcare community at large. When Non-Invasive Prenatal Screening (NIPS) using cell-free DNA was emerging as a clinical tool, ACMG published its 2013 “Statement on Noninvasive Prenatal Screening (NIPS) for Fetal Aneuploidy,” clearly delineating test limitations and major points to consider with regard to test implementation.

HR 3441 recognizes that NIPS is unique. NIPS has rapidly become a high volume test being offered to a large proportion of pregnant patients, thereby shifting the rendering of a prenatal testing modality away from the maternal-fetal-medicine experts into primary prenatal care. As such, pretest education and counseling, and some posttest education and genetic counseling, is being done by obstetricians, family physicians and other members of the prenatal healthcare team — many of whom are unfamiliar with offering these tests and delivering appropriate follow-up care. HR 3441 fills an acknowledged gap by addressing the need for ongoing professional education to meet standards set forth in professional guidelines and to establish inter-professional consistency.

ACMG agrees that it is imperative for clinicians to provide patients with both pretest and posttest counseling when offering NIPS, in order to avoid any potential patient harm or confusion; in fact, pretest education and counseling leading to informed decision-making are critical components of any genetic screening process. We appreciate that HR 3411 includes such principles as having pretest education and counseling collaboratively conducted by members of the prenatal healthcare team who have the training and time to provide clear, accurate, balanced, and evidenced-based information in order to facilitate informed consent. HR 3441 emphasizes the need for follow-up (including genetic counseling by an appropriately trained genetics healthcare professional, and possibly invasive diagnostic confirmation) in the event that a high probability of a fetal genetic abnormality is discovered

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and the patient seeks a definitive diagnosis. ACMG is also pleased that HR 3441 stipulates that a broadly representative group of stakeholders be brought together to identify gaps and needs. Additionally, the bill makes appropriate provisions for the distinct educational needs of providers and patients to be taken into account, including various patient populations' needs for readily accessible pre-and posttest educational materials that contain uniquely tailored information about the tested-for condition(s).

ACMG looks forward to working with the Centers for Disease Control and Prevention, as the lead DHHS agency, by providing technical assistance in carrying out the work outlined in HR 3441. ACMG and its members are ideally poised to address this issue because we represent the clinical and laboratory healthcare providers with the experience and expertise in dealing with the nuances of genetic test interpretation, the meaning of test results, and the complexity of discussing and managing the rare genetic conditions potentially detected by NIPS. As you well know, this is of paramount importance to those patients who receive test results requiring further action, where making decisions should be based on the best possible information.

We look forward to working with you, your staff, and the CDC when this bill becomes law.

Sincerely,



Michael S. Watson, PhD, FACMG  
Executive Director



Judith L. Benkendorf, MS, CGC  
Special Assistant to the Executive Director