Written Testimony

Of

The American Congress of Obstetricians and Gynecologists

Submitted by:

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Before the

House Energy and Commerce Subcommittee on Health

Regarding

Examining Legislation to Improve Health Care and Treatment

December 9, 2015

Chairman Pitts, Ranking Member Green, and distinguished Members of the Energy & Commerce Subcommittee on Health, I am pleased to submit written testimony on behalf of the American Congress of Obstetricians and Gynecologists (ACOG), representing more than 58,000 physicians and partners in women's health, for your hearing titled "Examining Legislation to Improve Health Care and Treatment." My testimony will focus on two pieces of legislation that are before the Subcommittee: ACOG is very supportive of H.R. 1209, the Improving Access to Maternity Care Act, and unfortunately must oppose H.R. 3441, the Accurate Education for Prenatal Screenings Act.

Regarding H.R. 1209, the Improving Access to Maternity Care Act

I would like to thank Representatives Michael Burgess, MD, FACOG (R-TX) and Lois Capps (D-CA) for their leadership in introducing this legislation, and the three additional cosponsors on the Health Subcommittee: Representatives Marsha Blackburn (R-TN), Susan Brooks (R-IN), and Ben Ray Lujan (D-NM). I would also like to thank the American College of Nurse-Midwives for their support and partnership on this legislation. ACOG enthusiastically endorses H.R. 1209 and we urge the Subcommittee to act swiftly in reporting out this legislation.

H.R. 1209 represents a bipartisan, bicameral effort to address the problem of inadequate access to maternity care across the United States. As the population grows and the need for women's health care expands, not only do we have a shortage of obstetrician-gynecologists (ob-gyns), we also have a maldistribution problem, both resulting in major pockets of the U.S. where women do not have access to needed maternity care. **Adequate maternity care is critical to the health and well-being of women and babies across the country.** Women with access to prenatal care have more positive birth outcomes, as well as a reduced rate of newborn hospitalization costs. This legislation would create a maternity care health professional shortage area (HPSA) designation within the National Health Service Corps, encouraging the collection of stronger data regarding women's access to maternity care and helping place maternity care providers in areas of greatest need.

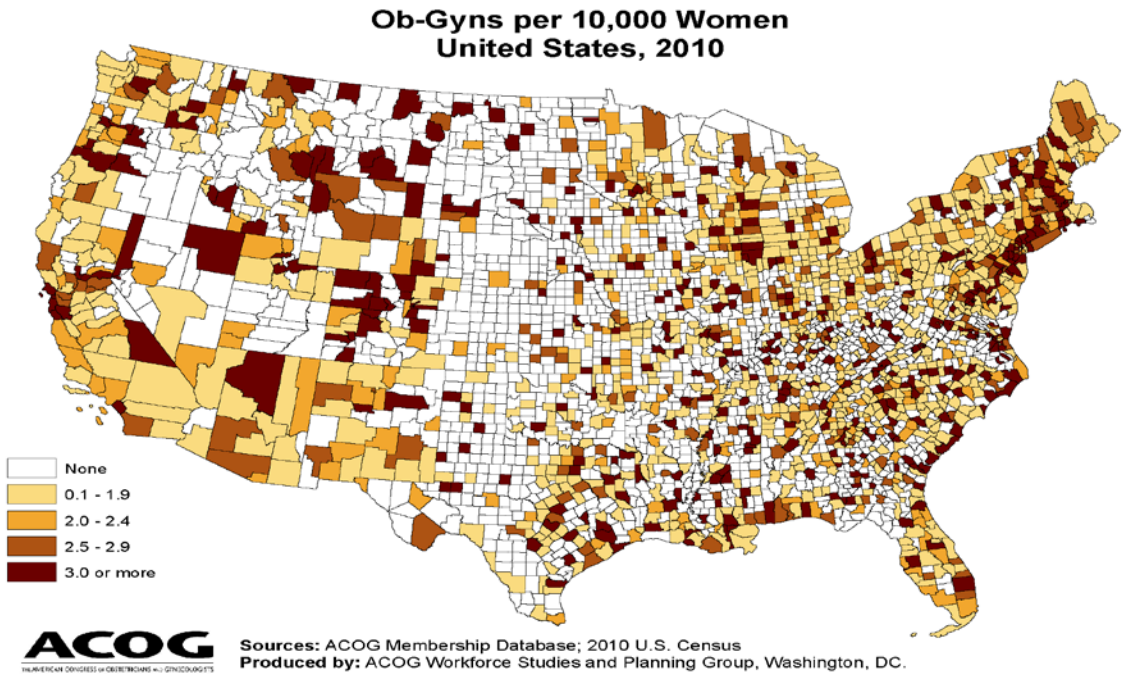
Background

The National Health Service Corps (NHSC) was created in 1972 to help encourage physicians to practice in rural or underserved areas through scholarships or loan repayments of up to $50,000 for two years of full-time service. Since its establishment, the program has placed more than 50,000 providers in underserved communities, and there are currently more than 9,600 NHSC providers serving more than 10 million Americans. A 2012 retention assessment survey confirmed the enduring positive impact of the NHSC on underserved areas. The survey concluded that 82% of NHSC clinicians continued to practice in underserved areas up to one year after completion of their service, while 55% remained in underserved areas 10 years after completing their service.[i] Eligible sites are determined based on scores in three HPSA designation categories: dental care, mental health care, and primary care, which includes ob-gyns and certified nurse-midwives (CNMs). Yet, the **National Health Service Corps does not currently have a mechanism to specifically assess maternity care shortage needs**.

The primary care shortage determination is based on population, physician-to-patient ratios, travel times, and the area's birth and infant mortality rates, demonstrating the clear importance of maternity care services in ensuring a healthy population. However, any provider in the primary care category (including pediatrics, internal medicine, geriatrics, general psychiatry, family medicine, and ob-gyn) can be sent to any primary care shortage area. For example, internists may be sent to areas with critical maternity care needs, while ob-gyns and CNMs may be sent to areas that do not require their specific expertise.[ii] This legislation would be the first step towards correcting this imbalance. Creating a specific maternity health care designation would **place maternity care providers in underserved areas as well as strengthen the existing data on women's access to critical health services**.

Maternity Care Shortage Crisis

Currently, 49% of US counties do not have an ACOG Fellow and 9.5 million Americans live in these often rural counties.[iii] Even in urban areas where more ACOG Fellows are present, it is often still not enough for the large urban population. Additionally, the physician workforce is aging, the average number of hours worked is decreasing compared with historical levels, and a large number of physicians is approaching retirement age. ACOG's data also indicates that, due to liability concerns, ob-gyns may stop practicing obstetrics early in their career, widening the access gap even further.



A shortage of maternity care providers can have very dangerous results. When it comes to prenatal care, long travel times and long wait times can be one factor leading to poor maternal and infant outcomes. Each year, one million babies are born in the United States to mothers who did not receive adequate prenatal care. Babies born to mothers who do not receive prenatal care are three times more likely to be low birthweight and five times more likely to die than babies whose mothers received prenatal care.[iv]

Currently, nearly half of all births in the U.S. (48%) are financed by Medicaid.[v] Inadequately addressing the growing need for maternity care providers may not only result in worse outcomes for moms and babies, but also in rising costs for the federal government.

Unfortunately, the shortage is not improving. The population is increasing rapidly, as is the number of insured women, yet the number of new ob-gyns entering the field each year remains virtually stagnant, due to the Balanced Budget Act of 1997 that placed a cap on the number of Medicare-funded residency slots. As a result, the physician shortage is growing, leading to a projected ob-gyn shortage of at least 18% by the year 2030.[vi]

A Solution

H.R. 1209, the Improving Access to Maternity Care Act, is bipartisan, bicameral and budget-neutral. It would help alleviate the maternity care shortage by addressing the maldistribution of maternity care providers and improving access to maternity care by:

- Creating a maternity care shortage designation, to ensure that maternity care providers are sent where they are needed most;
- Enabling HRSA to collect and analyze data to determine the locations of the biggest maternity care shortages; and
- Allowing for more efficient and strategic utilization of the specialized skills of ob-gyns and CNMs, thereby improving maternal and infant health and reducing problems associated with inadequate prenatal care, such as low birthweight.

It is also important to note that the addition of this much-needed shortage designation would not take NHSC slots away from other specialties, as current acceptance rates for physicians are based on applicant qualifications, regardless of the field of practice. The bill would also not create any new slots or expand program eligibility, but simply enable providers already participating in the NHSC to be placed where their services and expertise are most needed, improving access to quality maternity care nationwide. Ensuring women's access to adequate maternity care, as well as generating more accurate data on maternity health care shortages, will lead to better health outcomes for moms and babies.

I want to reiterate ACOG's strong support for H.R. 1209, the Improving Access to Maternity Care Act. We look forward to continuing to work with the Subcommittee to move this legislation forward.

<u>Regarding H.R. 3441, the Accurate Education for Prenatal Screenings Act</u>

As the President of ACOG, I am acutely aware of the tremendous potential of noninvasive cell-free DNA screening for fetal aneuploidy, an abnormal number of chromosomes. At the same time, I am cognizant of the confusion that this rapidly evolving technology is causing some ob-gyns and patients regarding which patients are the best candidates for screening and how to interpret results. However, the approach taken by HR 3441, the Accurate Education for Prenatal Screenings Act, is not the appropriate path forward. While we appreciate the opportunity to discuss this important issue, ACOG must oppose HR 3441 because of the reasons outlined

below. We hope to work together with the Subcommittee to find a path forward that meets the needs of ob-gyns and their patients, without legislative interference in the practice of medicine or duplication of efforts.

Background

In 2011, ACOG and the Society for Maternal and Fetal Medicine (SMFM) began recommending cell-free DNA screenings from the plasma of pregnant women as a screening option for women at increased risk of fetal aneuploidy. ACOG and SMFM have defined increased risk as women ages 35 years or older, fetuses with ultrasound signals of increased risk of aneuploidy, women with a history of trisomy-affected pregnancies or offspring, a parent carrying a balanced robertsonian translocation with an increased risk of trisomy 13 or trisomy 21, and women with positive first-trimester or second-trimester screening test results.[vii]

Additional research on this rapidly changing technology prompted ACOG and SMFM to update our clinical guidance in September 2015 to discuss advantages and limitations of using these tests not just on women with increased risk of fetal aneuploidy, but in the general obstetric population. Given the performance of conventional screening methods, the limitations of cell-free DNA screening performance, and the limited data of cost-effectiveness in the low-risk obstetric population, ACOG and SMFM concluded that conventional screening methods remain the most appropriate choice for first-line screening for most women in the general obstetric population.[viii]

Concerns with HR 3441, the Accurate Education for Prenatal Screenings Act

ACOG opposes H.R. 3441, and urges the Subcommittee not to report out the bill. Our concerns include that the legislation is too prescriptive, premature, duplicative, and does not allow for flexibility of rapidly changing science and research.

HR 3441 is far **too prescriptive**. Congress should not make laws that direct clinical guidelines. The September 2015 ACOG-SMFM Committee Opinion makes very thorough clinical recommendations for ob-gyns on the use of cell-free DNA tests. For example, the guidelines recommend the following measures be taken by providers regarding the use of these tests:

- Providers should discuss risks, benefits and alternatives of various methods of prenatal screening and diagnostic testing, including the option of no testing, with all of their obstetric patients.
- Given the performance of conventional screening methods, the limitations of cell-free DNA screening performance, and the limited data on cost-effectiveness in the low-risk obstetric population, conventional screening methods remain the most appropriate choice for first-line screening for most women that are not considered to be high risk in the obstetric population.
- Although any patient may choose cell-free DNA analysis as a screening strategy, the patient choosing this testing should understand the limitations and benefits of this screening paradigm in the context of alternative screening and diagnostic options.

- Given the potential for inaccurate results, a diagnostic test should be recommended for a patient who has a positive cell-free DNA test result.

Congress should not be in the business of legislating clinical and scientific guidelines. Clinical and scientific guidelines should be the responsibility of medical specialty societies like ACOG and SMFM, the medical and scientific experts.

HR 3441 is also **premature**. There is already a pending request from Congress, through report language included in the House Labor, Health and Human Services, Education, and Related Agencies Appropriations bill directing the Centers for Disease Control and Prevention (CDC) to assess the use of tests and the need for additional physician and patient education. Congress should wait for the results and recommendations of this assessment to be made public before passing a law that deals with the same issue.

This legislation is **duplicative**. In July 2015, the Perinatal Quality Foundation launched the National Initiative to Advance Clinically Appropriate Noninvasive Prenatal Screening, an exciting new public-private partnership. This initiative will include:

- An online patient registry to collect additional data on the validity of these tests; and
- An education and outreach component aimed at informing ob-gyns and their patients about these tests.[ix]

ACOG looks forward with confidence to the rollout of this initiative, and commends the Perinatal Quality Foundation for its forward-thinking work in this space.

ACOG is concerned that the programs established by HR 3441 will not be able to keep up with the **rapidly changing science and technology** of cell-free DNA prenatal screening. Should recommendations change or research develop to differ from what is contained in the legislation-directed programs, both patients and providers could be negatively impacted by outdated statutory requirements.

Medical specialty societies, as well as the aforementioned public-private partnership, are well-poised to respond with educational materials to this rapidly changing technology. As is shown by the ACOG-SMFM updated guidance and other ACOG-endorsed educational documents for both patients and providers, we continually and accurately respond to changes and answer questions regarding cell-free DNA prenatal screening.[x,xi,xii,xiii]

For these reasons, ACOG opposes H.R. 3441. We hope the Subcommittee will not report this bill to the floor, and we look forward to working with the bill sponsors and the Subcommittee to find other more appropriate ways to meet the needs of our patients.

Thank you for the opportunity to provide written testimony on H.R. 1209, legislation strongly supported by ACOG, and H.R. 3441, legislation opposed by ACOG.

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[i] U.S. Department of Health and Human Services Health Resources and Services Administration. NHSC Clinician Retention: A Story of Dedication and Commitment. 2012. Retrieved from http://nhsc.hrsa.gov/currentmembers/membersites/retainproviders/retentionbrief.pdf

[ii] Based on Health Resources Services Administration National Health Service Corps public statistics.

[iii] Based on ACOG Fellow and member statistics. ACOG represents about 90% of all board certified obstetricians and gynecologists in the United States.

[iv] Wymelenberg S; Institute of Medicine (US). Science and Babies: Private Decisions, Public Dilemmas. Washington (DC): National Academies Press (US); 1990. 5, Prenatal Care: Having Healthy Babies. Retrieved from http://www.ncbi.nlm.nih.gov/books/NBK235274/

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[vii] Cell-free DNA screening for fetal aneuploidy. Committee Opinion No. 640. American College of Obstetricians and Gynecologists. Obstet Gynecol 2015;126:e31-7.

[viii] Ibid.

[ix] Miller, Susan. (2015, July 24). Initiative aims to ease prenatal testing fears. *USA Today*. Retrieved from http://www.usatoday.com/story/news/nation/2015/07/23/prenatal-tests-initiative-registry/30586893/

[x] Prenatal Cell-free DNA Screening [PDF]. National Society of Genetic Counselors (NSGC), November 2014. (Endorsed October 2015)

[xi] Prenatal Cell-free DNA Screening: Q&A for Healthcare Providers. National Society of Genetic Counselors (NSGC), November 2014. (Endorsed October 2015) Retrieved from http://nsgc.org/page/non-invasive-prenatal-testing-healthcare-providers

[xii] Abnormal Prenatal Cell-free DNA Screening Results: What do they mean? National Society of Genetic Counselors (NSGC), November 2014. (Endorsed October 2015) Retrieved from http://nsgc.org/page/abnormal-non-invasive-prenatal-testing-results

[xiii] NIPT/Cell Free DNA Screening Predictive Value Calculator. National Society of Genetic Counselors (NSGC) and Perinatal Quality Foundation (PQF). (Endorsed December 2015) Retrieved from https://www.perinatalquality.org/Vendors/NSGC/NIPT/