

EXAMINING LEGISLATION TO IMPROVE HEALTH CARE AND TREATMENT

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FOURTEENTH CONGRESS FIRST SESSION

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EXAMINING LEGISLATION TO IMPROVE HEALTH CARE AND TREATMENT

WEDNESDAY, DECEMBER 9, 2015

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:59 a.m., in room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Present: Representatives Pitts, Guthrie, Shimkus, Murphy, Burgess, Blackburn, Lance, Griffith, Bilirakis, Ellmers, Bucshon, Brooks, Collins, Green, Engel, Capps, Schakowsky, Castor, Matsui, Schrader, Kennedy, Cardenas, and Pallone (ex officio).

Staff Present: Leighton Brown, Press Assistant; Rebecca Card, Assistant Press Secretary; Karen Christian, General Counsel; Peter Kielty, Deputy General Counsel; Carly McWilliams, Professional Staff Member, Health; Katie Novaria, Professional Staff Member, Health; Graham Pittman, Legislative Clerk; Adrianna Simonelli, Legislative Associate, Health; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Jen Brennan, Minority Press Secretary; Jeff Carroll, Minority Staff Director; Waverly Gordon, Minority Professional Staff Member; Samantha Satchell, Minority Policy Analyst; and Arielle Woronoff, Minority Health Counsel.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. The subcommittee will come to order. The chair will recognize himself for an opening statement.

Today's hearing will examine several different legislative proposals that will address shortcomings in current law, and reauthorize an important nursing training program.

H.R. 921, the Sports Medicine Licensure Clarity Act sponsored by the Health Subcommittee vice chair, Brett Guthrie, clarifies medical liability rules for athletic trainers and medical professionals to ensure they are properly covered by their malpractice insurance while traveling with their athletic teams to other states.

H.R. 1209, the Improving Access to Maternity Care Act, sponsored by another member of our Health Subcommittee, Dr. Michael Burgess, requires the Health Resources and Services Administration to designate maternity care health professional shortage areas inside existing primary care health professional shortage areas, and review these designations at least annually. The Department

of Health and Human Services would also be required to collect and publish data on the shortage areas to better ensure access to maternity care.

H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act, sponsored by Representative Lois Capps, reauthorizes the current nursing workforce development programs to continue nursing education at all levels and provide additional support for nurses practicing in medically underserved communities.

H.R. 3441, the Accurate Education For Prenatal Screening Act, sponsored by Representative Jaime Herrera Beutler, directs the Centers for Disease Control and Prevention to develop, implement, and maintain programs to educate patients as well as healthcare providers on the purpose of cell-free DNA prenatal screenings. The reasons for such screenings, what conditions may be detected as well as the risk, benefits, and alternatives to such screenings.

H.R. 4152, the Cardiac Arrest Survival Act, sponsored by Representative Pete Olson, expands immunity from civil liability related to the use of automated external defibrillator devices.

H.R. 4153, the Educating to Prevent Eating Disorders Act of 2015, sponsored by Representative Renee Ellmers, yet another Health Subcommittee member, establishes a pilot program to test the impact of early intervention on the prevention, management, and course of eating disorders.

We will hear from a panel of experts and stakeholders as to their ideas and recommendations on these bills.

I now yield to Dr. Burgess.

[The statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

The subcommittee will come to order.

The Chairman will recognize himself for an opening statement.

Today's hearing will examine several different legislative proposals that will address shortcomings in current law and reauthorize an important nursing training program.

H.R. 921, the Sports Medicine Licensure Clarity Act, sponsored by the Health Subcommittee Vice Chairman Brett Guthrie (KY) clarifies medical liability rules for athletic trainers and medical professionals to ensure they are properly covered by their malpractice insurance while traveling with their athletic teams to other states.

H.R. 1209, the Improving Access to Maternity Care Act, sponsored by another Member of our Health Subcommittee Dr. Michael Burgess (TX) requires the Health Resources and Services Administration (HRSA) to designate maternity care health professional shortage areas inside existing primarily care health professional shortage areas, and review these designations at least annually. The Department of Health and Human Services would also be required to collect and publish data on these shortage areas to better ensure access to maternity care.

H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act, sponsored by Rep. Lois Capps (CA) reauthorizes the current Nursing Workforce Development programs to continue nursing education at all levels, and provide additional support for nurses practicing in medically underserved communities.

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H.R. 4153, the Educating to Prevent Eating Disorders Act of 2015, sponsored by Rep. Renee Ellmers (NC), yet another health subcommittee member, establishes a

pilot program to test the impact of early intervention on the prevention, management, and course of eating disorders.

Today we have two panels, including. Additionally, we will hear from a panel of experts and stakeholders as to their ideas and recommendations on these bills.

I will now yield to Dr. Burgess.

Mr. BURGESS. Thank you, Mr. Chairman.

I just want to comment on the bill we have before the panel today. Across the country, women with the greatest need for maternity care services lack access to providers of such care. This bill introduced with Representative Capps will help place more maternity providers where they are needed and to improve access to maternity care and advance the health of mothers and babies. The National Health Service Corps provides for student loan repayment to physicians and other health professionals in exchange for our commitment to provide care in a designated health professional shortage area.

The program has been effective in reducing provider shortages by inspiring new providers to start where they are needed the most. Maternity care providers currently participate in the program based on a determination in an area that is a primary care shortage area. This bill would more effectively allocate maternity care providers based on an area or population's specific needs.

In other words, a maternity care provider will continue to be able to participate, but their participation will be based on a designation of a maternity care shortage area, not just simply a primary care shortage area. We are continuing to work with HRSA to ensure that this narrow targeted provision will improve access to mothers and the care that they and their babies need.

And thank you, Mr. Chairman. I will yield back.

Mr. PITTS. The chair thanks the gentleman. The chair now recognizes the distinguished ranking member of the Health Subcommittee, Mr. Green, from Texas, 5 minutes for opening statement.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman. Today we are here to review six bills aimed at improving our healthcare system. But, first, and since this is, hopefully, our last hearing of the year, I want to start by thanking all of my colleagues on the Health Subcommittee, Ranking Member Pallone, Chairman Upton, and, of course, Chairman Pitts, for all of their work that went into the bills that comprise our shared success. It has been an incredibly productive year, and this subcommittee serves as an example of what we can accomplish when we work together on behalf of the American people.

From the 21st Century Cures Act, which passed with overwhelming support in the House last summer, to the Medicare Access and CHIP Reauthorization Act, which repealed and replaced the SGR and extended funding for the CHIP program in community health centers to dozens of public health bills signed into law, to ongoing efforts along the salient issues such as regulation of laboratory developed tests, the success of undertakings of this subcommittee are numbered in significance. None of this would have happened without the strong leadership on both sides of the aisle

and the commitment to bipartisanship and a tireless dedication of staff, House legislative counsel and advocates, including the administration. I want to thank all of you and look forward to seeing what we can accomplish in the coming year.

Now to our bills today. H.R. 921, the Sports Medicine Licensure Clarity Act, will promote the safety of our athletes by ensuring that sports teams' physicians and athletic trainers who treat their athletes while outside their home state can treat their patients regardless of whether they are home or away. Many medical liability insurance carriers do not offer coverage for care provided outside of the State in which the provider is licensed, making it difficult for team physicians to maintain adequate coverage while traveling throughout a sport season. This legislation would clarify certain aspects of the medical liability and malpractice insurance for those providers to address this issue in a targeted manner.

H.R. 4152, the Cardiac Arrest Survival Act, aims to increase the deployment of automated external defibrillators, or AEDs, by providing a baseline protection from civil liability for persons who own or use AEDs and doing a good-faith medical emergency. Numerous studies have demonstrated the value of prompt use of AED during an out-of-hospital cardiac arrest as the likelihood of survival decreases by 7 or 10 percent for every minute delayed until defibrillation.

H.R. 3441, the Accurate Education for Prenatal Screening Act, aims to advance the use of cell-free DNA prenatal screening. The development and delivery of genetic and genomic health care will continue to transform the practice of medicine and improve the diagnosis, prevention, and treatment of disease. While I thank the bill sponsors for their commitment to the promise of genetics and the improving care for women with high-risk pregnancies, I have some concern that this legislation is overly prescriptive and premature and that information surrounding these tests is not evaluated by the FDA for their clinical or analytical validity.

H.R. 1209, Improving Access to Maternity Care Act, was introduced to increase access to maternity care services by creating a new designation within primary care health professional shortage areas, HPS designation—HPSA. As someone who represents an underserved area, I appreciate the bill sponsors, Representative Mike Burgess and Lois Capps, for their commitment to targeting gaps in access and ensuring women can obtain vital maternity care services.

H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act, will extend successful advanced nurse—education nursing grants to support clinical nurse specialist programs. The Title VIII nursing workforce development programs have a long history of success and bipartisan support in Congress. Continued investment in these programs will ensure we have an adequate nursing workforce in the future. I want to thank Congresswoman Capps, the bill's sponsor, an unwavering champion for her work to reauthorize these critical programs, for her long history of working to improve nursing workforce demand, education, practice, recruitment, and retention.

H.R. 4153, the Educating to Prevent Eating Disorders Act, will create a pilot program through the Agency on Healthcare Research and Quality to test the efficiency of early interventions on eating

disorders. According to the NIH, eating disorders frequently present during teens and early adulthood, affect as many as 25 million Americans.

I look forward to hearing from our witnesses and learning more about the merits of each legislative proposal before the subcommittee.

And I thank you, and I yield back my time.

Mr. PITTS. The chair thanks the gentleman.

And now, in lieu of the chairman, Mr. Upton, the chair recognizes the gentlelady from North Carolina, Mrs. Renee Ellmers, 5 minutes for opening statement.

OPENING STATEMENT OF HON. RENEE L. ELLMERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mrs. ELLMERS. Thank you, Mr. Chairman.

And thank you to our panelists for being here today for this subcommittee hearing today. Through my experience as a nurse, I recognize and have witnessed the serious implications that stem from eating disorders.

These disorders impact a person's emotional and physical health. So it is all the more important that we put in evidence-based programs in place to better understand the early warning signs of the disease. Our legislation, H.R. 4153, creates a pilot program within middle schools to begin educating school counselors, teachers, nurses, and parents about the signs and symptoms typically associated with these disorders.

Education is a critical first step, if we hope to prevent, identify, manage, and intervene on behalf of the struggling adolescent. It is my hope that this legislation provides school officials and healthcare professionals with the education and resources they need to help thwart this mental illness from taking root. Thirty million Americans will struggle with an eating disorder at some point in their lives.

H.R. 4153 aims to amend the Public Health Service Act to establish a pilot program to test the impact of providing students with interventions to prevent, identify, intervene, and manage eating disorders. The bill would establish a 3-year pilot program to provide grants to eligible schools for eating disorder screening, which would be implemented based on best practices recommendations from experts in the field of eating disorders. The pilot program would also include educational information and seminars on eating disorders developed by experts in the field for teachers, and parents, and eligible schools.

The intent of H.R. 4153 is to detect risk factors and symptoms so that young people can be directed to help when it is most effective. H.R. 4153 could be the most important proactive piece of legislation for the early intervention and prevention of deadly eating disorders.

I look forward to beginning this important discussion today, and thank you, again.

I yield back the remainder of my time.

Mr. PITTS. The chair thanks the gentlelady.

Is anyone else on this side of the aisle seeking recognition?

The chair thanks the gentlelady, and I now recognize the distinguished ranking member of the full committee, Mr. Pallone, 5 minutes.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman. This morning we will be discussing a wide variety of bills. The first, H.R. 921, the Sports Medicine Licensure Clarity Act, stipulates that if a team doctor or athletic trainer crosses State lines for a game, any care provided at the out-of-State event will be treated as if it were a home game for the purpose of medical licensure and liability.

The second bill, H.R. 4152, the Cardiac Survival Act, expands civil liability protections related to the usage of automated external defibrillator devices, or AEDs. This bill would offer broad protections for both the owners of AEDs and any lay person that may use it. While I strongly support the intended goal of this bill, I do have some concerns surrounding State law preemption, especially as it may relate to various State AED training laws.

Third is H.R. 3441, the Accurate Education for Prenatal Screenings Act, would direct CDC to develop patient and provider education programs and materials to inform them about the use of cell-free DNA prenatal screening tests for genetic conditions such as Down syndrome. These screenings are intended to provide patients with genetic information regarding their pregnancy. However, these screenings are not regulated by FDA and have a history of false positives and false negatives. Further, these tests are often misunderstood by both patients and providers. More must be done to ensure that the information provided about these tests is accurate and truthful to ensure that patients and providers can better understand these screenings and their limitations.

The fourth bill, H.R. 1209, the Improving Access to Maternity Care Act, as introduced by Representatives Burgess, Capps, and Duckworth, would make changes to the National Health Service Corps definition of a primary care health professional shortage area by creating a subcategory specifically for maternity care providers. This would allow the National Health Service Corps to better target maternity care providers towards the areas with the most need.

And then we have H.R. 2713, the Title VII Nursing Workforce Reauthorization Act as introduced by Representative Capps and Joyce, would reauthorize the Title VIII nursing workforce programs which provide valuable training to our Nation's nursing workforce through 2020. It also provides technical updates that more accurately reflect the current state of the nursing profession.

And, finally, H.R. 2153, the Educating to Prevent Eating Disorders Act, as introduced by Representatives Ellmers, Clark, and Castor, creates a pilot program to test new approaches to early interventions for eating disorders.

I would like to yield the remainder of my time to Mrs. Capps. Mrs. CAPPS. I thank my colleague for yielding.

And I thank you, Mr. Chairman and Ranking Member Green, for holding this hearing. I am particularly pleased that two pieces of

legislation I have worked on for a long time are also included in this discussion. Each would help strengthen our healthcare workforce and improve access to care for patients across the Nation.

H.R. 1209, the Improving Access to Maternity Care Act, would help identify and fill gaps in maternity care through the National Health Service Corps. My colleague from Texas has already described this, but I want to underscore the fact that the National Health Service Corps is one of our most effective programs to improve access to care in underserved areas.

Maternity care professionals are already included in the program, but their placement is based on data looking at primary care access shortages, not maternity care data. And this bill would make this more efficient by allowing these professionals to serve in areas with shortages in maternity care access, not just those with primary care deficiencies. It may seem like a small thing, but it is actually pretty significant.

I am pleased to have also co-authored this legislation with Dr. Burgess, and I want to highlight the work of our colleague, Representative Roybal-Allard on this issue over the years. Quality maternal care is vitally important for both the health of women and their future children, and it is our interests to do all we can to break down barriers to access for this care.

I am also very pleased that we are considering H.R. 2713, the Title VIII Nursing Workforce Reinvestment Act—Workforce Reauthorization Act. Sorry. Title VIII is the primary program our Nation has to strengthen and grow the nursing workforce. Title VIII has supported the recruitment, retention, and distribution of the highly educated professionals who comprise our Nation's nursing workforce and have been doing so for over 50 years through Title VIII. These programs bolster nursing education at all levels, from entry-level preparation through graduate study, and they provide support for institutions that educate nurses for practice in rural and medically underserved communities. Moreover, these programs are designed to address specific needs within the nursing workforce and America's patient population. The Nursing Workforce Reauthorization Act would ensure that these critical programs are available for years to come.

I want to thank my nursing caucus co-chair, Representative David Joyce, for coauthoring this legislation and the over 50 nursing groups that we have worked with to move this reauthorization forward. It is a great day.

So, again, thank you for including these bills in today's hearing.

And with that, I yield back to my colleague, but I don't think there is any time. Thank you.

Mr. PITTS. The chair thanks the gentlelady.

As usual, all written opening statements of the members will be made a part of the record.

I have a UC request. I would like to submit the following documents for the record: Statements from Representative Herrera Beutler, from the American Congress of Obstetricians and Gynecologists, from National Nursing Centers Consortium, from the National Association of Clinical Nurse Specialists, from the Nursing Community Coalition, from the Society for Maternal Fetal Medicine, from the National League for Nursing, and the National Ath-

letic Trainers' Association. Without objection, these will be made a part of the record.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. I will now introduce the panel. We have six witnesses today. I will introduce them in the order of their testimony.

First of all, Dr. Chad Asplund, Director, Athletic Medicine, Head Team Physician for Georgia Southern University, and Dr. Jonathan Reiner, Director, Cardiac Catheterization Laboratory, George Washington University Hospital, and Dr. Anthony Gregg, Professor and Chief, Division of Maternal Fetal Medicine, University of Florida, Department of Obstetrics and Gynecology.

Dr. Ginger Breedlove, President, American College of Nurse Midwives; Dr. Deborah Trautman, President and CEO of American Association of Colleges of Nursing, and Dr. Ovidio Bermudez, Chief Clinical Officer and Medical Director of Child and Adolescent Services Eating Recovery Center, Senior Board Adviser, National Eating Disorders Association.

Thank you, each, for coming today. Your written testimony will be made a part of the record. You will each be given 5 minutes to summarize your testimony. You have a little series of three lights; green for the first 4 minutes, yellow for the last minute, red when your time has expired. So thank you for coming.

And at this point, Dr. Asplund, you are recognized 5 minutes for your summary.

STATEMENTS OF CHAD ASPLUND, MD, MPH, FACSM, DIRECTOR, ATHLETIC MEDICINE AND HEAD TEAM PHYSICIAN, GEORGIA SOUTHERN UNIVERSITY; JONATHAN REINER, MD, DIRECTOR, CARDIAC CATHETERIZATION LABORATORY, GEORGE WASHINGTON UNIVERSITY HOSPITAL; ANTHONY R. GREGG, MD, PROFESSOR AND CHIEF DIVISION OF MATERNAL-FETAL MEDICINE, UNIVERSITY OF FLORIDA DEPARTMENT OF OBSTETRICS AND GYNECOLOGY; GINGER BREEDLOVE, PHD, CNM, APRN, FACNM, PRESIDENT, AMERICAN COLLEGE OF NURSE MIDWIVES; DEBORAH E. TRAUTMAN, PHD, RN, FAAN, PRESIDENT, AMERICAN ASSOCIATION OF COLLEGES OF NURSING; AND OVIDIO BERMUDEZ, MD, FAAP, FSAHM, FAED, F.IAEDP, CEDS, CHIEF CLINICAL OFFICER AND MEDICAL DIRECTOR OF CHILD AND ADOLESCENT SERVICES, EATING RECOVERY CENTER SENIOR BOARD ADVISOR, NATIONAL EATING DISORDERS ASSOCIATION

STATEMENT OF CHAD ASPLUND

Dr. ASPLUND. Thank you, Mr. Chairman, Ranking Member Green, members of the committee. Thank you for inviting me here to discuss H.R. 921, the Sports Medicine Licensure Clarity Act. My name is Chad Asplund. I am a family medicine, sports medicine physician, and I am the head team physician at Georgia Southern University.

I graduated from the United States Coast Guard Academy, completed medical training at the University of Pittsburgh, family medicine residency at DeWitt Army Community Hospital at Fort Belvoir, and my sports medicine fellowship at Ohio State Univer-

sity. Additionally, I completed a master's of public health degree at the University of Florida.

In my experience as a sports medicine physician, I have had the opportunity to take care of athletes at all levels; Olympic, professional, NCAA division 1, 2, and 3, as well as recreational and high school athletes. I am here today representing the American Medical Society for Sports Medicine, the largest organization of team physicians in the world, which I serve as its chair of the practice and policy committee. I would not be here also without the support of the National Athletic Trainers' Association, the American Academy of Orthopedic Surgeons, and many others.

Nearly every day in this country, athletic teams travel across state lines to compete in their contests. Every day those athletes are out on the field they are subject to danger and to harm. And because of this, physicians and athletic trainers are there to ensure their safety. In the United States there are approximately 14,000 athletic trainers and physicians that are dedicated to team care, and each week in America 300 to 500 of these professionals travel across state lines to provide care to the teams that they support.

What you may not realize is that in many cases by doing this, by crossing state lines to perform their jobs, they are risking their professional licenses and personal assets to make sure that those athletes have the best care by the medical professionals who know them best.

H.R. 921 would protect medical professionals that keep these athletes safe. H.R. 921 has three main components. First, to ensure medical professionals' licenses are valid when crossing state lines when they travel with their teams for sanctioned events as long as the care they provide is within the confines of the bill.

Second, to ensure that the Medical Practice Act in the medical professional's home state dictates their scope of practice, licensure requirements, laws, rules, and regulations governing their actions. And third, to ensure that a medical professional's medical malpractice and liability coverage can and will cover them while they were traveling to support their teams.

As you are aware, it is college football bowl season. Many teams will travel across state lines to play football, which at times can be a violent and dangerous sport. Athletic trainers and physicians travel with these teams in order to ensure their safety. I would like to share a personal story of an incident that happened to us.

During this football season, during a game at Troy University, one of our Georgia Southern football players received a hit to the head and was laying unconscious, face down on the football field. Our medical team ran onto the field, and upon finding him, he was found to be unconscious and unresponsive. It was determined that he would need to be spine boarded and transported to the nearest emergency medicine facility.

The complex choreography of stabilizing the cervical spine, managing the remainder of the spine while rolling the patient and placing him on a backboard is something that takes lots of training and lots of practice between physicians and athletic trainers that work together all the time. Our athlete was placed on a spine board and was transported to EMS. Thankfully, his further evaluation was all

negative. He was diagnosed with a concussion, and has since made a full recovery.

At the beginning of this incident, the Georgia Southern University medical team provided the medical care to this patient, which was then transferred to the emergency medical services when he was placed in the ambulance. Had there been an adverse event and a lawsuit had been filed, the protection of those members that provided that care would be uncertain. Their medical licenses and their personal assets would be at risk.

But there is no need to put medical professionals at risk. Today you can take a significant step to solve this problem. You can choose to protect athletes and medical professionals by supporting and passing H.R. 921. I urge you, again, to support and pass this bill. And thank you very much for your time today.

[The statement of Dr. Asplund follows:]

Summary of Testimony of Chad A. Asplund, M.D., MPH, FACSM
Director, Athletic Medicine and Head Team Physician
Adjunct Associate Professor, Health and Kinesiology
Georgia Southern University

On Behalf of the American Medical Society for Sports Medicine
IN SUPPORT OF HR 921, THE SPORTS MEDICINE LICENSURE CLARITY ACT
Before the Health Sub-Committee of the House Energy and Commerce Committee

What Is HR 921:

HR 921, THE SPORTS MEDICINE LICENSURE CLARITY ACT is a bill that will allow fully-licensed medical professionals that travel with their sports teams, to continue to treat athletes and staff under their care during times when those sanctioned events require them travel across state lines into states where the medical professional is not licensed to practice.

What Does HR 921 Do:

- To ensure that medical professionals' licenses are valid when crossing state lines with their teams for officially sanctioned events, as long as care is confined within the parameters of the bill
- To ensure the medical practice act in the medical professional's home state dictates the scope of practice, licensure requirements and laws, rules and regulations governing their actions
- To ensure that a medical professional's medical malpractice and liability coverage can and will cover them when they are traveling outside of their state borders for an officially sanctioned event

What Does HR 921 Not Do:

- Try to bypass state licensing rules and regulations. - These medical professionals must be fully licensed and insured in their home state.
- Allow a medical professional to practice on the general population. - Their scope of practice is limited to treating only team athletes and staff that the medical providers are contractually hired and insured to treat.
- Allow a medical professional to expand their scope of practice to match the state they are in.
- Allow a team physician or trainer to treat an athlete in a hospital or clinic.
- Allow a team medical professional to practice indefinitely in any state they are not licensed in.
- This act allows a physician to act in a state, only as long as their team is in that state for a sanctioned event.

Who Supports HR 921:

- The American Medical Society for Sports Medicine
- The National Athletic Trainers' Association
- The American Academy of Orthopedic Surgeons
- Physicians Insurance Association of America
- Leading national professional and collegiate sports organizations, including: NCAA, MLB and NFL

Testimony of Chad A. Asplund, M.D., MPH, FACSM
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On Behalf of the American Medical Society for Sports Medicine
IN SUPPORT OF HR 921, THE SPORTS MEDICINE LICENSURE CLARITY ACT
Before the Health Sub-Committee of the House Energy and Commerce Committee

December 9, 2015

Mr. Chairman, Ranking Member, Members of the Committee:

Thank you for inviting me here to discuss HR 921 – The Sports Medicine Licensure Clarity Act. My name is Chad Asplund. I am a sports medicine physician and the Head Team Physician at Georgia Southern University.

I graduated from the U.S. Coast Guard Academy and received my Doctorate of Medicine from the University of Pittsburgh. I trained in family medicine at Dewitt Army Community Hospital, in Ft. Belvoir, Virginia and completed a sports medicine fellowship at the The Ohio State University. In addition, I received my Masters of Public Health at the University of Florida. In my career as a sports medicine physician, I have provided care to athletes at all levels – professional, Olympic, NCAA division I, II and III, high school and recreational athletes.

I am representing the American Medical Society for Sports Medicine (AMSSM), the largest organization of team physicians in the world, and serve as chair of its Practice and Policy Committee. AMSSM provides a forum to foster professional relationships among sports medicine physicians to advance the discipline of sports medicine through education, research, advocacy and excellence in patient care. AMSSM was formed in 1991 to fill a void that has existed in sports medicine from its earliest beginnings. AMSSM's founders – most being recognized sports medicine specialists – realized that while there were several physician organizations which supported sports medicine, there was not a forum specific for primary care non-surgical sports medicine physicians. Upholding and promoting priority issues in sports

medicine affecting members, patients, and their communities is a key objective of AMSSM, and it is in that spirit of advocacy that I appear before you today.

I would like to recognize some of our partner organizations in this effort, including: the National Athletic Trainers' Association, the American Academy of Orthopedic Surgeons, and Physician Insurers Association of America. Each has been actively involved in the writing of this bill. In addition, leading collegiate and professional sporting bodies: National Collegiate Athletic Association; National Football League; Major League Baseball; National Hockey League; United States Tennis Association; NFL Team Physician's Association; Major League Baseball Team Physician's Association. I know many of these organizations submitted individual or joint letters of support for HR 921.

Nearly every day (if not actually every day) of the year in this country, one sports team travels across state lines, sometimes across the country, to compete against another team. These athletes might be members of elite travel, college, semi-professional teams up to and including those athletes that compete at the highest professional and international levels. These athletes give their all to represent their teams, their colleges and universities, their cities or their countries.

And every day that those athletes are out on the field of play, there are team physicians and athletic trainers ensuring their health and safety. There are approximately 14,000 physicians and athletic trainers that provide care to athletic teams, and of these it can be estimated that approximately 300-500 that would be affected by this bill would travel across state lines each week. What you may not realize is that in many cases, when these medical professionals travel with their teams, they do so risking their professional licenses and personal assets to make sure those athletes have access to the medical professionals that know them best and are in a position to offer the best possible medical care for most non-emergency situations.

HR 921 would protect the medical professionals that keep these athletes safe -- helping them return to the field when possible, and keeping them off the field when necessary to protect them and avoid further injury.

HR 921 has **three main components**:

- To ensure that medical professionals' licenses are valid when crossing state lines with their teams for officially sanctioned events, as long as care is confined within the parameters of the bill
- To ensure the medical practice act in the medical professional's home state dictates the scope of practice, licensure requirements and laws, rules and regulations governing their actions
- To ensure that a medical professional's medical malpractice and liability coverage can and will cover them when they are traveling outside of their state borders for an officially sanctioned event

AMSSM members assisted with drafting HR 921 because there does not appear to be a feasible state-based solution. There is no consistency to state laws that allow for team physicians to practice in their state. Some states allow temporary exemption for team physicians from contiguous states. Some states have reciprocity for states that allow similar exemptions for physicians in their state.

AMSSM has looked at several options to solve the licensure problem, including leveraging the new state licensure compact and introducing and passing model legislation for each state. The compact cannot be adapted as a fix to this problem and changes in state law are decades away from providing a solution for a problem that is critical now. Any delay will continue to put athletes and the people that care from them at risk.

It is worth noting, that Federation of State Medical Boards (FSMB) recently recognized that traveling team physicians' and athletic trainers' work is different from traditional out-of-state practitioners, and in need of an exemption from state medical boards. FSMB made the following recommendation through its workgroup on state medical board innovation:

The recommendations are as follows: A recommendation that sports team physicians are held exempt from the state licensure requirement, as follows: A physician licensed in another state, territory or jurisdiction of the United States is exempt from the licensure requirements in (state) if the physician is employed or formally designated as the team physician by an athletic team visiting (state) for a specific sporting event and the physician limits the practice of medicine in (state) to medical treatment of the members, coaches and staff of the sports entity that employs (or has designated) the physician.

The full report can be found here -

http://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/report_of_state_innovations_adopted.pdf

However, even if states could get together and solve the licensing problem quickly, that would not solve the insurance problem. There is no mechanism that would force medical malpractice insurers to cover any action outside of the state that the medical physician is licensed to practice in. And this is a very real concern.

A group of our organization's physicians recently canvassed a sample of twenty (20) U.S.-based malpractice insurance providers to see if coverage would extend to situations when a team physician was treating an athlete at a sanctioned event outside of their home state. The results were published in the October 2012 issue of the British Journal of Sports Medicine. I am submitting the article with my testimony. What the researchers found was that roughly 18% of the insurers that responded would cover a team physician out of state regardless of whether the physician was licensed in the second state. Approximately 45% of the respondents would only cover the physician in cases where they were licensed in the second state, and 36% would not cover the physician at all. Therefore team physicians are essentially closed off from 90% of their malpractice insurance market.

I have outlined what HR 921 does, but I also want to stress what HR 921 does *not* do. HR 921 **DOES NOT**:

- **Try to bypass state licensing rules and regulations.**

These medical professionals must be fully licensed and insured in their home state. And their actions in their non-home state are limited to non-clinical facilities, such as a team bus, hotel, locker room or field of play, considering them essentially extensions of the team's home facility.

- **Allow a medical professional to practice on the general population.**

Their scope of practice is limited to treating only team athletes and staff that the medical providers are contractually hired and insured to treat. This bill does not extend to traveling fans, alumni, boosters or any member of the general population in either the "state of origin" or "state of entry." Thus HR 921 in no way establishes a precedent to limit a state's ability to regulate medical practice affecting its own citizens, and in every instance, the provider is limiting

care to individuals who already exist within the population that the clinician's malpractice carrier underwrote for when premiums were established.

- **Allow a medical professional to expand their scope of practice to match the state they are in.**
If a state where a medical professional has travelled into allows a broader scope of practice than the medical professional's home state, that medical professional is still restricted by their home state's laws, even if the medical professional might have adequate education and training to complete the expanded function or procedure.
- **Allow a team physician or trainer to treat an athlete in a hospital or clinic.**
Team athletic trainers and physicians often provide stop-gap measures when traveling with teams. These medical professionals work hard to ensure that their athletes are treated thoroughly enough to get them home, but that is not always possible. In instances when an athlete requires more extensive local care (often emergency care) the team physician must pass that care responsibility to a physician or other emergency responder who is licensed in that state.
- **Allow a team medical professional to practice indefinitely in any state they are not licensed in.**
This act allows a physician to act in a state, only as long as their team is in that state for a sanctioned event. If a medical professional wishes to practice in that state beyond that period of time, the medical professional would have to comply with that state's licensure rules and regulations.

Earlier this week, my university, Georgia Southern, received its first ever NCAA Bowl Bid. We will be traveling to Mobile, Alabama to play in the GoDaddy.com Bowl. This is a tremendous accomplishment for our team. As the team physician, as part of my job requirements, I will be traveling with them. And when I travel outside of my state of Georgia, I will be essentially practicing without a license, because Alabama does not recognize licensure reciprocity, and the period of time to obtain licensure in Alabama far outweighs the time we have between our bowl assignment and the actual game. Of course the fact that I am not considered licensed does not bar a student athlete from suing. And if I am sued, my home state license is at risk and my medical malpractice insurance coverage will likely not cover me. My

personal assets and the assets of my family are at risk. Currently, there is no legal mechanism in place to protect me.

Limiting my ability to provide care for my team is not in the best interest of the athletes under my supervision. Having physicians and athletic trainers who know their athletes' medical and injury history always results in the best protection and care for that athlete.

But there is no need to continue to put both physicians and athletes at unnecessary risk.

Today, you can take a significant step to solve this problem. You can chose to protect athletes and medical professionals, by ensuring athletes have access to the best care available and by ensuring that the medical professionals that provide that care during a sanctioned sporting event are protected regardless of where that care is given.

I urge you to help me and other physicians and athletic trainers continue to treat and serve the athletes under our care to the best of our ability and with the full protection of the law. I urge you to support and pass HR 921, the Sports Medicine Licensure Practice Act.

Thank you.

Respectfully Submitted

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Chair, Policy and Practice Committee
American Medical Society for Sports Medicine

Mr. PITTS. The chair thanks the gentleman.
And, Dr. Reiner, you are recognized 5 minutes for your summary.

STATEMENT OF JONATHAN REINER

Dr. REINER. Mr. Chairman, Ranking Member Green, members of the committee, thank you for the opportunity to testify on behalf of the Cardiac Arrest Survival Act and the many thousands of lives this bill has the potential to save. I am a professor of medicine and cardiologist at the George Washington University, and I have spent most of my adult life treating people with heart disease. This is a topic I care about deeply.

Every year approximately 350,000 Americans experience an out-of-hospital cardiac arrest. Sudden cardiac arrest, or SCA, is a condition that results most often from the abrupt onset of a heart rhythm abnormality called ventricular fibrillation. This extremely rapid and chaotic arrhythmia causes the heart to quiver, effectively blocking its ability to pump. With no heart function, blood pressure drops to zero, breathing stops, and organs, most quickly the brain, begin to die. Without immediate measures, the victim has just a few minutes to live. SCA is a supremely lethal event that results in the death of about 90 percent of those it afflicts.

Sudden cardiac arrest is an equal opportunity killer. It kills the young and the old, the rich and the poor, those suffering from chronic heart disease, and those who have never before been sick. It kills our husbands and our wives, our parents, and our partners, our friends, and neighbors, and our children. The annual death toll from sudden cardiac arrest is about twice the number of those who die from breast cancer, lung cancer, and HIV–AIDS combined.

Defibrillation with an automated external defibrillator, an AED, is the only effective treatment for sudden cardiac arrest. An AED is a small device, about the size of a lunch box, that can deliver a therapeutic shock to essentially reset the electrical circuitry of the heart. Contemporary AEDs, the type you see throughout airports and here in the hallways of the Capitol, have algorithms that automatically determine whether a shock is indicated and step-by-step audio prompts that guide the rescuer through the surprisingly simple process of saving a life.

This is time-tested technology designed for use by people who have had no prior medical training. In the late 1990s, when clinical studies proved unequivocally that public access to defibrillation saved lives, states began to enact AED laws. Over the next several years, all 50 states and the District of Columbia passed such legislation. Unfortunately, the unintended consequence of this effort was that the enacted AED measures were all different, creating a confusing patchwork of regulatory requirements and liability provisions.

The American Heart Association has stated that the variations and complexities of state laws have complicated efforts to disseminate AEDs around the country. For example, more than 30 states require the registration of AEDs with local authorities, a process that is different in each state and can be quite cumbersome. Despite the fact that AEDs are designed to be used by lay rescuers, several states still prohibit AEDs by untrained operators.

Forty states require oversight of an AED program by a licensed physician. Although all 50 states have enacted some form of Good Samaritan protection for AED responders, the laws differ as to who in particular is eligible for immunity. Collectively, the varied state laws create a confusing series of bureaucratic hurdles that must be crossed before an AED program can commence. While individual state laws make the process of instituting a single AED program cumbersome, state-to-state regulatory heterogeneity and differences in Good Samaritan protections create an air of liability uncertainty for national corporations considering enterprise-wide AED programs.

The Wall Street Journal, noting that hotels around the United States have been reluctant to deploy defibrillators, describe their liability concerns as the, quote, “no good deed goes unpunished exposure.” American retail stores have been similarly reluctant to deploy defibrillators. For example, you can purchase an AED from Walmart for about \$1,000, however, should you experience a cardiac arrest while shopping in most stores, resuscitation will have to wait until the paramedics arrive.

To facilitate the placement of AEDs in businesses and public places across the United States, there must be a single unambiguous nationwide platform of liability protections. This is what the Cardiac Survival Act of 2015 does. The bill essentially decouples liability protection from the very state requirements for AED implementation, and in so doing, creates a national uniform baseline of civil liability protection for Good Samaritan rescuers and the entities that own the device. Reducing the current uncertainty surrounding AED acquisition and use will encourage the deployment of additional AEDs across the Nation and ultimately, this will save lives that otherwise that would have been lost.

In conclusion, Mr. Chairman, the current jumble of state AED provisions creates great uncertainty regarding liability exposure and has become a virtual speed brake on the dissemination of the simple, irreplaceable, decades-proven therapy. Congress has the ability to remedy this problem with the passage of the Cardiac Arrest Survival Act. Thank you.

[The statement of Dr. Reiner follows:]

Dr. Jonathan S. Reiner

Committee on Energy and Commerce, Subcommittee on Health

December 9, 2015

Summary/Key Points:

1. Sudden cardiac arrest (SCA) kills more than 350,000 American per year, twice the number of those who die from breast cancer, lung cancer, and HIV/AIDS combined.
2. The key to survival is early treatment with an automated external defibrillator (AED). Every minute in delay to defibrillation results in a 7-10% decline in survival.
3. Survival rates for SCA are poor, varying regionally in the United States from 3.0% to 16.3%.
4. All 50 states and the District of Columbia have passed legislation concerning regulations for deploying AEDs and liability protections for AED owners and Good Samaritan rescuers. Unfortunately, the enacted AED laws differ from state-to-state creating a diverse patchwork of legislation that has produced an air of liability uncertainty for businesses wishing to deploy AEDs.
5. HR 4152 (The Cardiac Arrest Survival Act of 2015) will create a nationally uniform baseline of protection from civil liability for persons who use AEDs in perceived medical emergencies, who own or hold other property interests in AEDs, or who own, occupy, or manage premises in which an AED is used or from which an AED is taken for use in a perceived medical emergency.
6. Reducing the current uncertainty surrounding AED acquisition and use will encourage the deployment of additional AEDs, which will ultimately save lives that would otherwise have been lost to cardiac arrest.

Every year in the United States more than 350,000 people will die as a result of sudden cardiac arrest (SCA). The annual death toll from sudden cardiac arrest is about twice the number of those who die from breast cancer, lung cancer, and HIV/AIDS combined. Sudden cardiac arrest is a supremely lethal event that results in the death of 90% of those it afflicts.

Despite the manifold advances in cardiovascular medicine over the past 2 decades, survival from out-of-hospital SCA remains unlikely varying regionally in the United States from 3.0% to 16.3%.¹ In 1991, in an effort to improve SCA outcomes, the American Heart Association introduced the “chain of survival” concept stressing 4 “links”: early activation of emergency medical services (EMS), early cardiopulmonary resuscitation (CPR), early defibrillation, and early advanced cardiovascular care.² The most crucial of these links appears to be prompt defibrillation. Every minute in delay to defibrillation results in a 7-10% decline in survival.³ Although CPR can attenuate the severe survival penalty resulting from defibrillation delays, most patients with SCA do not receive bystander CPR prior to EMS arrival. In Gallagher’s report of 2071 consecutive out of hospital cardiac arrests in New York, upon EMS arrival, only 32% of patients were receiving bystander CPR⁴. Survival for patients who were not receiving CPR was a near futile 0.8%, while those who did receive bystander CPR fared minimally better with a survival rate of only 2.9%.

In 1994 The American Heart Association’s Public Access Defibrillation Conference noted that making AEDs more widely available should significantly improve SCA survival and recommended clinical trials to further evaluate AED use by first responders and the lay public.⁵ Multiple studies followed, with a variety of responders

and venues, including Nevada casinos⁶, commercial aircraft⁷, community units⁸, police cars^{9, 10}, and Chicago airports¹¹. These experiences consistently demonstrated the positive impact on survival of early defibrillation using trained and untrained non-medical responders. In 2005 an advisory statement from the American Heart Association noted that lay rescuer AED programs will be most cost effective if they are instituted at high-density sites where at least 1 witnessed SCA is likely to occur every few years.¹² Data from Copenhagen refined this concept and suggested that a high proportion of cardiac arrests in public can be covered by strategic placement of AEDs in areas with the highest rates of cardiac arrest such as large shopping centers, train stations, high-density public areas, central bus terminals, and sports centers¹³.

In 2006 the American Heart Association's Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy noted that variations in state and federal legislation and regulations complicated efforts to promote lay rescuer AED programs¹⁴. Thirty-five states currently require the registration of AEDs with local authorities, a process that is different in each state and may be quite cumbersome. In New York¹⁵, for example, to institute a public access defibrillation (PAD) program one must:

1. Identify a physician or hospital knowledgeable and experienced in emergency cardiac care to serve as "emergency health care provider" and participate in a collaborative agreement.
2. Develop a written collaborative agreement which includes written practice protocols for the use of the AED as well as written policies and procedures.
3. File with the Regional Emergency Medical Services Council serving the area a

copy of the "Notice of Intent to Provide PAD" along with a signed copy of the Collaborative Agreement.

4. Select and implement an approved PAD training course for AED users.
5. Provide written notice to 911 of the availability of AED service at the organization's location.

Although most states permit any rescuer to use an AED, 7 states still prohibit AED use by untrained operators. New York Law states: "No person may operate an AED unless the person has successfully completed a training course in the operation of an AED approved by a nationally-recognized organization or the state emergency medical services council."¹⁵ Consequently, signage at AEDs in New York airports include the warning, "for emergency use by trained rescuers only". In contrast, in Virginia there is no specific training requirement and signage on AEDs in Virginia public places do not warn against use by novice rescuers.¹⁶ The prohibition of the use of an AED by an untrained operator seems to suggest that it is preferable to wait for EMS arrival (which on average will take more than 7 minutes¹) than it is to have a true first responder attempt defibrillation. In reality, AEDs are designed for effective and expeditious use by individuals with no prior medical experience. As the name implies, these devices are "automated", feature audio prompts, and require little more than the placement of 2 adhesive patches on an exposed chest. Rhythm analysis algorithms determine whether a shock is appropriate and will not allow delivery of a shock to a patient with a "non-shockable" rhythm. The intuitive nature of these devices was highlighted in a study comparing the performance of 15 AED naïve 6th grade children to 22 emergency medical technicians and paramedics using a mock cardiac arrest scenario¹⁷.

In this study, the children placed the electrode patches correctly on all subjects and all operators remained clear of the “patient” during shock delivery. The children achieved a mean time to defibrillation of 90 seconds, only 23 seconds slower than the mean time achieved by the trained professionals. Data from the Resuscitation Outcomes Consortium, demonstrates the dramatic advantage in survival when an AED shock is delivered by a bystander.¹⁸ In this study of 9867 patients with out of hospital cardiac arrest 249 (2.5%) had an AED placed by a bystander. Survival was 8% with bystander CPR but no AED, 33% when a shock was delivered by a bystander applied AED, and 15% with an EMS delivered shock.

Forty states and the District of Columbia require oversight of an AED program by a licensed physician. In New Jersey, oversight may be provided by any licensed physician¹⁹, whereas in New York State, program monitoring must be provided by a physician or hospital knowledgeable and experienced in emergency cardiac care¹⁵. South Carolina allows program oversight by a physician, physician’s assistant, nurse practitioner, or nurse²⁰. Ten states have no requirement for program monitoring. The rationale for physician monitoring is, as Louisiana law states, “to ensure compliance with the requirements for training, emergency medical service notification, and maintenance”.²¹

Although all 50 states and the District of Columbia have enacted some form of Good Samaritan protection for AED responders, these laws differ as to who, in particular, is eligible for liability protection. Nineteen states provide liability protection only to AED users who have been trained by a sanctioned organization. In Kansas, for instance, “any qualified person who gratuitously and in good faith renders emergency care or treatment

by the use of or provision of an AED shall not be held liable for any civil damages as a result of such care or treatment...”²² The law defines a “qualified” person as one who received training or has demonstrated proficiency in the use of an AED. Thirty-two states and the District of Columbia offer Good Samaritan protection to all AED users. In Illinois only trained AED users are protected from civil damages arising out of the use of an AED but all entities providing the AED are protected from liability²³.

Federal laws addressing Good Samaritan AED protections have been limited. In 1998 President Clinton signed the Aviation Medical Assistance Act which directed the Federal Aviation Administration to determine whether AEDs should be mandated on passenger aircraft and established liability limitations to encourage air carriers and qualified passengers to provide in-flight assistance during medical emergencies.²⁴ This law did not provide liability protection for airlines deploying AEDs other than to shield the airline from any potential liability arising from the assistance of a passenger during an in-flight medical emergency. In 2000 Congress passed the Cardiac Arrest Survival Act which, in theory, provided Good Samaritan protection to both the users and acquirers of AEDs for damages occurring as a result of the emergency use of an AED in a public setting²⁵. This federal law applied only to states without existing Good Samaritan AED protections and explicitly did not preempt existing state law. In practice, as all 50 states have enacted some form of Good Samaritan AED provision this federal statute adds no additional protection.

Collectively the varied state laws create a series of bureaucratic hurdles that must be crossed before an AED program can commence. While individual state laws make the process of instituting a single AED program cumbersome, state-to-state regulatory

heterogeneity creates a complex environment for national corporations considering enterprise-wide AED programs. Perhaps most importantly, state-to-state differences in Good Samaritan laws create an air of liability uncertainty for prospective AED providers and responders. The experience in the US hotel industry with more than 49,000 properties, 4.6 million guestrooms and 1.8 million workers, which has largely not pursued AED deployment, is illustrative. The American Hotel and Lodging Association has noted several issues with respect to widespread implementation of defibrillators in U.S. hotels, including “liability concerns for both individuals and businesses in the absence of strong national Good Samaritan protections”²⁶. The Wall Street Journal noting that hotels around the United States have been reluctant to deploy defibrillators also raised the industry’s concern about Good Samaritan protections and described the liability concerns “as the ‘no good deed goes unpunished’ exposure.”²⁷ A representative for the hotel association was quoted as stating, “none of those arguments could be made if you had no AED at all.” The hotel industry is far from alone in its ambivalence toward AED technology. American retail stores have been similarly reluctant to deploy defibrillators. For example, a customer can purchase an AED from Walmart for \$1,235 however, should that same customer experience a sudden cardiac arrest while shopping in the store, defibrillation will have to wait until the paramedics arrive.

To facilitate the placement of AEDs in public places across the United States and assuage concerns regarding liability risk there must be an unambiguous, nation-wide baseline of liability protections. To achieve this goal Congress should pass HR 4152, the Cardiac Arrest Survival Act of 2015. The bill will create a nationally uniform baseline of protection from civil liability for persons who use AEDs in perceived medical

emergencies, who own or hold other property interests in AEDs, or who own, occupy, or manage premises in which an AED is used or from which an AED is taken for use in a perceived medical emergency. Reducing the current uncertainty surrounding AED acquisition and use will encourage the deployment of additional AEDs, which will ultimately save lives that would otherwise have been lost to cardiac arrest.

Conclusions

Uncertainty regarding liability exposure is the unintended consequence of the current menagerie of state laws governing AED deployment and liability protection. The result is a virtual speed brake on the dissemination of this now mature technology. The current legislative melange of state AED provisions impedes the deployment of this simple, irreplaceable, decades-proven, therapy. Congress can remedy this problem with the passage of the Cardiac Arrest Survival Act of 2015, which will provide a nationwide baseline of liability protections for the owners of AEDs and the Good Samaritan rescuers.

REFERENCES

1. Nichol G, Thomas E, Callaway CW, et al. Regional variation in out-of-hospital cardiac arrest incidence and outcome. *JAMA*. 2008;300:1423-143.
2. Cummins RO, Ornato JP, Thies WH, Pepe PE. Improving survival from sudden cardiac arrest: the “chain of survival” concept”: a statement for health professionals from the Advanced Cardiac Life Support Subcommittee and the

- Emergency Cardiac Care Committee, American Heart Association. *Circulation*. 1991;83:1832-47.
3. Cobb LA, Fahrenbruch CE, Olsufka M, Copass MK. Changing incidence of out-of-hospital ventricular fibrillation, 1980–2000. *JAMA*. 2002;288: 3008–3013.
 4. Gallagher JE, Lombardi G, Gennis P, et al. Effectiveness of Bystander Cardiopulmonary Resuscitation and Survival Following Out-of-Hospital Cardiac Arrest. *JAMA*. 1995;274:1922-1925.
 5. Weisfeldt ML, Kerber RE, McGoldrick RP, et al. Public access defibrillation: A statement for healthcare professionals from the American Heart Association Task Force on Automatic External Defibrillation. *Circulation*. 1995;92:2763.
 6. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med*. 2000;343:1206-9.
 7. Page RL, Joglar JA, Kowal RC et al. Use of automated external defibrillators by a US airline. *N Engl J Med*. 2000;343:1210-16.
 8. The Public Access Defibrillation Trial Investigators. Public-access defibrillation and survival after out-of- hospital cardiac arrest. *N Engl J Med*. 2004;351:637-46.
 9. White RD, Hankins DG, Bugliosi TF. Seven years' experience with early defibrillation by police and paramedics in an emergency medical services system. *Resuscitation*. 1998;39:145-51.

10. Myerburg RJ, Fenster J, Velez M, et al. Impact of community-wide police car deployment of automated external defibrillators on survival from out-of-hospital cardiac arrest. *Circulation*. 2002;106:1058-1064.
11. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. *N Engl J Med*. 2002;347:1242-7.
12. Hazinski MF, Idris AH, Kerber RE, et al. Lay rescuer automated external defibrillator ("public access defibrillation") programs: lessons learned from an international multicenter trial: advisory statement from the American Heart Association Emergency Cardiovascular Committee; the Council on Cardiopulmonary, Perioperative, and Critical Care; and the Council on Clinical Cardiology. *Circulation*. 2005;111:3336-40.
13. Folke F, Lippert FK, MD; Nielsen SL. Et al. Location of Cardiac Arrest in a City Center. Strategic Placement of Automated External Defibrillators in Public Locations. *Circulation*. 2009;120:510-517.
14. Aufderheide T, Hazinski F, Nichol G, et al. Community lay rescuer automated external defibrillator programs. Key state legislative components and implementation strategies. A summary of a decade of experience for healthcare providers, policymakers, legislators, employers, and community leaders from the American Heart Association Emergency Cardiovascular Care Committee, Council on Clinical Cardiology, and Office of State Advocacy. *Circulation*. 2006;113:1260-1270.
15. New York State Public Health Law Article 30 § 3000-b
16. Virginia H.B. 1860, April 2003.

17. Gundry JW, Comess KA, DeRook FA, et al. Comparison of naïve sixth-grade children with trained professionals in the use of an automated external defibrillator. *Circulation*. 1999;100:1703-07.
18. Weisfeldt ML, Griffith C, Aufderheide TP, et al. Bystander administered AED shock improves survival from out of hospital cardiac arrest in US and Canada. *Circulation*. 2007;116:II-385-II-386. Abstract
19. New Jersey Chapter Law 34 1999; Title 2A: 62A
20. South Carolina Title 44, chapter 76
21. Louisiana S.B. No 100, 1999
22. K.S.A. 1997 Supp. 65-6144 §18A
23. Illinois Senate Bill 458, 91st General Assembly
24. Public Law 105-170, 105th Congress
25. 66 FR 19028
26. <http://www.ahla.com/PressRoom.aspx?id=26468&terms=aed>
27. <http://online.wsj.com/article/SB123543325221454001.html>

Mr. PITTS. The chair thanks the gentleman, now recognizes Dr. Gregg, 5 minutes for your summary.

STATEMENT OF ANTHONY GREGG

Dr. GREGG. Good morning, Mr. Chairman, members of the subcommittee. I am Anthony Gregg, professor and chief of the Division of Maternal-Fetal Medicine at the University of Florida. I am board certified in obstetrics and gynecology, maternal-fetal medicine, and clinical genetics. I have been in practice for over 20 years specializing in high-risk pregnancies. I am here today as a representative of the American College of Medical Genetics and Genomics.

ACMG is a specialty society representing U.S. clinical and laboratory medical geneticists, who are certified by the American Board of Medical Genetics and Genomics. There are nearly 2,000 ACMG members, including genetic counselors, nurses, and public health geneticists. Delivery of genetic and genomic health care is an exciting area that has transformed and continues to alter the practice of medicine.

Medical genomics refers to the knowledge of human DNA organization and structure along with an appreciation of the environmental impacts that lead to health and disease. Medical genomics is now applicable in the delivery of prenatal and postnatal patient care, including fetal and neonatal screening for genetic conditions.

I am also here today in the capacity as lead author of the May 2013 ACMG policy statement on noninvasive prenatal screening for fetal aneuploidy. The genetics and genomics world is fast moving. Noninvasive prenatal screening, NIPS, using cell-free DNA was introduced clinically in the United States about 4 years ago. The ACMG statement on this technology outlines test limitations and major issues to consider with regards to test limitations. It emphasizes the screening nature of this test and states clearly that false positive and false negative results occur. In fact, ACMG introduced the name, noninvasive prenatal screening, NIPS. The S in the acronym is meant to emphasize the screening nature of this test.

The ACMG document addresses the importance of clear language when conveying laboratory test results and recommends that laboratories offering this testing adhere to accepted standards and guidelines for practice. Uniquely, the statement includes a number of information resources available to patients and providers.

ACMG supports H.R. 3441, the Accurate Education for Prenatal Screenings Act. H.R. 3441 recognizes that NIPS is unique. It has better screening test metrics than any technology which has preceded it and any other currently in use. It is a technology that is easy to implement. It is noninvasive, which means it requires only a blood draw from a patient's perspective. These features within a rapidly changing genetics and genomic medical practice environment creates challenges for many patients and providers of obstetric care.

NIPS has seen rapid uptake by providers and their patients, and it is increasingly offered to a large proportion of pregnant women. This has caused a paradigm shift in the way prenatal genetic screening takes place. Every aspect of screening is impacted, including pretest counseling, sample collection and shipping, laboratory testing, and post-test counseling, and follow-up.

Counseling patients is at the heart of the clinical utility of NIPS. Nondirective, but informed counseling requires training and skill. Patient aids, literacy level, spoken language, and baseline anxiety varies among patients. Medical geneticists are uniquely trained to address patient heterogeneity. ACMG agrees with the goal of H.R. 3441. Clinicians are going to provide patients with both pretest and post-test counseling when offering NIPS in order to avoid any potential harm or confusion.

There are nearly 4 million U.S. births annually, and it is imperative that obstetric care providers, including obstetricians, family medicine doctors, nurse midwives, and practitioners have access to accurate educational materials that ensure patients receive accurate pretest counseling. Pretest education and counseling leading to informed decisionmaking are critical components of any genetic screening process. The great majority of normal results are communicated to patients by the provider or their designee that counseled and offered the test. However, abnormal results may not be easy for nongenetics trained professionals to interpret. Sometimes these must be put into the context of personal and medical family history in order for patients to receive accurate information. A deep understanding of genomic medicine is required.

We applaud Congressmen Herrera Beutler and Roybal-Allard for including provisions in H.R. 3441 that emphasize the importance of both pretest education and counseling as well as the need for accurate and patient-specific follow-up when results point to a possible fetal genetic condition.

Mr. Chairman and members of the committee, thank you for focusing on this important issue for women and families. ACMG looks forward to working with you to ensure access to accurate, reliable, and up-to-date information. Thank you.

[The statement of Dr. Gregg follows:]

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On Behalf of the
American College of Medical Genetics and Genomics (ACMG)

House Committee on Energy and Commerce
Subcommittee on Health
Hearing: "Examining Legislation to Improve Health Care and Treatment" and on
H.R. 3441, the "Accurate Education for Prenatal Screenings Act"

December 9, 2015

Good morning, Mr. Chairman and Members of the Subcommittee. I am Anthony Gregg, Professor and Chief of the Division of Maternal-Fetal Medicine at University of Florida Department of Obstetrics and Gynecology. I am board-certified in Obstetrics and Gynecology, Maternal-Fetal Medicine, and Clinical Genetics. I have been in practice for over 20 years, specializing in high risk pregnancies.

I am here today as a representative of the American College of Medical Genetics and Genomics (ACMG). Delivery of genetic and genomic healthcare is an exciting and rapidly moving area that has transformed and continues to alter the practice of medicine. ACMG is the specialty society representing U.S. clinical and laboratory Medical Geneticists who are certified by the American Board of Medical Genetics and Genomics. There are nearly 2,000 ACMG members including genetic counselors, genetics nurses, and public health geneticists. Medical genetics refers to the application of the principles of inheritance and our knowledge of human genes to diagnose, prevent, and treat disease with the aim of improving health. Medical genomics refers to the knowledge of human DNA organization and structure, along with an appreciation of environmental interactions that lead to health and disease. Medical genomics is now applicable in the delivery of prenatal and postnatal patient care including fetal and neonatal screening for genetic conditions.

I am also here today in my capacity as lead author of the May 2013 ACMG Policy Statement on "Noninvasive Prenatal Screening for Fetal Aneuploidy". The genetics and genomics world is fast-moving. Non-invasive prenatal screening using cell free DNA was introduced clinically in the U.S. about 4 years ago. The ACMG statement on this technology outlines test limitations and major issues to consider with regard to test implementation. The statement addresses NIPS in the context of other prenatal screening options, the need for pre- and post-test education, and the importance of result confirmation when feasible using diagnostic approaches such as chorionic villous sampling (CVS) and amniocentesis. It emphasizes the screening nature of this test and states clearly that false positive and false negative results occur. In fact, ACMG introduced the name "Noninvasive prenatal screening" (NIPS). The "S" in the acronym is meant to emphasize the screening nature of this test. The ACMG document addresses the importance of clear language when conveying laboratory test results, and recommends that laboratories offering this testing adhere to accepted standards and guidelines for practice. Uniquely, the statement includes a number of information resources available to patients and providers.

The ACMG writing group has reformed and is in the process of incorporating recent scientific advances in understanding NIPS technology. This includes clinical utility across the reproductive age spectrum, and added cautions related to results interpretation.

ACMG supports H.R. 3441, the Accurate Education for Prenatal Screenings Act. H.R. 3441 recognizes that NIPS is unique. This genomics based technology offers great promise for patients and their families. It has better screening test metrics (sensitivity, specificity, positive and negative predictive values) than any technology which has preceded it and any other currently in use. It is a technology that is easy to implement. It is non-invasive, which means it requires only a blood draw from a patient's perspective. These features, within a rapidly changing genetics and genomic medical practice environment, create challenges for many patients and providers of obstetric care. NIPS has seen rapid uptake by obstetric providers and their patients and is increasingly offered to a large proportion of pregnant women. This has caused a paradigm shift in the way prenatal genetic screening takes place. Every aspect of screening is impacted, including pre-test counseling, sample collection and shipping, laboratory testing, and post-test counseling and follow-up. Counseling patients is at the heart of clinical utility of NIPS. Non-directive, but informed counseling requires training and skill. Patient age, literacy level, spoken language, and baseline anxiety vary among patients. Medical geneticists and genetics counselors are uniquely trained to address patient heterogeneity. Board certified laboratory geneticists typically direct the laboratories in which NIPS is performed.

ACMG agrees with the goal of H.R. 3441, that it is imperative for clinicians to provide patients with both pre-test and post-test counseling when offering NIPS, in order to avoid any potential patient harm or confusion. We recognize that with nearly 4 million US births annually, it is imperative that obstetric care providers, including obstetricians, family medicine physicians, nurse midwives and nurse practitioners, have access to accurate educational materials that ensure patients receive accurate pre-test counseling. Pre-test education and counseling leading to informed decision-making are critical components of any genetic screening process. The great majority of "normal" results are communicated to patients by the provider (or their designee) that counseled and offered the test. However, results that are "abnormal" may not be easy for non-genetics trained professionals to interpret. Sometimes results must be put into the context of a person's medical and family in order for patients to receive the most accurate information. A deep understanding of genomic medicine is often required. Educational content for patients along with provider education and

clinical decision support tools will continue to be important long into the future as genomic technology advances rapidly in the laboratory and is applied with great hope in the clinical setting.

We applaud Congresswomen Herrera Beutler and Roybal-Allard for including provisions in H.R. 3441 that emphasize the importance of both pre-test education and counseling as well as the need for accurate and patient specific follow-up when results point to a possible fetal genetic condition. As NIPS technology has become more widely utilized, H.R. 3441 seeks to ensure that a broad representative group of stakeholders, such as those mentioned earlier in my testimony, be brought together to identify gaps and needs, that will ensure broad and specific educational needs of providers and patients are taken into account.

ACMG has experience working with government agencies in bringing stakeholders together and allowing broad input and deliberations in genetic and genomic screening. At the direction of the Health Resources and Services Administration, we worked to create a uniform standard across the country for newborn screening, which ensures all babies are afforded screening for genetic conditions that have been carefully vetted for inclusion in statewide screening programs. These efforts continue under the Newborn Screening and Translational Research Network program, where data is shared nationwide in an effort to improve child health. ACMG also works through the National Human Genome Research Institute to curate genetics and genomics data as part of the ClinGen Project. ClinGen assists laboratories in reporting results that would otherwise have uncertain clinical impact on patient care. In essence, ClinGen curation of data provides patients and providers accurate and data-driven information leading to the right diagnoses, prognoses, and treatment decisions. The rapid evolution of NIPS technology and the growing pains that result from new technologies being incorporated into clinical care require input from many stakeholders, timely response, dissemination of accurate information, and constant curation. ACMG commends H.R. 3441 for furthering these critical goals.

Mr. Chairman and Members of the Committee, thank you for focusing on this important issue for women and families. ACMG looks forward to working with you to ensure access to accurate, reliable, and up-to-date information.

ACMG statement on noninvasive prenatal screening for fetal aneuploidy

Anthony R. Gregg, MD¹, S.J. Gross, MD², R.G. Best, PhD³, K.G. Monaghan, PhD⁴, K. Bajaj, MD², B.G. Skotko, MD⁵, B.H. Thompson, MD⁶ and M.S. Watson, PhD⁶; are The Noninvasive Prenatal Screening Work Group of the American College of Medical Genetics and Genomics

Disclaimer: This statement is designed primarily as an educational resource for clinicians to help them provide quality medical services. Adherence to this statement is completely voluntary and does not necessarily assure a successful medical outcome. This statement should not be considered inclusive of all proper procedures and tests or exclusive of other procedures and tests that are reasonably directed to obtaining the same results. In determining the propriety of any specific procedure or test, the clinician should apply his or her own professional judgment to the specific clinical circumstances presented by the individual patient or specimen. Clinicians are encouraged to document the reasons for the use of a particular procedure or test, whether or not it is in conformance with this statement. Clinicians also are advised to take notice of the date this statement was adopted, and to consider other medical and scientific information that becomes available after that date. It also would be prudent to consider whether intellectual property interests may restrict the performance of certain tests and other procedures.

Noninvasive assessment of the fetal genome is now possible using next-generation sequencing technologies. The isolation of fetal DNA fragments from maternal circulation in sufficient quantity and sizes, together with proprietary bioinformatics tools, now allows patients the option of noninvasive fetal aneuploidy screening. However, obstetric care providers must become familiar with the advantages and disadvantages of the utilization of this approach as analysis of cell-free fetal DNA moves into clinical practice. Once informed, clinicians can provide efficient pretest and posttest counseling with the goal of avoiding patient harm. It is in the public's best interest that test

results contain key elements and that laboratories adhere to established quality control and proficiency testing standards. The analysis of cell-free fetal DNA in maternal circulation for fetal aneuploidy screening is likely the first of major steps toward the eventual application of whole fetal genome/whole fetal exome sequencing.

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Key Words: cell-free fetal DNA; noninvasive prenatal testing; prenatal genetic screening

The American College of Medical Genetics and Genomics (ACMG) believes that the application of genetic technology, particularly when used in the prenatal setting, needs to be supported by prospective clinical trials and considered carefully before its incorporation into routine clinical care. The ACMG has previously published guidelines on prenatal screening for Down syndrome, which have successfully assisted health-care providers and their patients during pregnancy.¹

One of the major breakthroughs in obstetrical care was the advent of prenatal genetic diagnosis, initially by amniocentesis in the second trimester of pregnancy. Subsequently, chorionic villus sampling during the first trimester allowed for earlier diagnosis and management. However, the potential risk of fetal loss secondary to an invasive procedure has driven the search for noninvasive approaches for genetic screening and diagnosis. Until recently, noninvasive screening for aneuploidy relied on either the measurement of maternal serum analytes and/or ultrasonography with positive screen rates of ~5% and detection rates of 50–95%, depending on the screening strategy

utilized. More recent advances in genomics and genomic technologies have resulted in the development of a noninvasive prenatal screening (NIPS) test using cell-free fetal DNA sequences isolated from a maternal blood sample.^{2–6} About 10% of DNA in maternal serum is of fetal origin,^{4,7,8} this has been used for prenatal Rh determination and gender identification. Using next-generation sequencing platforms, millions of amplified genetic fragments can be sequenced in parallel (massively parallel sequencing). Platforms differ according to whether amplified regions throughout the genome, chromosome-specific regions, or single-nucleotide polymorphisms are the targets for sequencing. Furthermore, by using powerful bioinformatics tools, differences between maternal and fetal sequences and dosage differences in identical sequences or a reference chromosome can be determined and used for noninvasive screening for fetal aneuploidy.^{9,10}

Although studies are promising and demonstrate high sensitivity and specificity with low false-positive rates, there are limitations to NIPS. Specificity and sensitivity are not uniform for

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all chromosomes; this is due, at least in part, to differing content of cytosine and guanine nucleotide pairs.⁹ False-positive screening results do occur. Furthermore, the sequences derived from NIPS are derived from the placenta and therefore, like chorionic villus sampling, may not reflect the true fetal karyotype. Therefore, invasive testing is recommended for confirmation of a positive screening test and should remain an option for patients seeking a definitive diagnosis. This document addresses some of the challenges of incorporating NIPS for fetal aneuploidy into obstetrical practice.

WHERE DOES NIPS FIT INTO THE ANEUPLOIDY SCREENING PARADIGM?

NIPS is, as the acronym implies, a screening test to identify pregnancies at risk for common autosomal aneuploidies (e.g., trisomy 21, 18, and 13).⁶ Some laboratories also offer screening for sex chromosome aneuploidies.

For women seeking a definitive diagnosis, invasive procedures for diagnostic testing, such as amniocentesis or chorionic villus sampling, should be offered.

WHAT ARE THE CURRENT LIMITATIONS OF NIPS?

1. Risk assessment is limited to specific fetal aneuploidies (trisomy 13, 18, and 21) at this time. Some platforms also screen for sex chromosome abnormalities. Approximately 50% of cytogenetic abnormalities routinely identified by amniocentesis will not be detected when trisomy 21, 18, and 13 are the only aneuploidies being screened. When patients <35 years or >35 years are considered separately, 75 and 43% of cytogenetic abnormalities will be missed, respectively.^{11,12}
2. Chromosomal abnormalities such as unbalanced translocations, deletions, and duplications will not be detected by NIPS. Therefore, when fetal anomalies are detected, invasive diagnostic testing and cytogenomic microarray analysis are more likely to detect chromosomal imbalances than NIPS and may be a better testing option.¹³
3. NIPS is not able to distinguish specific forms of aneuploidy. For example, NIPS cannot determine if Down syndrome is due to the presence of an extra chromosome (trisomy 21), a Robertsonian translocation involving chromosome 21, or high-level mosaicism. Identification of the mechanism of aneuploidy is important for recurrence risk counseling and emphasizes the importance of diagnostic testing following NIPS.
4. NIPS does not screen for single-gene mutations.
5. Uninformative test results due to insufficient isolation of cell-free fetal DNA could lead to a delay in diagnosis or eliminate the availability of information for risk assessment. Biologic factors associated with reduced available cell-free fetal DNA include a high body mass index and early gestational age (<10 weeks gestation).^{14,15}
6. Currently, it takes longer for NIPS test results to be returned than for test results on maternal serum analytes. Providers should keep this in mind when offering patients NIPS if timing is important for reproductive decision making. In

most cases, NIPS is offered between 10 and 20 weeks gestation, which allows time for follow-up of positive test results. It is reasonable to offer NIPS after 20 weeks if an expectant woman desires information regarding risk, reassurance, or knowledge in order to inform obstetrical management and/or preparation for birth.

7. NIPS does not screen for open neural tube defects. Maternal serum α -fetoprotein testing should still be offered at 15–20 weeks gestation to screen for open neural tube defects even when NIPS is performed.¹
8. NIPS does not replace the utility of a first-trimester ultrasound examination, which has been proven to be useful for accurate gestational dating, assessment of the nuchal translucency region to identify a fetus at increased risk for a chromosome abnormality, identification of twins and higher-order pregnancies, placental abnormalities, and congenital anomalies.^{16–19}
9. Limited data are currently available on the use of NIPS in twins and higher-order pregnancies. Utilization in these clinical settings may depend on specific laboratory platforms, proprietary bioinformatics, and clinical validation studies.
10. NIPS has no role in predicting late-pregnancy complications.

SHOULD PRETEST OR POSTTEST GENETIC COUNSELING ABOUT ANEUPLOIDY SCREENING BE PERFORMED?

Pretest information should be provided by a prenatal care provider, a trained designee, or a genetic counselor to ensure patients make informed decisions. Aneuploidy screening is not a routine prenatal test; it is acceptable for patients to decline screening.

Pretest information should include:

1. A brief explanation of the purpose of NIPS.
2. Advantages of NIPS as compared with maternal serum analyte screening.
 - On the basis of available data, detection rates appear to be higher.
 - There is a high negative predictive value for Down syndrome. This may be important for patients seeking to avoid the risks (e.g., fetal loss) inherent with invasive testing.
 - NIPS has a lower false-positive rate, meaning fewer women will receive a “positive” screen, necessitating fewer invasive procedures.
 - Risk assessment is less dependent on gestational age.
3. Considerations for follow-up invasive testing if NIPS indicates an increased risk for aneuploidy.
4. Limitations of NIPS.

Posttest counseling is recommended when NIPS indicates that a patient is at high risk or has a “screen-positive” result. When a “screen-negative” result is encountered, residual

risk should be reinforced. When obstetric care providers are uncomfortable with providing posttest counseling, referral to a certified genetics professional is warranted. Posttest counseling should be individualized but should include at least the following discussion points:

1. There is a possibility of false-positive screening results, which may be due to confined placental mosaicism or theoretically a "vanishing twin."
2. NIPS is not diagnostic; therefore, confirmatory testing (chorionic villus sampling or amniocentesis) is recommended, and the risks of those procedures should be reviewed.
3. If the patient declines invasive testing, an effort should be made to obtain a sample of cord blood for postnatal confirmation by karyotype or cytogenomic microarray analysis.
4. Accurate, up-to-date, and balanced information about Down syndrome (or other tested conditions) should be provided. There are a number of resources available (see Resources).

Posttest counseling after a "screen-uninformative" result should include the offer of invasive diagnostic testing.

Commentary

The importance of sensitivity and specificity in comparing clinical tests and the use of these measures in a public health environment cannot be overstated; however, patient care focuses on two distinctly different metrics used to determine the validity of clinical tests: positive and negative predictive value (PPV and NPV, respectively). Clinical sensitivity and specificity are independent of the prevalence of Down syndrome and are known to be high when comparing NIPS technologies with other methods of screening for fetal aneuploidy. However, PPV and NPV can be expected to vary with the population prevalence of Down syndrome. Although the NPV can be considered high, PPV is not as desirable owing to the relatively low prevalence of Down syndrome across the age spectrum of women giving birth (0.6% at second trimester amniocentesis).¹¹ By definition, diagnostic tests, as compared with screening tests, have very high PPV and NPV, approaching 100%.

WHAT SHOULD LABORATORIES PERFORMING NIPS DISCLOSE WHEN REPORTING RESULTS TO HEALTH-CARE PROVIDERS?

There are multiple ways to express risk; however, test results should be expressed in the clearest form possible to avoid confusion and misinterpretation. All reports should clearly state that NIPS is a screening test and not diagnostic. The language in the report should clarify the need for posttest counseling for patients with "screen-positive" or "screen-uninformative" results.

WHAT TYPES OF OVERSIGHT ARE REQUIRED OF THE ANALYTICAL AND BIOINFORMATICS ASPECTS OF NIPS TEST SYSTEMS?

The ACMG recommends compliance with its standards and guidelines for clinical genetics laboratories. Considering the

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nature of the methods used, NIPS is subject to the same quality control and proficiency testing requirements as those for clinical molecular laboratory tests. Quality control should include the entire test process, including preanalytical, analytical, and postanalytical phases. Until external proficiency testing programs sponsored by a professional or regulatory organization are available, alternative methods for proficiency testing, preferably using an interlaboratory comparison method, is required. Test performance characteristics should be available to patients and providers accessing testing.

NIPS methodologies take advantage of proprietary bioinformatics to determine the risk of specific aneuploidies for a given pregnancy. Comparative effectiveness studies of the performance of the different algorithms should be performed.

CONCLUSION

NIPS for fetal aneuploidy has arrived; however, as with most new technologies, there is room for refinement. The ACMG encourages providers of NIPS technology to make serious efforts to provide the more clinically relevant metrics—PPV and NPV. This can be accomplished through a funded registry where efforts are made to confirm and archive not only true positives, but also false positives and true negatives. The ethical principle of distributive justice causes us to reflect on who will pay for NIPS and who should be insured for the procedure. No doubt NIPS costs will come down; however, for NIPS to establish roots in the perinatal aneuploidy screening paradigm, cost as a barrier to population-based screening must be minimized. NIPS technology is perhaps only a few steps removed from an eventual whole-genome array, whole-genome sequencing, or whole-exome sequencing of noninvasively isolated cell-free fetal DNA. Whether this best comes about by simultaneously amplifying maternal sequence and subtracting this from fetal sequence, or after isolation and amplification of fetal sequences unique from maternal, is yet to be resolved.

RESOURCES

Understanding a Down syndrome diagnosis

This material (<http://www.lettercase.org>), available in print and digital versions, both in English and in Spanish, is intended for expectant couples who have received a prenatal diagnosis of Down syndrome but have not yet made a decision regarding their pregnancy options. The book was prepared with assistance from the ACMG, the American Congress of Obstetricians and Gynecologists, the National Society of Genetic Counselors, the National Down Syndrome Society, and the National Down Syndrome Congress.

"Brighter Tomorrows"

This site (for medical professionals: <http://www.brightertomorrow.org>; for expectant parents: <http://www.brightertomorrow.org>) provides simulation training for health-care professionals who deliver a prenatal diagnosis to expectant couples; the Web page also provides information, in English and Spanish, about Down syndrome to new and expectant couples

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who have received a prenatal diagnosis of Down syndrome. The project was funded by federal grants; efficacy was researched and published in peer-reviewed journals.

“Health-care supervision for children with Down syndrome”

This clinical report (<http://pediatrics.aappublications.org/content/128/2/393>), written by the Committee on Genetics of the American Academy of Pediatrics, provides guidance to the health-care professional involved in prenatal consultations; resources for parents are also listed.

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DISCLOSURE

S.J.G. discloses grants related to prenatal screening. B.G.S. volunteers in a nonpaid capacity with Down syndrome advocacy organizations. The other authors declare no conflict of interest.

REFERENCES

1. Driscoll DA, Gross SJ. First trimester diagnosis and screening for fetal aneuploidy. *Genet Med* 2008;10:73–75.
2. Paimonaki GE, Kloza EM, Lambert-Messerlian GM, et al. DNA sequencing of maternal plasma to detect Down syndrome: an international clinical validation study. *Genet Med* 2011;13:913–920.
3. Ehrich M, Deciu C, Zwiefelhofer T, et al. Noninvasive detection of fetal trisomy 21 by sequencing of DNA in maternal blood: a study in a clinical setting. *Am J Obstet Gynecol* 2011;204:205.e1–205.11.
4. Norton ME, Brar H, Weiss J, et al. Non-Invasive Chromosomal Evaluation (NICE) Study: results of a multicenter prospective cohort study for detection of fetal trisomy 21 and trisomy 18. *Am J Obstet Gynecol* 2012;207:137.e1–137.e8.
5. Bianchi DW, Platt LD, Goldberg JD, Abuhamad AZ, Sehntert AJ, Rava RP. Genome-wide fetal aneuploidy detection by maternal plasma DNA sequencing. *Obstet Gynecol* 2012;119:890–901.
6. Nicolaides KH, Syngelaki A, Ashoor G, Birdir C, Touzet G. Noninvasive prenatal testing for fetal trisomies in a routinely screened first-trimester population. *Am J Obstet Gynecol* 2012;207:374.e1–374.e6.
7. Ashoor G, Syngelaki A, Poon LC, Rezende JC, Nicolaides KH. Fetal fraction in maternal plasma cell-free DNA at 11–13 weeks' gestation: relation to maternal and fetal characteristics. *Ultrasound Obstet Gynecol* 2013;41:26–32.
8. Sparks AB, Struble CA, Wang ET, Song K, Oliphant A. Noninvasive prenatal detection and selective analysis of cell-free DNA obtained from maternal blood: evaluation for trisomy 21 and trisomy 18. *Am J Obstet Gynecol* 2012;206:319.e1–319.e9.
9. Chen EZ, Chiu RW, Sun H, et al. Noninvasive prenatal diagnosis of fetal trisomy 18 and trisomy 13 by maternal plasma DNA sequencing. *PLoS ONE* 2011;6:e21791.
10. Liao GJ, Chan KC, Jiang P, et al. Noninvasive prenatal diagnosis of fetal trisomy 21 by allelic ratio analysis using targeted massively parallel sequencing of maternal plasma DNA. *PLoS ONE* 2012;7:e38154.
11. Forabosco A, Percesepe A, Santucci S. Incidence of non-age-dependent chromosomal abnormalities: a population-based study on 88965 amniocenteses. *Eur J Hum Genet* 2009;17:897–903.
12. Grati FR, Barlocco A, Grimi B, et al. Chromosome abnormalities investigated by non-invasive prenatal testing account for approximately 50% of fetal unbalances associated with relevant clinical phenotypes. *Am J Med Genet A* 2010;152A:1434–1442.
13. Wapner RJ, Martin CL, Levy B, et al. Chromosomal microarray versus karyotyping for prenatal diagnosis. *N Engl J Med* 2012;367:2175–2184.
14. Wataganara T, Peter I, Messerlian GM, Borgatta L, Bianchi DW. Inverse correlation between maternal weight and second trimester circulating cell-free fetal DNA levels. *Obstet Gynecol* 2004;104:545–550.
15. Ashoor G, Poon L, Syngelaki A, Mosimann B, Nicolaides KH. Fetal fraction in maternal plasma cell-free DNA at 11–13 weeks' gestation: effect of maternal and fetal factors. *Fetal Diagn Ther* 2012;31:237–243.
16. Bennett KA, Crane JM, O'Shea P, Lucelle J, Hutchens D, Copel JA. First trimester ultrasound screening is effective in reducing postterm labor induction rates: a randomized controlled trial. *Am J Obstet Gynecol* 2004;190:1077–1081.
17. Stenhouse E, Hardwick C, Maharaj S, Webb J, Kelly T, Mackenzie FM. Chorionicity determination in twin pregnancies: how accurate are we? *Ultrasound Obstet Gynecol* 2002;19:350–352.
18. Souka AP, Plais A, Kavalakis Y, Kosmas Y, Antsaklis P, Antsaklis A. Assessment of fetal anatomy at the 11–14-week ultrasound examination. *Ultrasound Obstet Gynecol* 2004;24:730–734.
19. Fong KW, Toi A, Salem S, et al. Detection of fetal structural abnormalities with US during early pregnancy. *Radiographics* 2004;24:157–174.

Mr. PITTS. The chair thanks the gentleman and now recognizes Dr. Breedlove, 5 minutes for your summary.

STATEMENT OF GINGER BREEDLOVE

Dr. BREEDLOVE. Chairman Pitts, Ranking Member Green, and members of the subcommittee on Health, it is truly my honor to be with you today to discuss the status of maternity care in the United States and the need for Congress to work with maternity care providers, including midwives, to improve a woman's access to these essential services.

I am a certified nurse-midwife with 37 years of clinical experience and a professor of graduate nursing and nurse-midwifery at Shenandoah University in Winchester, Virginia. Today I join you as president of the American College of Nurse-Midwives.

ACNM is the professional organization for certified nurse-midwives and certified midwives, and our vision is a midwife for every woman. Our mission is to support midwives and advance the practice of midwifery in order to achieve optimal health for women through their lifespan with expertise in well-women and gynecologic care promoting optimal pregnancy, physiologic birth, postpartum care, and care of the newborn through the first 28 days of life. CNMs are licensed, independent healthcare providers with prescriptive authority in all 50 states, the District of Columbia, American Samoa, Guam, and Puerto Rico.

Medicare, Medicaid, and all other Federal programs provide access to midwifery services. Approximately 82 percent of CNMs have a master's degree, and as of 2010, a graduate degree is required to entry into our practice. As president of ACNM, I am proud to fully support the Improving Access to Maternity Act, H.R. 1209, as authored by Representative Michael Burgess and Representative Lois Capps. I thank them for championing this important public health initiative on behalf of women in rural and urban areas experiencing shortages of qualified maternity care providers.

I also wish to thank the American College of Obstetricians and Gynecologists, which has been a strong partner supporting this legislation along with numerous nursing and maternal health groups.

H.R. 1209 would establish a maternity care shortage designation within existing designated health professional shortage areas. The goal of this legislation is to identify areas in the U.S. experiencing significant shortages of full scope professionals, including midwives. Such information will enable Congress and the administration to better understand and address needs of women of child-bearing age and allow appropriate resources to be focused on those unique needs.

ACNM believes enabling access to maternity care professionals in underserved areas can reduce overall maternity care costs by ensuring women have access to necessary prenatal and delivery options. For example, we know nearly half of the 4 million annual births in the U.S. each year are covered by the Medicaid program. Thus, both Federal and state governments have a clear financial stake in ensuring high-quality care is being provided at a reasonable cost. Too many of these births require expensive interventions that could double the cost of a birth and, in fact, increase a wom-

an's risk for maternal mortality. The CDC reports that the rate of maternal mortality has more than doubled in the past few decades.

Today, women giving birth in our country are at a higher risk of dying than those giving birth in China or Saudi Arabia. This tragedy must be addressed. While there are several causes, one solution is better access to maternity care providers, including midwives, who can monitor a woman's pregnancy, provide prenatal care, adequate postnatal care, and promote a healthy transition to parenthood without complications.

Research shows that in 2011, some 40 percent of counties had neither a certified nurse midwife nor an OB-GYN to provide direct patient care services. For millions of women, shortages in maternity care providers can result in long waiting times for appointments, and long travel times to their prenatal care or site of their birth. We know inadequate prenatal care is associated with increased risk of prematurity, stillbirth, and neonatal death.

H.R. 1209 will ensure policymakers have necessary information on maternity care shortage areas. Midwives and OB-GYNs are already full participants in the National Health Service Corps, which places practitioners in underserved areas, yet, no maternity care shortage designation exists. Allowing the National Health Service Corps to place them where their unique skills are most needed will benefit the women of our country.

Thank you for your consideration of this legislation today.

[The statement of Ms. Breedlove follows:]



**Testimony of the American College of
Nurse-Midwives**

**at a Hearing of the House Committee
on Energy and Commerce
Subcommittee on Health**

on the

**“Improving Access to Maternity Care
Act” (H.R.1209)**

Wednesday, December 9, 2015

Summary of Major Points in Testimony

- Ginger Breedlove, CNM, PhD, FACNM - President of the American College of Nurse-Midwives
- Existing and rapidly emerging shortages of midwives and other maternity care providers warrant action in the Congress to meet the needs of women in urban and rural underserved areas of the U.S.
- The Improving Access to Maternity Care Act (H.R.1209) would provide the Health Resources and Services Administration the authority it needs to conduct research into these critical shortages relating to delivery of maternity care services and provide for appropriate placement of midwives and other maternity care providers in areas of critical need.
- Nearly half of the 4 million annual births in the United States each year are covered by the Medicaid program, and thus both federal and state governments have a clear financial stake in ensuring high quality care is being provided at a reasonable cost.
- The CDC reports that the rate of maternal mortality has more than doubled in the past few decades. Whereas 7.2 women died per 100,000 births in 1987, that number has increased to 17.8 deaths per 100,000 live births in 2009 and 2011.
- One solution to address the excessive cost, health disparities and poor outcomes of maternity care is better access to maternity care providers, such as midwives, who can monitor a woman's pregnancy and provide prenatal care, adequate postnatal care and promote a healthy transition to parenthood without complications.
- Midwives and OBGYNs already participate as primary care providers in the National Health Service Corp. H.R.1209 would simply direct them to areas in critical need of maternity care providers rather than solely primary care.
- ACNM along with ACOG and many other national professional organizations support enactment of H.R.1209.

Chairman Pitts, Ranking Member Green, and members of the Subcommittee on Health, it is my honor to be with you today to discuss the status of maternity care in the United States and the need for Congress to work with maternity care providers, including midwives, to improve a woman's access to these essential services.

My name is Ginger Breedlove, CNM, PhD, FACNM. I am a certified nurse-midwife with 37 years of clinical experience. Currently, I am a Professor of graduate nursing and nurse-midwifery at Shenandoah University in Winchester, Virginia. I reside in Shawnee Mission, Kansas.

I join you today as the president of the American College of Nurse-Midwives (ACNM). ACNM is the professional organization for certified nurse-midwives (CNM) and certified midwives (CM). Our vision is "a midwife for every woman." Our mission is to support midwives and advance the practice of midwifery in order to achieve optimal health for women through their lifespan, with expertise in well woman and gynecologic care, promoting optimal pregnancy, physiologic birth, postpartum care, and care of the newborn thru the first 28 days of life.

CNMs are licensed, independent health care providers with prescriptive authority in all 50 states, the District of Columbia, American Samoa, Guam, and Puerto Rico. CNMs are defined as primary care providers under federal law. CMs are also licensed, independent health care providers who completed the same graduate midwifery education curriculum as CNMs and sit the same national certification boards, but do not complete a nursing degree. CMs are authorized to practice in Delaware, Missouri, New Jersey, New York, and Rhode Island. ACNM represents both CNMs and CMs.

In 2013, 94.6% of CNM/CM-attended births occurred in hospitals, 2.8% occurred in freestanding birth centers, and 2.6% occurred in homes. More than 50% of

CNMs/CMs list physician practices or hospitals/ medical centers as their principal employers.

Medicaid reimbursement for CNM care is mandatory in all states. Medicare and most Medicaid programs reimburse CNMs/CMs at 100% of physician rates. The majority of states also mandate private insurance reimbursement for midwifery services.

The Accreditation Commission for Midwifery Education (ACME) is the official accrediting body for CNM/CM education programs. There are 39 ACME-accredited midwifery education programs in the United States. Approximately 82% of CNMs have a master's degree. As of 2010, a graduate degree is required for entry to midwifery practice as a CNM/CM. 4.8% of CNMs have doctoral degrees, the highest proportion of all APRN groups.

As President of the ACNM, I am proud to fully support the "Improving Access to Maternity Care Act," (H.R.1209) as authored by Rep. Michael Burgess (R-TX) and Rep. Lois Capps (D-CA). I thank them for championing this important public health initiative on behalf of women, particularly those in rural and urban areas experiencing shortages of qualified maternity care providers. I also wish to thank the American College of Obstetricians and Gynecologists (ACOG) for their strong support of this legislation along with some 34 nursing organizations and other maternity related organizations. Copies of their support letters are part of my testimony today.

H.R.1209 would establish a maternity care shortage designation within existing designated health professional shortages areas. The goal of this legislation is to identify areas in the U.S. experiencing significant shortages of full scope maternity care professionals, including midwives and obstetricians/gynecologists. Greater information on the shortages of maternity care providers that exist will enable Congress and the Administration to better address needs of women of childbearing age and allow appropriate resources to be focused on those needs.

ACNM believes expanding access to maternity care professionals in underserved areas can reduce overall maternity care costs in the U.S. by ensuring women have access to necessary prenatal care and delivery options.

In a report issued in June of 2013, the Medicaid and CHIP Payment and Access Commission (MACPAC) highlights that having coverage for maternity services does not guarantee access to care. Access to maternity care professionals is a significant issue in many areas of the country due to the changing demographics of maternity care providers, variation among practice environments, and restructuring, regionalization and closure of many maternity care units.

Nearly half of the 4 million annual births in the United States each year are covered by the Medicaid program, thus both federal and state governments have a clear financial stake in ensuring high quality care is being provided at a reasonable cost. Too many of these births require expensive interventions, such as cesarean section (see Table 1 and Table 2), that can double the cost of a birth and increase a woman's risk of maternal mortality. We live in a country that spends more money on healthcare than any other industrialized nation, yet the U.S. ranks at or near the bottom on virtually all maternity care outcomes.

The CDC reports that the rate of maternal mortality has more than doubled in the past few decades. Whereas 7.2 women died per 100,000 births in 1987, that number has increased to 17.8 deaths per 100,000 live births in 2009 and 2011 (700-800 women die each year). Other countries less developed than the US have experienced a decline. Today women giving birth in the U.S. are at a higher risk of dying than those giving birth in China or Saudi Arabia. This is a national tragedy that must be addressed. While there are several causes, including a high cesarean rate in the U.S., one solution is better access to maternity care providers, such as midwives, who can monitor a

woman's pregnancy and provide prenatal care, adequate postnatal care and promote a healthy transition to parenthood without complications.

Using data from the Health Resource and Services Administration, Dr. Eugene R. Declercq, PhD, a professor in Boston University's School of Public Health, has shown that in 2011, 56 percent of US counties had no certified nurse-midwives (see Table 3), 46 percent of counties had no OB/GYN and 40 percent of counties had neither a certified nurse-midwife nor OB/GYN to provide direct patient care. For millions of women, shortages of maternity care providers can result in long waiting times for appointments and long travel times to prenatal care and/or birthing sites. We know that inadequate prenatal care is associated with increased risk of prematurity, stillbirth and neonatal death. (Partridge S, Balayla J, Holcroft CA, Abenhaim HA), " Inadequate prenatal care utilization and risks of infant mortality and poor birth outcome: A retrospective analysis of 28,729,765 U.S. deliveries over 8 years." *American Journal of Perinatology*, November 2012, vol 29, no. 10, pp. 787-793.)

Maternity care providers also face several workforce challenges. Concerns surrounding professional liability and unpredictable working hours affect an individual's enthusiasm for the field. Furthermore, flat entries into OB/GYN residencies by medical school graduates, and increasing sub-specialization by graduating medical residents are having an effect on the number of skilled providers available to attend births. In addition, A 2011 study by ACOG on the OB/GYN workforce showed that the profession is going through a demographic transition from a largely male to a largely female workforce. Women make different choices about their personal and professional lives than their male counterparts. For example, they work fewer hours per week and retire from obstetric practice a few years earlier. These individual choices are changing the productive capacity of the profession as a whole. (William F. Rayburn, MD, MBA, FACOG, "The Obstetrician Gynecologist Workforce in the United States: Facts, Figures, and Implications, American Congress of Obstetricians and Gynecologists, 2011.)

The number of certified nurse-midwives (CNMs) and certified midwives (CMs) completing their education each year has been increasing in recent years. In fact, it's increased by almost 50 percent since 2007. However, many more midwives are needed to meet the needs of most women, who are capable of experiencing a normal, healthy, physiologic birth.

A clearer picture of the outlined problems is needed. H.R.1209 will ensure policymakers have the necessary information on maternity care shortage areas so that concerns can be addressed by placing maternity care providers through the National Health Service Corp (NHSC).

Midwives and OB/GYNs are already full participants in the NHSC, and are currently placed in designated primary care shortage areas. However, our students increasingly tell us that upon graduation they want to provide their full scope of professional services, which would include prenatal care, labor care, attending birth of their patients, and postpartum care. A maternity care shortage designation will allow the Health Resources and Services Administration (HRSA) to better target maternity care professionals to these areas of critical need. Having a clear picture of where maternity care providers, obstetrical hospital units, and free-standing birth centers are located in relation to childbearing women will ensure that qualified professionals will be sent by the NHSC to areas of critical need.

We are pleased H.R.1209 enjoys bipartisan support in the House of Representatives. Thank you for your consideration of this legislation today. I urge this subcommittee and the House to pass this bill without delay. I am happy to answer any questions you may have regarding the status of maternity care in the U.S., the role of midwifery care, or components of the legislation.

Tables

Table 1

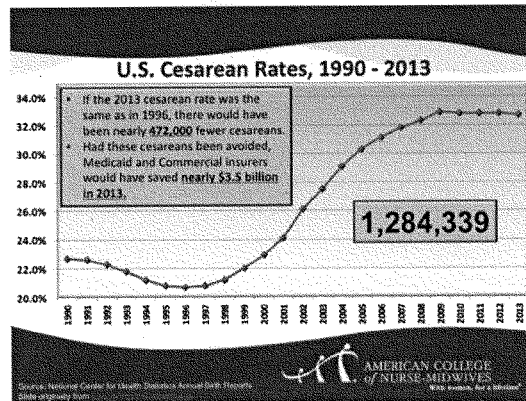


Table 2

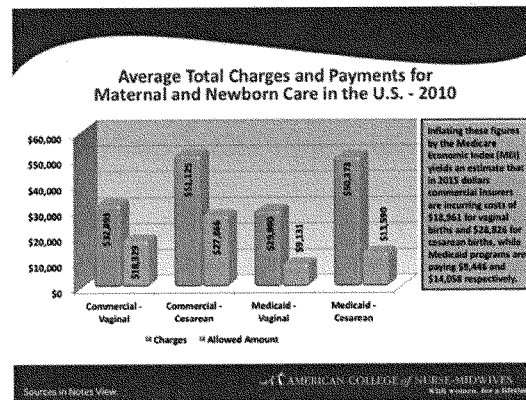
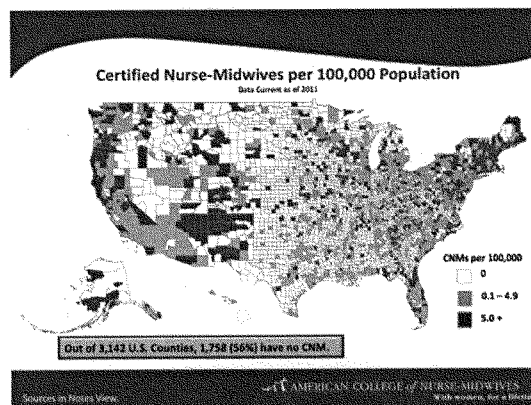


Table 3



Mr. PITTS. The chair thanks the gentlelady, now recognizes Dr. Trautman, 5 minutes for your summary.

STATEMENT OF DEBORAH E. TRAUTMAN

Ms. TRAUTMAN. Good morning. My name is Deborah Trautman, and I am the chief executive officer for the American Association of Colleges of Nursing. I want to thank the chairman for hosting this important meeting today, also recognizing Ranking Member Green and the opportunity to speak to you all about a very important issue for our Nation's health.

On behalf of H.R. 2713, Title VIII Nursing Workforce, I would also like to extend my gratitude to Representatives Capps and Joyce for introducing this legislation and for their work as the nursing caucus. Both of them are fierce champions for the nursing profession and for improving health in our Nation.

Additionally, I wish to thank House Energy and Commerce Committee members who have cosponsored this legislation, including Representatives Castor, Kennedy, Loeb sack, Matsui, Schrader, and Yarmuth. AACN, as you may know, represents 781 schools of nursing across the country in all 50 States and the District of Columbia. Our membership extends to 475,000 individuals, 18,000 full-time faculty, 457,000 nursing students, and deans who lead these institutions.

Healthcare delivery models are not static, as you know, neither is nursing education. This legislation would modernize the Title VIII nursing workforce development programs, thus creating alignment with transformational efforts underway in nursing and health care. With over 3 million licensed providers, registered nurses are the largest healthcare workforce in America and essential members of the healthcare team.

As we continue to ensure that all communities have access to care, it is essential that Title VIII nursing workforce development programs be reauthorized. This will ensure a continued pipeline of support for providers who spend the most time with patients, our Nation's nurses.

AACN, along with 51 other nursing organizations, collaborated with Representatives Capps and Joyce to identify four technical changes. The mutually agreed-upon changes promote the clinical nurse specialist role, which employs expertise to specific patient populations, nurse managed health clinics, which provide essential primary care, and the clinical nurse leader role, which is vital to care coordination.

Title VIII programs have supported the nursing profession for over five decades. In 2015, the Title VIII programs awarded 1,166 new and continuing grants. These grants bolster the nursing workforce, address nursing workforce diversity, improve and increase nursing faculty, improve quality, promote inter-professional education and training, and help meet the needs of our aging population.

Today, regional demands for nurses reflect some of the barriers to recruitment and retention, particularly in areas of nursing shortage. One Title VIII program, the advanced education nursing traineeship, helps us address this. In a study HRSA did recently, this program supported 5,650 students, of which 56 percent of

these students received training in medically underserved areas, and 48 percent received training in primary care settings.

One future nurse, who is a recipient of this traineeship, Britney Keplera, a doctor of nursing practice student at the University of Pittsburgh, students like Britney are prime examples of how this program reaches those who provide care to the underserved. Britney, as others, look forward to serving their local community, and Title VIII funding allows students to prioritize their future practice settings over choosing an area where salary will help offset their loans.

Another nurse, Lisa Van Cleave, a Ph.D. student at Hardin-Simmons University in Abilene, Texas, is supported through the nurse faculty loan programs. Lisa states that this financial aid will assist her in becoming a doctorally prepared faculty member. There is a critical demand for doctorally prepared faculty across the country.

Each year, hundreds of students like Britney and Lisa share with AACN how the nursing workforce development programs have provided them financial opportunity to work towards their ultimate career goal, providing high-quality, cost-effective care, and for many of them that includes becoming the faculty of the future who will teach tomorrow's nurses.

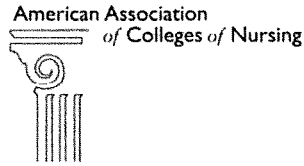
I thank the subcommittee for the opportunity to share the tremendous impact that Title VIII programs have had and how its recipients and their careers have and will continue to improve the health of our Nation.

I applaud the subcommittee for bringing H.R. 2713 to a hearing, as it is the necessary legislative step to support America's patients, their families, and the communities in which they live.

AACN is dedicated to working with this subcommittee and Congress to advance this legislation.

Thank you for the opportunity to comment.

[The statement of Ms. Trautman follows:]



WRITTEN TESTIMONY FOR THE RECORD
HOUSE COMMITTEE ON ENERGY AND COMMERCE, SUBCOMMITTEE ON HEALTH HEARING,
“EXAMINING LEGISLATION TO IMPROVE HEALTH CARE AND TREATMENT”

SUBMITTED BY: DEBORAH TRAUTMAN, PhD, RN, FAAN
PRESIDENT AND CHIEF EXECUTIVE OFFICER
ON BEHALF OF THE AMERICAN ASSOCIATION OF COLLEGES OF NURSING

DECEMBER 7, 2015

On behalf of the American Association of Colleges of Nursing (AACN), I respectfully submit this written testimony for the record to the House Committee on Energy and Commerce, Subcommittee on Health regarding H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act of 2015. This legislation is vital to preparing the nursing workforce to meet the nation’s healthcare needs today and in the future. H.R. 2713 was introduced by House Nursing Caucus Co-Chairs, Representatives Lois Capps and David Joyce, and has the bipartisan support of 50 additional cosponsors. AACN applauds Representative Capps for her work to advance the health of the nation through nursing care, and would also like to thank House Committee on Energy and Commerce members Representatives Kathy Castor, Joseph Kennedy, David Loebsack, Doris Matsui, Kurt Schrader, and John Yarmuth who have also cosponsored this legislation.

AACN represents 781 baccalaureate and graduate schools of nursing across all 50 states and the District of Columbia. Our membership extends to over 475,000 individuals, including 18,000 full-time faculty members, more than 457,000 nursing students, and the deans who lead these institutions. Healthcare delivery models are not static. Neither is

nursing education. This legislation would modernize the Title VIII Nursing Workforce Development programs, thus creating alignment with transformational efforts underway in nursing and health care.

For 52 years, the Title VIII programs have supported nursing students, practicing nurses, as well as academic and clinical institutions. In Fiscal Year (FY) 2015, the Title VIII Nursing Workforce Development programs awarded 1,166 new and continuing grants.¹ These grants bolster the nursing workforce, address nursing workforce diversity, increase nursing faculty, improve quality, promote interprofessional education, and help meet the needs of our aging population.

The Title VIII programs have been a consistent federal solution in responding to nursing workforce supply and demand challenges. The projected number of retirements in the nursing workforce will accelerate from 20,000 a decade ago to nearly 80,000 in the next decade as Baby Boomer registered nurses continue to age,² thus impacting potential growth in the profession. Currently, regional demands for nurses are reflective of the recruitment and retention barriers that impact communities, particularly in those that have health professional shortages, such as rural and underserved areas. The Title VIII programs provide a common-sense solution to address the workforce pipeline, and to

¹ Health Resources and Services Administration. (2015). HRSA Data Warehouse. Active Grants Data Portal Custom Download by Grant Activity Code: A10, A22, D09, D11, D19, D62, E01, E4C, E4D, UD7, UF1. Retrieved December 3, 2015 from

<http://datawarehouse.hrsa.gov/tools/DataPortalResults.aspx?paramGrantId=active¶mFilterId=BHW>.

² Auerbach, D. I., Buerhaus, P., & Staiger, D. O. (2015). Will the nursing workforce weather the retirement of the baby boomers? *Medical Care*, 53(10), 850-856.

promote practice in areas of national need. For example, the Advanced Education Nursing Traineeship (AENT) program assists graduate nursing students by providing support for the cost of their education. In Academic Year 2013-2014, this program supported 5,650 students, of which 40% were from minority or disadvantaged backgrounds. Fifty-six percent of these students received training in medically underserved areas, and 48% received training in primary care settings.³

One future nurse practitioner who is a recipient of the Title VIII AENT program, Krista Harmon, is a nursing student at the University of Tennessee, Chattanooga. She is a prime example of how this funding reaches those who want to provide care to underserved populations. Krista hopes to serve her Tennessee community and states, “When I graduate, I will be able to accept a lower salary instead of worrying about the highest-paying salary to pay off loans.” This will enable her to practice in an underserved community despite possibly lower pay. Britney Keplera, a Doctor of Nursing Practice student at the University of Pittsburgh, received the AENT program, and, like Krista, aspires to provide care as a future nurse practitioner in her local community.

The ability for our nation’s nursing programs to educate future practitioners such as Krista and Britney is not possible without graduate-prepared nursing faculty, and in particular doctorally-prepared faculty. According to AACN data from a survey on faculty vacancy, the top issue related to faculty recruitment in Academic Year 2015-2016 was a

³ U.S. Department of Health and Human Services. (2015). *Health Resources and Services Administration Fiscal Year 2016 Justification of Estimates for Appropriations Committee*.

limited pool of doctorally-prepared faculty.⁴ Of the vacancies reported (1,274), nearly 91% are positions that require or prefer a doctoral degree.⁴ Title VIII funding helps to address this demand. In fact, future graduate-prepared nursing faculty like Lisa Van Cleave, a PhD student at Hardin-Simmons University in Abilene, Texas, are supported through the Title VIII Nurse Faculty Loan Program. This funding allows her to pursue her degree full-time. Lisa states that this financial aid will assist her in becoming a doctorally-prepared nursing faculty member, and she will be instrumental in educating future nurses to deliver that care.

Additionally, educating a diverse nursing workforce that is representative of the increasingly diverse population is supported through the Title VIII Nursing Workforce Diversity program. This endeavor is reinforced by the Institute of Medicine in its recent report which assessed the progress of the 2010 *Future of Nursing: Leading Change, Advancing Health* report recommendations. The IOM emphasizes continuing to make diversity in the nursing workforce a top priority.⁵ In Academic Year 2013-2014, the Nursing Workforce Diversity program supported 16,997 students and aspiring students as well as partnered with over 1,000 clinical training sites, of which over half were located in a medically-underserved area.¹ Tina Meehan-Regnani is an Alaska-Native nursing student and recipient of this program. She attends Montana State University, Bozeman and states, “This program has been so beneficial to my academic success and I view it as

⁴ American Association of Colleges of Nursing. (2015). *Special Survey on Vacant Faculty Positions for Academic Year 2015-2016*. Washington, D.C.

⁵ Institute of Medicine. (2015). *Assessing Progress on the IOM Report The Future of Nursing*. Retrieved from: <http://iom.nationalacademies.org/Reports/2015/Assessing-Progress-on-the-IOM-Report-The-Future-of-Nursing.aspx>.

a true gift. Because I am so grateful, and have always wanted to work in rural or underserved communities, I can now continue along that path.”

Each year, hundreds of students like Krista, Britney, Lisa, and Tina share with AACN how the Title VIII Nursing Workforce Development programs have provided them the financial opportunity to work towards their ultimate career goal— providing high-quality, cost-effective care— and for many of them that includes becoming the faculty who will teach these future practitioners.

As the nation continues to address how all communities, including the underserved, have access to care, it is essential that the Title VIII Nursing Workforce Development programs be reauthorized. This will ensure a continued and sustainable pipeline of support for the providers who spend the most time with patients and are involved in care across the entire continuum— nurses.

AACN, along with 51 other national nursing organizations, collaborated with Representatives Capps and Joyce to identify four technical changes that would modernize the programs. These 52 organizations fully support H.R. 2713.⁶ The mutually-agreed upon changes promote the Clinical Nurse Specialist, who employs their expertise to specific patient populations; Nurse-Managed Health Clinics (NMHCs), which provide essential primary care; and the Clinical Nurse Leader role, which is critical to improving care coordination and evidence-based practice.

⁶ The Nursing Community Coalition. (June 10, 2015). *The Nursing Community Commends the Introduction of Legislation That Would Secure Future Investments for America's Health*. Retrieved from: <http://www.thenursingcommunity.org/#1/cphp>.

More specifically, the first and second technical changes to the statute promote parity among the four Advanced Practice Registered Nurse (APRN) roles to align with the APRN Consensus model, which defined these four roles as nurse practitioner, certified registered nurse anesthetist, certified nurse-midwife, and clinical nurse specialist (CNS).⁷ As one of the four APRN roles, CNSs are graduate-prepared nurses that specialize in an area of practice defined by population, setting, or disease type. Both the Advanced Education Nursing Grants [42 U.S.C. S 296j] and the National Advisory Council on Nurse Education and Practice [42 U.S.C. S 297t] is amended to include the CNS, consistent with the other APRN roles.

The third technical change includes NMHCs in the Title VIII Definitions [42 U.S.C. S 296] among the other eligible entities defined. NMHCs provide individualized care, including health promotion, disease prevention, management of chronic conditions, treatment of acute illness, and counseling. NMHCs are run by nurse practitioners and traditionally focus on populations underserved by the larger healthcare system. Moreover, NMHCs often serve as clinical training sites, not only for nursing students, but also for a multitude of health professions, thus promoting interprofessional education and practice.

The final change would include the Clinical Nurse Leader (CNL) in the definition of advanced education nurses under the Advanced Education Nursing Grants [42 U.S.C. S 296j]. The CNL is a prime example of a transformation in nursing education in the last decade in response to the nation's changing healthcare needs. CNLs oversee the lateral

⁷ APRN Consensus Work Group. (July 7, 2008). *Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education*. Retrieved from: https://ncsbn.org/Consensus_Model_for_APRN_Regulation_July_2008.pdf.

integration of care for a distinct group of patients. The CNL evaluates patient outcomes, assesses cohort risk, and has the decision-making authority to alter care plans as appropriate.⁸ Including the CNL role allows for parity with other graduate degree programs that apply for the AEN program.

AACN applauds the Subcommittee for bringing H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act of 2015 to a hearing, as it is a necessary legislative step to support America's patients, their families, and the communities in which they live. On behalf of our member deans, faculty, and students, AACN appreciates the opportunity to share the tremendous impact that Title VIII Nursing Workforce Development programs have on its recipients and how their careers have and will continue to improve our nation's health. We stand ready to work with the Committee and Congress on timely passage of this important legislation.

⁸ American Association of Colleges of Nursing. (2013). *Competencies and Curricular Expectations for Clinical Nurse Leader Education and Practice*. Retrieved from: <http://www.aacn.nche.edu/publications/white-papers/cnl>.

Mr. PITTS. The chair thanks the gentlelady, now recognizes Dr. Bermudez, 5 minutes for your summary.

STATEMENT OF OVIDIO BERMUDEZ

Dr. BERMUDEZ. Thank you, Mr. Chairman, and members of the Subcommittee on Health for the opportunity to testify before you today to support H.R. 4153, the Educating to Prevent Eating Disorders Act of 2015.

My name is Dr. Ovidio Bermudez, and I serve as chief clinical officer and medical director of child and adolescent services for the Eating Recovery Center, a treatment facility in Denver, Colorado.

I also serve as senior advisor for the board of the National Eating Disorders Association, which is a not-for-profit organization that supports both families and individuals who have been impacted by eating disorders.

I applaud this subcommittee for their consideration of this legislation, and in particular Congresswoman Ellmers for her leadership in championing this very important cause. As a medical doctor working in the field of eating disorders now for over 25 years, I would like to emphasize the importance of screening and early recognition and intervention in the prevention of eating disorders.

Over the last two and a half decades, I have treated thousands of children and adolescents suffering from eating disorders and have learned a few things about them that I would like to share with you. First, those who suffer from an eating disorder and their families bear a heavy burden of disease. However, many of the personality characteristics that have rendered them at risk for the development of these illnesses also render them productive members of society once they have recovered from their illness.

Second, those in touch with the daily lives of young people, meaning parents and school personnel, specifically teachers, are in the best position for early detection. There are attitude changes in a young person that often precede the development of eating related pathology and behaviors, and thus can clue us into the needs for assessment and further intervention.

Third, eating disorders are curable mental illnesses, but the later the diagnosis and the institution of appropriate intervention, the harder the course of illness and worse the outcome. So early recognition and early intervention are essential to improve treatment outcomes and avoid the chronicity and early death often associated with eating disorders.

In the U.S., 20 million women and 10 million men suffer from a clinically significant eating disorder at some point in their lives, including anorexia nervosa, bulimia nervosa, or binge eating disorder. Eating disorders are real; they are complicated, complex, and devastating conditions and can have serious consequences for health, productivity, and relationships. They are not a fad. They are not a phase. They are not a lifestyle choice. In fact, they are not a choice at all.

Eating disorders are serious, potentially life-threatening conditions that affect a person's emotional and physical health and can impact every organ of their body, including the brain. If left untreated they can damage the brain, the liver, kidneys, gastrointestinal tract, teeth, skin, hair, bones, and heart. They can result

in serious medical conditions such as retarded growth, osteoporosis, kidney problems, gastrointestinal dysfunction, and heart failure.

In fact, eating disorders have the highest mortality rate of any mental illness, yet, due to the lack of awareness and education about them, many people do not receive the treatment they need and deserve. Due to this lack of information, eating disorders are often not recognized or diagnosed until the physical health of an individual is compromised, at which point irreversible damage may have already occurred. But the good news is that eating disorders are treatable conditions. Early recognition may prevent the development of eating disorders and subsequent chronic physical and mental conditions, including a high risk of suicide.

Studies have demonstrated a link between early intervention and better treatment outcomes. The American Academy of Pediatrics has recommended the screening questions about eating patterns and body image be asked of all preteens and adolescents to detect the onset of eating disorders early and halt their progression. The cost of treating a full-blown eating disorder is quite expensive, and so prevention really pays.

H.R. 4153 aims to amend the Public Health Act to establish a pilot program to test the impact of early intervention through screenings, under-prevention management, and course of eating disorders that would establish a 3-year pilot program to provide grants to eligible schools for eating disorders screenings. The screenings would be implemented based on best practices from recommended experts in the field of eating disorders.

To me, the reality is, is that this is an important opportunity to protect one of the most valuable sectors of our population, which is young people.

So I want to thank you for hearing this testimony and for the consideration of supporting H.R. 4153 to improve the health and well-being of youth across our Nation by helping to prevent eating disorders. Thank you.

[The statement of Dr. Bermudez follows:]

Statement of Ovidio Bermudez, MD, FAAP, FSAHM, FAED, F.iaedp, CEDS
Chief Clinical Officer and Medical Director of Child and Adolescent Services,
Eating Recovery Center
Senior Board Advisor, National Eating Disorders Association
U.S. House of Representatives Committee on Energy and Commerce,
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H.R. 4153, Educating to Prevent Eating Disorders Act of 2015
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Thank you, Mr. Chairman and members of the Subcommittee on Health for the opportunity to testify today in support of H.R. 4153, The Educating to Prevent Eating Disorders Act of 2015. My name is Dr. Ovidio Bermudez, and I am the chief clinical officer and medical director of child and adolescent services at the Eating Recovery Center, an eating disorders treatment center located in Denver, Colorado. I also serve as a senior board advisor for the National Eating Disorders Association, a non-profit organization that supports families and individuals who have been impacted by eating disorders.

I applaud this subcommittee for their consideration of this legislation, and, in particular, Congresswoman Renee Ellmers for her leadership in championing this important cause. As a medical doctor working in the field of eating disorder for over 25 years, I would like to emphasize the importance of screenings for early recognition and intervention and the prevention of eating disorders. Over the last two and a half decades I have treated thousands of children and adolescents suffering from eating disorders and I have learned a few things about them. First, those who suffer from eating disorders and their families bear a heavy burden of disease. However, many of the personality characteristics that render them at risk for the development of these illnesses also render them productive members of society once they recover. Second, those in touch with the daily lives of young people, parents and school personnel, are in the best position for early detection. There are attitude changes in a young person that often precede the development of eating-related pathology and thus can clue us in to the need for assessment and intervention. Third, eating disorders are curable mental illnesses, but the later the diagnosis and appropriate interventions, the harder the course of illness and worse the outcome. So early recognition and intervention are essential to improve treatment outcomes and avoid chronicity and early death.

In the United States, 20 million women and 10 million men suffer from a clinically significant eating disorder at some time in their life, including anorexia nervosa, bulimia nervosa, and binge eating disorder. Eating disorders are real, complex, and devastating conditions that can have serious consequences for health, productivity, and relationships. They are not a fad, phase, or lifestyle choice. Eating disorders are serious, potentially life-threatening conditions that affect a person's emotional and physical health, and can impact every organ in the body, including the brain. If left untreated, they can damage the brain, liver, kidneys, GI tract, teeth, skin, hair, bones, and heart. They can result in such serious medical conditions as retarded growth, osteoporosis, kidney problems, gastrointestinal dysfunction, and even heart failure.

In fact, eating disorders have the highest mortality rate of any mental illness, yet due to the lack of awareness and education about eating disorders, many people do not receive the treatment they need and deserve. Due to this lack of information, eating disorders are often not recognized or diagnosed until the physical health of an individual is compromised, at which point irreversible damage may have already occurred.

But the good news is that eating disorders are treatable. Early recognition may prevent the development of eating disorders and subsequent chronic physical and mental health conditions, including a high risk of suicide. Studies have demonstrated a link between early intervention and better treatment outcomes. The American Academy of Pediatrics has recommended that screening questions about eating patterns and body image be asked of all preteens and adolescents to detect the onset of eating disorders early and halt their progression.

Treatment of full syndrome eating disorders costs over \$30,000 a month. This figure does not include the cost of treating the secondary health conditions resulting from these disorders. By

preventing the development of full syndrome disorders and the chronic health problems they cause, early detection and intervention through this pilot program for school screenings would significantly reduce treatment costs and could even save lives.

H.R. 4153 aims to amend the Public Health Service Act to establish a pilot program to test the impact of early intervention through screenings on the prevention, management, and course of eating disorders, and would establish a three-year pilot program to provide grants to eligible schools for eating disorders screenings. The screenings would be implemented based on best practices from recommendations from experts in the field of eating disorders.

The pilot program would also include funding to provide educational information and seminars on eating disorders developed by experts in the field for teachers and parents in eligible schools. In my work with the National Eating Disorders Association, for the past eight years I have moderated a panel annually that incorporates the stories of diverse individuals whose lives have been affected by eating disorders. Parents, siblings, and spouses have all spoken up about the challenges of supporting someone who is in the throes of an eating disorder. So many of these stories highlight early signs that were missed, or the lack of information and confusing misinformation surrounding eating disorders. I could share many quotes, but suffice it to say that the clear common thread is the need for early recognition and early intervention strategies that include educating those in the front lines, including parents and teachers. This pilot program would be extremely useful in raising awareness and educating those who are in the most critical positions to identify and recognize the early symptoms of an eating disorder. By arming parents and teachers with the knowledge to recognize an eating disorder in its early stages, we are helping to dispel dangerous myths about eating disorders and get individuals into treatment

earlier. Early diagnosis leads to early treatment, which means those who are struggling have a better chance of a successful recovery.

An important aspect of this legislation is that each school participating in the pilot program would be required to complete a report evaluating the process and outcomes of the pilot program. This will help us assess the impact of the screening program, and will provide a framework for an evidence-based intervention that could save countless lives.

Finally, I would like to make a point about the value potential here. The more we learn about what causes eating disorders, the more we believe as a field that it is the interaction of latent genetic vulnerability with certain environmental and cultural conditions that increase the likelihood of the expression of the genetic vulnerability to occur. This has been called gene-environment interaction. So in any given population, it is the more genetically vulnerable that will likely suffer from an eating disorder given the promoter vs. protective factors in this environment. My point then is that by investing in a better understanding of how to prevent eating-related pathology in the most vulnerable in the population, we will learn a lot about the resiliency of those who in the same environment do not express similar pathology. So, not only will be enhancing our ability to improve outcomes for the ill, but also enhancing our understanding of how to protect those who are well. I like to tell my patients that my work with them comes from a humble stance since I have not personally suffered from an eating disorder. However, having walked this journey side-by-side with many individuals and families, I can tell them that no one, in my experience, regrets recovery. My hope is to motivate them. In a similar fashion, I can tell you that in my opinion, no society will regret investing in eating disorders prevention. It makes sense to me from a variety of points of view. Perhaps most importantly, it

will allow us to protect a bright and sensitive sector of our population. This drives a stake in the ground toward a brighter future for our most precious resource, young people.

Once an eating disorder takes hold, it is very difficult to reverse; the physical, emotional, and financial toll it takes on families is devastating. In the case of eating disorders, an ounce of prevention is worth many pounds of cure. I urge you to please support H.R. 4153, to improve the health and well-being of youth across our nation by helping to prevent eating disorders. Thank you for your consideration of this important matter and thank you again for the opportunity to testify before you this morning.

Mr. PITTS. The chair thanks the gentleman. That concludes the oral presentations of the witnesses. We will now begin questioning. I will recognize myself 5 minutes for that purpose.

Dr. Asplund, has your organization discussed H.R. 921 with any medical malpractice insurers, and if so, what are their thoughts on the need to clarify lines of jurisdiction when a team physician or trainer is providing care for an athlete outside the state which they are licensed or insured?

Dr. ASPLUND. Thank you for the question. A group of colleagues from the American Medical Society for Sports Medicine contacted 20 of the Nation's largest medical malpractice providers and asked them the question, would you cover a team physician practicing across state lines?

Approximately 25 to 30 percent said that they would regardless of the place where care was covered, 45 to 50 percent said it would depend, and 30 percent outright said that they would not cover that medical professional who provided that care outside of the state. So there is a potential for anywhere from 30 to 80 percent of medical providers who may not be covered by their malpractice, simply for traveling with their team and doing their job.

Mr. PITTS. Thank you.

Dr. Reiner, you mentioned in your testimony that all 50 states have passed legislation, including the liability protection for citizens that use a defibrillator on someone during the course of an apparent medical emergency, and for businesses that have defibrillators installed for such purposes. Can you speak to how these laws vary and the impact such variation is having on increased deployment of lifesaving devices? And how would H.R. 4152 lead to more widespread deployment, and how many lives could they save?

Dr. REINER. Mr. Chairman, in Pennsylvania, for instance, if a business wants to institute an AED program, they can do so, but they are required to train their employees in the use of the device.

Mr. Green, in Texas, there is no such training requirement. In Virginia, there are no requirements at all. So if you want to purchase a defibrillator for your coffee shop or your hardware store, you can buy one on Amazon and put it on the wall.

So the essential problem is that although all states have enacted some form of legislation, the legislation differs from state to state. So if you are a national corporate entity that wants to do business around the United States, you have the problem of getting 50 different state laws correct. And they differ just enough to create an uncertainty in your mind that, if I don't get this right, then this is my problem.

Imagine if you have a hotel and your state requires a trained employee on duty 24/7, and that night someone dies in your hotel and somehow the resuscitation doesn't go well. Well, now, that is potentially your problem. And the owner of the hotel might say, gee, it might have been better for me just not to have a defibrillator at all.

So simply what this bill does is decouple all of the state provisions, training, supervision. If the states find an interest in those, that is great. But it just decouples those different training and supervision requirements from liability protection. If you have a

working defibrillator that is kept in good order, you are protected from liability.

Mr. PITTS. Thank you.

Dr. Gregg, does the training OB-GYNs receive in genetics prepare them to interpret cell-free DNA prenatal screening results and communicate them effectively to patients?

Dr. GREGG. I think this is the fundamental problem and probably what brings this bill to this body today. The obstetrician, gynecologist can certainly read a report where the report says normal and can read a report that says the patient has an abnormal test result. What follows is a detailed discussion on post-screening test results in the context of what does an abnormal test result really mean.

Patients have taken that test result to mean that they definitely have a child that has Down Syndrome, and in some cases due to time constraints, fear has led them in directions that, as we have heard through the lay press, were directions that weren't what they would have expected.

The problem, then, becomes in understanding that this is a screening test and what types of tests need to follow. In addition, understanding the positive and negative predictive value of the results at hand.

Mr. PITTS. The chair thanks the gentleman. My time is expired. The chair recognizes the ranking member, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

Dr. Trautman, we appreciate you joining to discuss the Title VIII nursing workforce programs. Title VIII programs have long enjoyed bipartisan support, and I am glad that it has continued with the introduction of H.R. 2173. The Title VIII Nursing Workforce Reauthorization Act by Representative Capps and Joyce, like many, I am concerned about the nursing shortage facing the U.S. and baby-boomer generations further exaggerating the great need for more healthcare providers.

According to a report, the United States registered nurse workforce report card and shortage forecast published in the American Journal of Medical Quality in January of 2012, the shortage of registered nurses is projected to spread across the country to 2030 with the most intense shortages in the South and the West. I understand that one of the contributing factors in the shortage of nursing facilities. In fact, in 2012, nursing undergraduate and graduate programs turned away 80,000 qualified applicants due to the lack of capacity.

Doctor, could you elaborate on the difficulty in attracting students and professionals entering in the nursing faculty workforce?

Ms. TRAUTMAN. Yes, thank you, Chairman. That is a very good question. And I want to thank you, again, for the support that has occurred over the decades that has allowed us to attract individuals to nursing programs.

We have a strong desire to continue to advance those who are interested in not only the sciences but in caring for individuals to join the nursing profession. And we have done more with respect to these programs and recognizing that it is important to get to our

youth earlier and speak to them about the profession, educate them.

Title VIII funding, as you know, has been targeted recently, some of the advance practice work in serving the underserved areas. As you mentioned, it is correct that the nursing workforce, like the American public is aging, so while our past efforts have been successful, we must do more. A part of doing more, which Title VIII supports, is advancing doctoral education for nursing because we need doctorally prepared nurses to be faculty to teach the future nurses. It is an extraordinary profession, and we will continue to work with our colleagues in Congress and outside to educate others about the benefits of being a member of the nursing profession.

Mr. GREEN. OK. Since we had so many applicants, qualified applicants who couldn't get in, does this legislation help in that lack of capacity?

Ms. TRAUTMAN. Yes, it does. It helps in two regards. The problem is primarily related to either clinical placements and/or faculty. Although, again, there is regional variation, some areas of the country have no problem. But in those areas that do, Title VIII helps support, as well as some other programs, but it helps support, again, preparing doctorally prepared faculty. And the clinical placements are not a part of Title VIII, but the nursing community and other stakeholders recognize the importance.

The nurse managed clinics, though, which are in Title VIII, do provide an opportunity for additional clinical settings, and that will help us accept more students.

Mr. GREEN. OK. Great, thank you.

We also have all heard about the difficulty in accessing maternity care services in certain areas and where there is certain populations. It is surprising that we do not have good data to understand the problem.

Dr. Breedlove, what do we know about the existing shortage in maternity care providers?

Dr. BREEDLOVE. We know there is an increasing shortage of OB/GYNs graduating from residency programs. And ACOG has supported data on the critical workforce shortage of OB/GYNs, I believe, in their testimony. We also know that 40 percent of counties in our country have no maternity care provider, whether that be an OB/GYN or a midwife. So it is astounding that so much of the geographic region of our country can provide services through the National Health Service Corps through primary care providership, which both these professions are a part of. However, the specialty they provide often is not identified in the primary care shortage definition. So a physician, OB, or midwife may go to one of these primary care shortage areas but not be able to deliver the services they are uniquely trained for.

Mr. GREEN. OK.

Will H.R. 1209, Improving Access to Maternity Care, help us collect that information?

Dr. BREEDLOVE. Absolutely. This directs HRSA to create definitions and collect data that can help us place particularly new graduates in these professions and setting where they are most needed.

Mr. GREEN. OK.

Thank you, Mr. Chairman. I yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Illinois, Mr. Shimkus, for 5 minutes for questions.

Mr. SHIMKUS. Thank you, Mr. Chairman.

Welcome. This is a great panel, great issues. The challenge of health care is apportionment of costs because everyone is really there to serve the public. And it is just a great aspect of being on this committee. I just have two—I think, Dr. Reiner, so in the 108th Congress, we passed the Adam's Memory Act, which allowed emergency auxiliary defibrillators to be placed throughout in public areas. And it was based upon an act of young boy who got hit in the chest with a baseball at a diamond and went down. And just, fortunately, there was a policeman there and had one in the truck of the car. And that caused us to move a year or two later to help place these throughout open-access areas. And they have changed quite a bit since technologically. So I think a good way to really kind of reinforce the language of this bill is to just have one here because they tell you what to do. It is like: Open the case; grab these little wires; put them here; press start. Right? So that is what you basically need, to be able to follow instructions and listen to them to use one of these auxiliary emergency defibrillators today. Isn't that correct?

Dr. REINER. That is right, sir. The devices were really made to be used by people with no training. And the favored study that I point to is a study that compared sixth grade kids, basically 12-year-olds, to trained paramedics. So they set up a mock cardiac arrest. And they told the kids outside the room—who had never seen a defibrillator—that all you have to do is open it because, as you said, there are audio prompts that talk you through. And, importantly, the device cannot deliver a shock to a person who would not benefit from it. So they compared 20 kids to 20 paramedics. And, obviously, the paramedics knew how to do it. And the paramedics beat the kids by only about 20 seconds, 20 seconds. Every kid could do it. Every kid did it properly. Every kid did it right the first time.

But the laws are confusing, and they are intimidating. I travel through O'Hare from time to time. And signage on the defibrillators is terrifying. The signage says "to be used only by trained responders." Well, why should it say that? The devices are designed to be used by anyone, trained or untrained. It says that because there is a piece of Illinois law that makes that necessary.

So all that this bill says is if you have a working defibrillator and it is used with good intent to try and save the life of somebody, that the owner of the defibrillator is protected, as is the Good Samaritan. It doesn't change the requirements that some States may have for training or supervision. It simply says that whatever the State rules are, if you are using it with good intent and you have a working device, everyone is protected.

Mr. SHIMKUS. Excellent. Thank you.

And I will just finish up with Dr. Gregg. And I appreciate this bill too. There is going to be a continued debate, I mean, between those who consider ourselves pro-life and believe life begins at conception and should be protected and then the challenges that we face under medical ethics, under genomic testing, and then decisions that are made because of that which may not sometimes—

as you pointed out, we need to make sure that they are an accurate as possible description to inform the family of what may or may not be. If you want to comment on that, you can. That is a challenge that I think the healthcare community has to work on.

Dr. GREGG. Sure. Let me just say that noninvasive prenatal screening, or NIPS, has the best test metrics for screening available today, better than anything we have used over the last 30 years, the best positive predictive value, negative predictive value, sensitivity, and specificity. In a New England Journal of Medicine paper published last spring, this best testing metrics was confirmed across all reproductive age groups, so not just what is classically defined as advanced maternal age patients, but all reproductive age groups.

Having said this, it is imperative that patients and the providers understand that it is still a screening test and that there is a need for follow up.

As far as women and their reproductive choices, I will say that the American College of Medical Genetics and Genomics has as a fundamental ethics tenet that counseling is performed in a non-directive fashion. And screening takes place today. This is not adding screening to a healthcare system that doesn't already have it, but it is trying to refine the educational piece. And, to me, that is what this bill does. It brings the educational piece to the forefront, not screening or not what women do with the screening.

Let me say that the false positive rate with this particular test is less than 1 percent—in fact, in some studies, less than a half a percent. Other screening tests that have been in play now for now more than 25, 30 years have a false positive rate of 5 percent. That brings more people to the high-risk obstetrician with anxiety. And it brings more people potentially to diagnostic procedures that have some small but real measurable risk associated with them.

So it is these educational aspects—I will just say one more thing, that this is becoming an increasingly complex testing environment as we move from common aneuploidies, Down syndrome being one of the most commonly talked about, to now other aspects of genomics. Other aspects where small pieces of DNA are deleted or duplicated, we are now able to identify these. These have a different positive and negative predictive value. And different things are done in response to these test results. And that is the educational piece, not sort of the simpler aneuploidy piece. I think that can be done in a paragraph. But it is how to keep in front of the evolution of this technology as it comes forward.

Mr. SHIMKUS. Thank you.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the ranking member of the full committee, Mr. Pallone, for 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

I want to ask Dr. Trautman some questions and then, if I have time, Ms. Breedlove.

Dr. Trautman, as you know, there are four advanced practice registered nurse roles: Nurse practitioner, certified registered nurse anesthetist, certified nurse midwife, and clinical nurse specialist. And I am interested in learning more about the role of the

clinical nurse specialist. Could you explain the role of the clinical nurse specialist within the healthcare system, and what are the education and training requirements of clinical nurse specialists?

Ms. TRAUTMAN. Thank you. As you have described, there are four advanced practice roles in nursing. The clinical nurse specialist is a role that is focused on a specialty, so a specialty area. The education for a clinical nurse specialist is a graduate degree. There are master's prepared clinical nurse specialists. And there are increasingly more doctorally prepared clinical nurse specialists.

Mr. PALLONE. OK. Now, the advanced nurse education grant program supports projects that develop and test innovative academic practice partnership models for clinical training and prepare primary care and advanced practice registered nurses to provide safe, quality care. Can you explain why this program is important to supporting the nursing workforce?

Ms. TRAUTMAN. Certainly. Thank you. That is an excellent question. Academic practice partnerships are critically important. Gone are the days where the academic community can be separate from the practice community. As we as a Nation move forward in all of our efforts to improve health and health care, those partners and leaders and practitioners in practice, as well as our educators, must come together. And when we do, we benefit from the expertise of both of those very important disciplines to not only advance the profession, but we have had significant examples in the VA and in other settings of how we improve the experience of care for individuals and their families.

Mr. PALLONE. OK. Now, currently only three of the four advanced practice registered nurse roles are eligible for this program. Could you elaborate on why it is important to include the clinical nurse specialists in the advanced nursing education program?

Ms. TRAUTMAN. Certainly. The request for the change, the technical change in the reauthorization, is to allow us to standardize, as you have just mentioned, across all advanced practice nursing roles. And because the education, as I have shared, is similar, at graduate level and above, the competencies of the clinical nurse specialist, it will, by making this technical change, it allows us to create parity within all of the advanced practice roles.

Mr. PALLONE. OK. Thank you.

So let me go to Ms. Breedlove, I wanted to ask some questions about the increase in maternal mortality. According to the CDC, the rate of maternal mortality has more than doubled in the past few decades, increasing from 7.2 deaths per 100,000 births in 1987 to 17.8 deaths per 100,000 births in 2011. Could you explain some of the reasons leading to this increase?

Dr. BREEDLOVE. Absolutely. Thank you for the opportunity to comment.

Just this morning, the World Health Organization released a statement related to maternal mortality with a specific focus on issues related to pre and postnatal care. Most specifically, contributors include preeclampsia, lack of early diagnosis, post partum hemorrhage, and post partum infection. And when you think about the provider shortage challenging the ability for pregnant and postdelivery women to access immediate care for evaluation and referral to appropriate services, particularly in rural areas of our

country, we know there are ways to address this. But we have to have providers who are accessible to the women who need that care.

Mr. PALLONE. And specifically how would the creation of the maternity care health professional shortage areas help reduce maternal mortality?

Dr. BREEDLOVE. By placing the most qualified providers of the unique services to women during the childbearing years in the areas where the need is more clearly defined. Right now, we have no ability to designate maternity shortage areas under the Health Service Corps definition, nor do we have any idea what that shortage area percentage might be. But we are aware from many stories and the poor outcomes that we are facing that health care is needed in those areas. So it would be a very simple way to introduce a new definition without changing those who already exist in the Health Service Corps.

Mr. PALLONE. Thank you very much.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentleman from Pennsylvania, Dr. Murphy, 5 minutes for questions.

Mr. MURPHY. Thank you, Mr. Chairman.

And thank you to the panel for being here.

Dr. Breedlove, let me continue on with some of those areas that Mr. Pallone was asking. With regard to the number of OB/GYNs available, do we have any idea of the cost we would encounter from having them involved in this?

Dr. BREEDLOVE. There would not be additional costs. We are talking about providers who already qualify in the National Health Service Corps. So what we are talking about in this bill is enabling the right provider to be at the right place at the right time.

Mr. MURPHY. But it comes out of the funding for the medical corps, medical service that is existing. So does that mean it takes away from the current areas designated for shortage are primary care, dental care, and mental health care. So it would pull from the same amount of money, not additional?

Dr. BREEDLOVE. I am not exactly sure how to answer your question, other than these provider types which we currently have already fulfill the primary care opportunities.

Mr. MURPHY. I am just trying to think in terms of funding. There is a certain block of money. So we add them to that list, and then they all pull from that same list. Am I correct in terms of—

Dr. BREEDLOVE. I am not able to answer your question.

Mr. MURPHY. That is OK. All right. I just want to make sure because given that—I don't know what the cost savings would be and maybe you could get us some estimates. I know we went to Dr. Tom Insel here, the immediate past head of the National Institute of Mental Health. He said the current cost in our mental health system is \$444 billion. That does not include the justice system, which is probably another \$50 billion to \$100 billion, so half a trillion dollars per year. I just want to make sure we are not cutting other services for a group that we already have a massive shortage on. But I agree with you; we need to do this part too.

Dr. Bermudez, welcome. I want to ask you about some of the aspects you brought out about eating disorders. And thank you for

talking about that. You said that there are perhaps tens of millions of mostly women and some men who are affected by this. But in your testimony, you really emphasized the role of the family and the role of teachers to early identification and facilitate treatment. And toward the end of your testimony, you also said basically once an eating disorder takes hold, it is very difficult to reverse. The physical, emotional, and financial toll it takes on families is devastating.

I am a psychologist by training so that you know. And in this, would you say—and I have seen this in other studies too, first of all—that a person who has an eating disorder can sometimes be so deeply involved in their psychiatric problems that they may resist treatment, true?

Dr. BERMUDEZ. True.

Mr. MURPHY. And under those circumstances, I read another study that says whether a person is involuntarily or voluntarily committed, that the outcome is good if you get them in treatment. It is much better if they are in treatment versus not in treatment. Is that correct?

Dr. BERMUDEZ. The data is clear on that.

Mr. MURPHY. OK. That is very important because sometimes people say, “Well, we shouldn’t involuntarily commit someone,” but a person’s mind may be so disturbed from the psychiatric illness, they are not cognitively aware of what they need. Further, some people with eating disorders may also be in the category of severe mental illness—schizophrenics, bipolar—so they have dual diagnoses on top of that, which makes it even more complicated. Am I correct?

Dr. BERMUDEZ. Absolutely.

Mr. MURPHY. So in this getting a family member involved, one of the big dilemmas that oftentimes occurs are HIPAA laws, where if you are treating someone with bulimia or anorexia and the issue is if they are not even going to their appointments and the family member doesn’t even know their diagnosis or the treatment plan or where they are supposed to go or a change in appointment or the medication, very often providers say, by HIPAA laws, I am not even allowed to tell you information to facilitate treatment. Am I correct?

Dr. BERMUDEZ. So what I wanted to tell you is that I agree with that for adults. Now, that is part of the beauty of the opportunity here is that we are talking about a group of illnesses that generally presents in early adolescence and toward the latter part of adolescence. So the opportunity of the involvement of the family at a very meaningful level is clearly there, in spite of HIPAA laws and wanting to work and respect—

Mr. MURPHY. And during that time, a provider could certainly build a relationship with family members and understand who to trust, who is part of the team. So even when that person turns 18, for example, severe mental illness, 50 percent of severe mental illness emerges by age 14; 75 percent by age 24. It is a critical time. They are no longer in school. They are past 18. HIPAA dynamics change. But from what I hear you saying, from your testimony, it is very important that, for the prognosis of that person, to keep the family member involved and find ways to make sure the HIPAA

law doesn't get in way so that person can be involved. Would that be fair to state?

Dr. BERMUDEZ. That is a fair statement. And we have clearly shifted as a field in our understanding of eating disorders and moving away from really blaming families to really partnering with families. Families are critical as agents of change, not only to be aware early on and recognize in a timely fashion and bring their loved ones to care, which secures better outcomes, but I think, at the same time, to remain involved and continue the appropriate followup of these illnesses. As you know, from a psychological perspective, these are not things that change overnight. And, therefore, involvement of a support system—i.e., the family—is critical in the success of treating these illnesses.

Mr. MURPHY. Thank you. I appreciate it.

I yield back.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentlelady from California, Mrs. Capps, 5 minutes for questions.

Mrs. CAPPS. Thank you, Mr. Chairman.

Thank you all for your testimony.

And before I begin, Dr. Trautman, I would like to ask my first question of you. But I want to clarify, my colleague, Mr. Murphy, just raised an issue about funding for maternal-child health. And I just want to clarify this money is already being spent, to my colleague. Mr. Murphy?

Mr. MURPHY. I am sorry?

Mrs. CAPPS. I just want to clarify something to you as I started because of the statement that you made regarding funding and allocations coming. This is money that is already now being spent. So there are no new providers being added or taken into the program for maternal-child health or for any of these nursing programs. It would just help to drill down within the existing programs for primary care designations to place these maternity care professionals where they are needed most.

Mr. MURPHY. I understand.

Mrs. CAPPS. I just want to make sure—

Mr. MURPHY. Make sure we are robbing from Peter to pay Paul. We need to do more. Not less.

Mrs. CAPPS. Exactly. So, Dr. Trautman, as you well know more than most of us, the Institute of Medicine's 2010 Future of Nursing Report is a landmark study for our profession. In it, the IOM laid out the current state of our nursing workforce and a roadmap of what needs to happen to prepare for the healthcare system of the future. Just last week, IOM's evaluation committee released a followup report reviewing the progress made on the Future of Nursing's recommendations. One of their recommendations was an increased focus on nursing workforce diversity. Title VIII Nursing Workforce Diversity program has supported increasing diversity. No one is arguing with this.

So, Dr. Trautman, can you discuss what progress you see being made in nursing school enrollments regarding diversity? And how does the title VIII program, for all of us to understand it better, how does this program support this goal?

Ms. TRAUTMAN. Thank you very much, Representative Capps. And thank you again for your fierce, strong commitment to the profession and what ultimately again is going to improve the health of our Nation. Thank you.

The importance of diversity in all health professions, most certainly in nursing, is clearly understood. And title VIII has been very effective in helping us make improvements. In the years, looking at the data, from 2010 to 2014, we have improved the diversity of the nursing student population at all levels. At the baccalaureate, at the master's, and at the doctoral level, we are now at 30 percent of those students represent diversity. And while that is significant progress, it is not yet enough. Much more needs to be done. Some of that, most certainly, has within the past been directly related to title VIII and so will the future in these programs that are specifically targeted to help us not only to bring diverse individuals into the profession but, as you know, equally important that we are serving areas of the country most in need.

Mrs. CAPPS. Yes.

Ms. TRAUTMAN. So that is very important. We will also do other things beyond the law, the legislation, the changes that are proposed in the health professions. One example that you are aware of, I know, is this holistic review, which is an approach to looking at individuals who enter the profession, and it includes the individual as a whole. So we look at personal attributes, in addition to the academic metrics that, in the past, most health professions had solely relied upon.

Mrs. CAPPS. I appreciate that. Thank you very much.

Switching gears here, the goal of the Improving Access to Maternity Care Act is to better target the maternity care professionals to the communities that need it most. We know that prenatal care is so critical to pregnant women. But far too many women are not getting the recommended care, as you know.

So, Dr. Breedlove, from your perspective as a certified nurse midwife—I am big supporter of that program, of course—and an educator of midwives, what impact does proximity to prenatal care—that, I think, is something we really want to zero in on—and post partum care, maternity care have on the quality of a pregnancy for a woman and for the child?

Dr. BREEDLOVE. Thank you so much for your fierce support of our profession but also of access to prenatal care for women in our country. The issue really is around whether or not there can be adequate screening, which we have heard a little bit about today, whether there is an opportunity to assess women for potential risk, could be preconception, early pregnancy, as well as routine prenatal visits, which we know have a huge impact on the ability to diagnose early signs of preeclampsia, again, one of the problems of maternal mortality in our country. So it really is critical that if women are driving, you know, an hour and an hour and a half to find prenatal care, the likelihood of her having routine care and not missing visits, in addition to driving even longer than that for the birth facility is a very challenging thing for our families and really is clearly evident of some of the challenges that we have in all women in our country having in the prenatal care they need in a timely fashion.

Mrs. CAPPS. Thank you very much both of you.

And I yield back my time.

Mr. PITTS. The chair thanks the gentlelady.

I now recognize the gentleman from Texas, Dr. Burgess, 5 minutes for questions.

Mr. BURGESS. Thank you, Mr. Chairman.

And, Ms. Breedlove, forgive me, Dr. Bucshon had eclipsed you temporarily.

Thank you, Doctor. You are so kind to me.

Let me ask you a question because, I mean, because in your statement, your testimony, the suggestion that the maternal mortality rate has increased over the last 10 to 12 years' time, can you give us—I know you have been asked this previously—but can you give us the breakdown of where those deaths have occurred?

Dr. BREEDLOVE. We are collecting data under the guidance of CDC and the Maternal Mortality Commission. I attended an all-day workshop at the ACOG annual meeting in San Francisco last year. It is very clear that not only is it based on prenatal and postnatal adequacy of care but also in systems of care within the hospital setting itself so that there are clearly defined clinical pathways and the management of women who are at risk of stroke, who are at risk for hemorrhage, and who are at risk for hypertension that is poorly managed. So there are a variety of projects that are interdisciplinary in nature going on around the country, developing we call them bundles for care that are collaborative in nature and codeveloped by all the disciplines within healthcare maternity services.

So we know more about some of the challenges. But we also are keenly aware that if you have no one available to help diagnose and early screen and provide services prior to hospital admission, you have increased risk of those families.

Mr. BURGESS. I think that is the lesson we are in danger of overlooking when we have this discussion. The drop in maternal mortality, not just in this country but worldwide, was dramatic. And it occurred about 1937. It is important to me because my grandfather was an academic obstetrician at the Royal Victoria Hospital in Montreal. So he was part of that generation of doctors. These are doctors who practiced before antibiotics were widely available, before anesthesia was as reliable or survivable as it is today. Certainly the same could be said about blood banks. If you were fortunate enough to get a blood transfusion, the likelihood that you would survive it was certainly problematic before modern blood banking techniques emerged. And all of that coalesced around 1937, and the numbers dramatically dropped. So it is the presence of a trained attendant at birth that really probably has made more difference in maternal mortality than anything else, which is why your testimony intrigued me because we shouldn't forget the lessons of the past. So one of the things that this will do, with all deference to my friend from Pennsylvania, we are not taking his money, but we are trying to make certain that the money that is available in the primary care space goes where it is most needed. And the other thing that, interestingly enough, has been found over the years is that doctors tend to go or stay, rather, where they train. We are not terribly imaginative, as it turns out. And so we

don't wander far from where it is that we took our—generally our residency training, perhaps subspecialty training. We tend to marry people who are in that area. And, as a consequence, we don't move from there unless our spouses give us permission. We tend to establish referral patterns: who you can trust, who you can't. So the degree of professional comfort is greatest in the area in which you train. It certainly was true for me and a great number of my cohort. The significance there is if we can bring to the medically underserved from a maternal standpoint, if we can bring practitioners to the medically underserved area, the likelihood that they will then populate those areas is higher than if we try to entice them with other inducements. So that is why this change in designation, although it is really not more money and we are not taking money from someone else, this is really an important thing to accomplish and why I am grateful that Representative Capps has partnered and that we are now having the legislative hearing, and we are working on getting it done.

And, Dr. Gregg, I just want to say to you—and thank you for your testimony—we are struggling—I shouldn't say “we” are struggling. I am struggling—the committee seems, everyone else seems comfortable with letting the FDA have further regulatory ability over what are called laboratory-developed tests. And I am nervous about that. And people on this committee know that. But I was encouraged by some of your comments. A screening test is a screening test. No one takes someone to the operating room because of a screening test. You do the confirmatory test.

Now, it is one of the idioms or one of the axioms of medicine that the confirmatory test will always be equivocal. But, nevertheless, you don't start a clinical action based on a screening test. So I appreciate your testimony on that very much.

Mr. Chairman, thank you. I will yield back.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentleman from Oregon, Dr. Schrader, 5 minutes for questions.

Mr. SCHRADER. Thank you, Mr. Chairman.

A question on the Cardiac Survival Act for Dr. Reiner. I am familiar with the use of the devices. And you indicated in the testimony some of the queries that anyone can pretty much use those. So the device discerns between like atrial fibrillation and ventricular fibrillation. So it is not up to the individual using the device?

Dr. REINER. That is right. And, in fact, there is really no way to deliver a shock to someone who doesn't have what is programmed into the system as a, quote, shockable rhythm, which is basically ventricular fibrillation or a very fast ventricular tachycardia. So if someone has just passed out, for instance, but they don't have one of those rhythms, you cannot actually deliver a shock.

Mr. SCHRADER. OK. Good to know.

For Dr. Gregg, I guess, on the cell-free DNA testings, screenings, those can be ordered by anybody, anywhere, any time? It is not through a physician?

Dr. GREGG. It can be, these can be ordered by advanced practice nurses, yes, sir.

Mr. SCHRADER. I mean, just laypeople.

Dr. GREGG. No.

Mr. SCHRADER. OK. OK.

Dr. GREGG. You would have to have an MPI number.

Mr. SCHRADER. And there is a concern that advanced practice nurses and physicians are unclear about how to interpret the results on these and, therefore, would advise people perhaps incorrectly?

Dr. GREGG. On the pre-test side, there is a concern that patients may not and are not getting the adequate information to understand well the tests that they are having done and what that test is actually doing.

Mr. SCHRADER. But if that is done in concert with the physician or advanced nurse practitioner, wouldn't that take care of that potential problem?

Dr. GREGG. Again, the concern here is that the advanced practice nurse and/or physician does not have the depth of knowledge to completely understand what it is they are ordering. And then when results come back, this becomes an even more complex problem when the result is abnormal. When the result is abnormal, it is not simply reading an abnormality is here, and then there is an algorithmic next step. In interpreting abnormal results, there are many subsequent steps that should take place following.

Obstetric care, as you know, is provided by people that range in their knowledge base. Midlevel providers provide obstetric care under the direction of physicians and so forth. Midwives provide obstetric care independently.

Mr. SCHRADER. Would they be interpreting these results too? Is that what you are—

Dr. GREGG. That is exactly right, that there is a wide variety of people interpreting these results.

Mr. SCHRADER. OK. I understand.

Then, I guess, for Dr. Breedlove, if I may, on the Maternity Care Act, my understanding from some of the information we have gotten is that primary care shortage areas, of which this is one, is already recognized. And the reason for this is to draw even more attention to it? Or I am not exactly clear why it is called that.

Dr. BREEDLOVE. Actually, no. The maternity care designation is not listed under the primary care scope. So what we are asking is that there be a definition within primary care.

Mr. SCHRADER. OK. Great. I misinterpreted that then. And then, I guess, last but not least our nursing person here, talk a little bit about title VIII and how we can develop the next generation of nursing educators so critical to improving the number of nurses out there and why there is such a shortage.

Ms. TRAUTMAN. Well, thank you very much. Title VIII has made a contribution already. We have improved significantly the number of doctorally prepared nurses. We now have had in both the research doctorate as well as the practice doctorate an increased number of enrollees that is unprecedented. What we now also need to do beyond quantity is also start earlier in the nurse's career. And so we have begun to create programs that facilitate earlier attainment of the knowledge and skills that are necessary for one to be competent and practice at the doctoral level. So it is a very exciting time and unprecedented in our Nation's history how the schools across the country are responding to assure that we have

quality, high standards in education programs but that we facilitate ease of access and progression.

Mr. SCHRADER. Thank you, Doctor.

With that, I yield back, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you very much, Mr. Chairman.

I appreciate all of you being here today. I want to start with Dr. Asplund and just say I am a cosponsor of the bill. I think it is a good concept. My reading of the bill, and I think it goes in a good direction, but my reading of the bill indicates this would also apply not only to college and professional athletes, but it would also apply to those folks who have trainers with high school teams if they are competing in a nationally sanctioned or sponsored event, something that some national organization puts on. Is that your understanding of the reading as well?

Dr. ASPLUND. Thank you for your question. So with the National Federation of High Schools being a sanctioning body of all high school athletes, it was the intent in our language for high school athletes to be covered by this bill as well. As many people are aware, there are far more high school athletes in America than at any other time. There are far more contests across state lines in the high school level. I live in Augusta, Georgia. We frequently cross the river to South Carolina pretty much weekly to do that and, as such, are crossing into a state where many of my colleagues do not have licensure. So, yes, high schools were intended to be included through the line with the national sanctioning body being the National Federation of High Schools.

Mr. GRIFFITH. I represent a district that borders four other states. And we have lots of high school competition going on. So I appreciate that. And I think that is a very good aspect of the bill. And I do appreciate that.

Dr. Reiner, I have got concerns about the AEDs or the bill at least. I think that the Federal policy does need to be looked at just simply because the good news is the bill that was passed in 2000, one of the criteria was you notify the local EMS. I think that at the time that made a lot of sense. Today, those AEDs are in a lot more places than they were in 2000. I think now it is impractical, in fairness, to notify local EMS for a lot of the small businesses that have these. Which EMS do they notify? Our area is all generally referred to where I live as the Roanoke Valley—but you have the city of Salem, the city of Roanoke, and Roanoke County, all of which are completely separate and have separate fire, police, and rescue squad folks. Some are paid. Some are volunteer. And so it might be difficult. I think we do need to look at that policy.

But that being said, one of your examples kind of struck something that—my friends who are trial lawyers have raised an issue, and that is, it appears that when you look at the actual lawsuits, there are more lawsuits for not having the AED on premises than there are for having it but using it improperly. In fact, they can't find a whole lot of cases where that has been the case based on the existing law. And I was concerned because one of your examples was Walmart sells them, but they may not have them. And I actu-

ally think that is a bigger liability issue for whatever retail establishment, whether it be Walmart, Kmart, whomever, if they are selling the device but they don't have one charged up ready to go, that is probably a bigger liability issue than having one prepared and then having somebody who is doing the best they cannot use it properly. What do you have to say to that? Because I am trying to decide what to do on this bill, and I think both sides have some merit to their arguments.

Dr. REINER. So it is important to know that the bill leaves State laws alone. So any provision in a State law that the folks in that State feel is important as it pertains to training or registration or supervision, any of those provisions remains in force. All that this bill says is that if you have a working defibrillator, you are protected. So that entities like Walmart or Target can know that, look, they are going to do the best they can to get all these local ordinances right. But it is important for them to protect their community and their employees. And they are going to do the best they can. But they need to know that if their defibrillator is in working order, they are protected.

So it doesn't create new law. It doesn't cost industry a cent. It doesn't cost the government a penny. But there are a lot of people who die from this. I see folks who come to my hospital in two conditions: One person has had an out-of-hospital cardiac arrest, and they have been in close proximity to a defibrillator, and if they have been shocked pretty quickly, that person goes home to their family. The second patient has been someplace; it has taken a while for paramedics to get there. And they come to my place in a different circumstance, and they go to the morgue.

Mr. GRIFFITH. And I appreciate that. I think we want to get that policy right. I apologize for cutting you off. But my time is up, and I have to yield back.

Thank you, sir. I appreciate your testimony today.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentlelady from Florida, Ms. Castor, 5 minutes for questions.

Ms. CASTOR. Good morning. Thank you, Mr. Chairman, for calling this hearing. And thanks to all the witnesses for being here today, especially for including H.R. 4153, the Educating to Prevent Eating Disorders bill, and H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act. And I want to thank my colleague, Representative Lois Capps, for introducing the Title VIII Nursing Workforce Reauthorization Act. I am a proud cosponsor of this bill, which would reauthorize critical nursing workforce initiatives that are so desperately needed.

And I hear from Dianne Morrison-Beedy, the dean of the College of Nursing at the University of South Florida in Tampa, and her excellent team there, some of the most passionate advocates for a strong nursing workforce. That is one reason why USF's College of Nursing was ranked as one of the top, the best graduate schools this year on the national ranking. I am very proud of them. Ensuring that we have qualified registered nurses and advanced practice nurses is critical to meeting our Nation's healthcare needs.

I would also like to thank my colleagues and friends, Representative Renee Ellmers and Yvette Clarke, for introducing H.R. 4153,

Educating to Prevent Eating Disorders. We filed this bill last week. It is an important bill that is aimed at reducing eating disorders with early intervention. Specifically, our bill would create a 3-year pilot initiative which would provide grants to schools, serving middle-school-aged children to test the impact of providing students with interventions to prevent, identify, intervene, and manage eating disorders. We will help the pilot schools hire a healthcare provider who will administer the initiative. The schools participating in the pilot will submit a report detailing the process they used and the outcomes that they achieved. And it will be posted on the Agency for Healthcare Research and Quality Web site. There is a huge desire for accurate, up-to-date information on these challenges. And we have got to do more to prevent young people from suffering from an eating disorder. I am a mother of two teenage girls. And we know some of their friends who have struggled with these issues. And, oftentimes, families just don't know where to turn. There are not resources out there to help them deal with this. And as Representative Ellmers knows and has championed, you have got to intervene early. So I am grateful to all of you.

I want to thank Dr. Bermudez for being here. And I would like to ask you, could you briefly discuss the different types of eating disorders and the serious health consequences they cause and whether or not we have seen a rise in the number of individuals impacted by an eating disorder?

Dr. BERMUDEZ. Sure. Glad to. Thank you.

The main eating disorders that we are really talking about—*anorexia nervosa*, *bulimia nervosa*, and *binge eating disorder*—now, an important characteristic here to distinguish is that these are not fads. These are serious mental illnesses. You can't tell somebody who has an eating disorder by looking at them. And this is no longer an illness of Caucasian, privileged young women. This is an illness that affects all genders, all races, all ethnicities, all social economic statuses. And that is important to come at it from.

Anorexia nervosa really constitutes a caloric restriction with loss of weight. These are people that when the disease is advanced, you can see them and you can recognize them as people who are alarmingly underweight.

In the case of *bulimia*, these people often binge eat, which means that they consume a very large amount of calories in a short period of time and then feel very guilty and tend to induce some form of purging, most of the time by vomiting, inducing vomiting, or abusing laxatives. But there are other forms as well.

And *binge eating disorders* are people who will binge recurrently and not engage in the compensatory mechanisms that include the purging behavior.

So that is really what we are talking about, the opportunity for early identification and appropriate early intervention I think would save many, many, many, lives.

Ms. CASTOR. Does the data show that the number of cases is increasing? Has it stayed level?

Dr. BERMUDEZ. So the data shows that the number of cases, number one, is increasing. But also that the presentation, the clinical presentations of the cases are also increasing. So we are seeing some what is called demographic drifts. We are seeing younger and

younger children involved in eating disorders, as young as 7 and 8 years of age. That was unheard of a few years ago. More mature people in midlife, more women than men but men also in midlife, people from different races, and different ethnicities. So the protective factors that certain groups, like African Americans or Asian Americans or Hispanic Americans, had, those protective factors have eroded. And we are seeing more men represented across the spectrum of eating disorders, from anorexia to bulimia to binge eating disorder.

Ms. CASTOR. Thank you very much.

I yield back my time.

Mr. PITTS. The chair thanks the gentlelady.

I now recognize the gentleman from Indiana, Dr. Bucshon, for 5 minutes for questions.

Mr. BUCSHON. Thank you, Mr. Chairman.

I was a cardiovascular and thoracic surgeon for 15 years prior to coming to Congress. So I want to comment primarily on the defibrillator issue.

I recently helped distribute defibrillators to a couple of the counties for law enforcement and other businesses based on grants through the Lugar Center, former Senator Lugar, and our state has a grant program that helps with these type of things. And H.R. 4152 is a necessary step in furthering the dissemination of AEDs.

Let me give you some personal experience. You commented, Dr. Reiner, about the two situations, that you see patients. And I have seen some also that have survived but have not survived in a state which is consistent with their pre-arrest state. I have specifically two patients that I ended up doing surgery on that have long-term brain injury that changed their lives dramatically and the lives of their family. And I have also been consulted on many patients who are in the ICU who were found to have coronary disease. But I ultimately ended up not treating that patient with surgery because of a very severe brain injury for which they never woke up essentially and did not recover.

My two patients that had brain injuries had cardiac arrest at work. They had colleagues who were trained in BLS, basic life support, almost immediate CPR, no defibrillator available, 5 to 10 minutes' time before a defibrillator became available. They survived but had injury. So this is really important.

The other thing is—and I am going to ask you to comment on this—education of the public in the use and importance of these is critical. Employees and businesses, school children, as is pointed out by your study, it is very important. And I think for the future we probably need to start training school children, I would think, in their health class or something just about this because one of the biggest barriers to use, even if they are available, is fear. And I had a colleague of mine in an airport traveling to Washington who saw a person that had an arrest. There were people standing around. And he was a physician. And he said: Is there a defibrillator available?

Of course, there was. And they used it. And that patient survived and, subsequently, had heart surgery and is normal. But had he not been there as someone who was available to overcome his fear

because of his training, that may not have happened. So there are some barriers.

So, in combination with availability, can you comment on what your thoughts are also on the importance of education and helping people overcome their fear?

Dr. REINER. I think that is a wonderful point, Congressman. The biggest issue is that people don't know that they can do this. We took a defibrillator out to the Verizon Center a couple years ago and filmed people as they walked down the street. We said: Hey, do you want to try and use a defibrillator? These were folks who had never used it. And they all could do it. They could do it very quickly. And the universal response: Oh, now I won't hesitate to use it if I ever have to.

But this kind of uncertainty is not just for the general public, but it exists for corporations. They are afraid of being sued if they get it wrong. All this bill says is if you have a defibrillator that works, you are protected from liability. It is a simple bill. But once national organizations start educating people about the bill, then I agree; we need to educate everyone how to use these devices. Imagine having a fire extinguisher in the corner that had labels on it that said "for use by trained rescuers only."

Mr. BUCSHON. Right. Right.

Dr. REINER. This is a fire extinguisher that talks to you.

Mr. BUCSHON. I agree with that. And that is why I have a real issue when trial lawyers, for example, have questions about people using things in good faith that save people's lives. And as a physician, my personal view is it is really sad that they would consider the financial benefits of suing people doing things in good faith. I really take offense to that, honestly.

Dr. Gregg, you commented on your screening test. Are they better than an amniocentesis?

Dr. GREGG. That is the point. An amniocentesis is the diagnostic test.

Mr. BUCSHON. I guess the reason I am asking is because at some point, when did the screening test supplant a more invasive study and become the standard?

Dr. GREGG. Screening tests have been in place for more than 30 years. The initial screening test was age alone. You will remember that age 35 was what rattled people's cage a little bit. Today, we recognize that the detection rate of age alone is not better than about 30 percent, just using age as a marker to go to the amniocentesis, as you are implying.

Over the last decades, multiple other screening paradigms have been put into place. Today, with noninvasive prenatal screening, we are at a 98-percent detection rate from that 30 percent for advanced maternal age. The followup test is the amniocentesis or the chorionic villus sampling.

Mr. BUCSHON. I guess my point is, at some point, a screening test becomes a standard of care for the test, and it supplants a more invasive test. My time is up.

Dr. GREGG. An EKG doesn't replace what you do.

Mr. BUCSHON. Understood. Fair point.

I yield back.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentleman from California, Mr. Cardenas, 5 minutes for questions.

Mr. CARDENAS. Thank you very much, Mr. Chairman.

Thank you Doctor, Doctor, Doctor, Doctor, Doctor, Doctor, and all of the people here who are on the panel giving us their expertise and also my colleagues who have practiced as well. Thank you so much for shedding light on many of these issues.

I am not a doctor, nor do I play one on TV. But I do care about the state of health care for our country and certainly now that a new chapter in my family's life has begun, as our daughter and her husband announced to us very nonchalantly that they are pregnant and our first grandchild is on the way. And that being the case, it leads to my first question having to do with prenatal screenings.

An article late last year in Disability Scoop discussed some limitations of cell-free DNA prenatal screenings and suggested that the need for quality control needs to be improved. So my first question is to Dr. Gregg. Are you aware of any noninvasive prenatal tests that are regulated by the FDA?

Dr. GREGG. No.

Mr. CARDENAS. No? OK. Some companies that make these tests have made claims about the high accuracy of their results or have made claims of very few false positives. Do any Federal agencies, such as the FDA, evaluate the claims that these companies are making to ensure that they are valid and supported by clinical data?

Dr. GREGG. Currently, the FDA does not regulate this particular LDT.

Mr. CARDENAS. So those claims, where and how are they validated by third parties today?

Dr. GREGG. By third parties?

Mr. CARDENAS. Yes.

Dr. GREGG. I am not aware that they have been validated by third parties.

There have been a significant number of peer-reviewed publications, large international trials, that validate the test metrics of these particular tests.

Mr. CARDENAS. Is that, do you feel that that suffices to ensure the public that that accuracy is in line with what the claims are? Or could we possibly enlist some kind of agency to go ahead and help us understand that accuracy and have more, at least more appreciation for that accuracy?

Dr. GREGG. I am satisfied with the claims. I would say that an involvement of a Federal agency has value. We think there should be some oversight of these laboratories. CLIA and CAP currently provide this oversight. To me and to ACMG, one of the principal values of FDA oversight would involve labeling and marketing aspects. Clinical validity has been established for other types of prenatal screening for aneuploidy. These out-of-the-box kits are probably regulated already but not molecular-based testing in this way.

Mr. CARDENAS. Yes. What can Congress possibly do to assure the quality of these tests and that the tests are providing accurate and reliable information to providers and specifically pregnant women?

Dr. GREGG. Well, the tests already provide accurate information. The laboratories themselves do currently have CLIA and CAP oversight. So that is already in place.

Mr. CARDENAS. So, right now, as you see it, Dr. Gregg, the environment is at least satisfactory for those assurances and understanding by not only the practitioners but also the patients?

Dr. GREGG. No, I don't think it is satisfactory as far as it relates to practitioners or patients. And that is what H.R. 3441 proposes to do, is put in place the educational initiatives so that they are detailed, indepth, and provide for a balanced and accurate information as the technology evolves.

Currently, the technology has expanded beyond simple aneuploidies or common aneuploidies. As I said earlier, there are genomic changes that the technology is now being used to report screening results to. There is a need for more studies. And what we haven't talked about here is the underlying bioinformatics that follows what happens in the laboratory. The bioinformatics is a big piece. It is proprietary. And at some level, there probably needs to be some digging into that black box to make sure that we can validate the bioinformatic pieces. The companies sure can play a better role in disclosing the data that they have access to. I think they probably with a nudge would be willing to do that. But that is the type of oversight I think that needs to be in place on the laboratory side.

Mr. CARDENAS. One last point, if you will allow me, Mr. Chairman, I think that, unfortunately, proprietary information should not preclude us from making sure that what is going on out there is safe. And I think the government can play a protective role in protecting that proprietary information and bringing a better semblance of the environment for what is going on. Thank you so much.

Thank you, Mr. Chair.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentleman from Florida, Mr. Bilirakis, 5 minutes for questions.

Mr. BILIRAKIS. Thank you, Mr. Chairman. I appreciate it so very much.

And I want to thank all of the sponsors of these really good bills.

And thanks for agenda-ing the bill today, Mr. Chairman, having the hearing.

Dr. Bermudez, the subject of eating disorders has been of great importance to several of my constituents. They have come to my office, both in D.C. but also locally. In October, I met with a group of advocates and heard their personal stories about how they or their loved ones were affected by these debilitating mental illnesses. What are some of the biggest challenges to identifying the early signs of an eating disorder?

Dr. BERMUDEZ. So eating-related pathology has an interesting characteristic, which is that people tend to not want to be discovered, right. So people in other areas of medicine want to seek the help and want others to know because that is the path to accessing help. In eating disorders, that is not the case. There is a lot of secretiveness in the clinical presentations of an eating disorder. So imagine a 14-year-old, who learns about some of this on the Inter-

net or may have some friends that have been affected. They talk about it, and she sort of begins to change her behavior through restriction and dieting and exercise. Well, she doesn't want anybody to know. That is one of the biggest challenges. This is not a child who is going to come to the parents and say: Mom, Dad, I am struggling; I have a problem. This is a child that is going to work hard not to be discovered. Hence, the importance of educating those in the front lines, those individuals that really, day to day, are interacting with children.

Mr. BILIRAKIS. So which are they—I know you brought it up. I hate to interrupt. What should we look for, our loved ones look for, a parent look for? How can we detect this?

Dr. BERMUDEZ. We should look for change. We should look for signs that are telling us that something is really changing in the way this individual views themselves and is trying to project themselves and fit into the world around them. So when a young person starts to make self-deprecating statements about their size, their weight, their appearance, their desirability; when a young person starts to make excuses to not eat; when a young person is losing weight and stops participating in the normal activities that they had interest in and love, especially social aspects of them, then I think families need to sort of pick that up and become concerned and seek appropriate assessment.

Mr. BILIRAKIS. Thank you. What are the most effective early intervention treatments?

Dr. BERMUDEZ. So formalizing the diagnosis becomes very important. So after a screening test that raises a level of suspicion or parental familial concern, a thorough assessment becomes really important. And that assessment includes looking for medical complications of the eating disorder behaviors and psychiatric complications of the eating disorder behaviors. Once that diagnosis is made, then you can sort of assess the level of severity: Where is the illness in the spectrum of severity of the illness? Because that may determine where we start the treatment process. And so the different levels of care, including medical stabilization, psychiatric stabilization, outpatient services that are age-appropriate, disease appropriate, intensive outpatient programs, partial hospitalization, residential treatment, and inpatient eating disorder specialized efforts are all in the armamentarium, and so that assessment helps guide the family in making the decision as to where is the appropriate place to start.

Mr. BILIRAKIS. How many millions of people are affected by this disorder?

Dr. BERMUDEZ. About 30 million people, so about 20 million women and 10 million men at some point in their lives will be affected by an eating disorder in the United States.

Mr. BILIRAKIS. Not just teenagers? All ages?

Dr. BERMUDEZ. All ages.

Mr. BILIRAKIS. OK. Thank you.

Thank you, very much, doctor.

Dr. Asplund, thank you for your testimony, again, today. As an avid sports fan and an attorney, the issue of athletes being able to receive medical attention from their team physician while across

State lines has been of interest to me for a very long time, even when I was in the legislature in Florida.

You mentioned that merely exempting team physicians from the State's licensure requirements would not be sufficient because there is still a risk of a lawsuit. Can you explain how this complicates or hinders your ability to provide the best possible care for athletes?

Dr. ASPLUND. Thank you for your question. I am not sure that the language of the bill or the law hinders an ability to provide health care. What it does, though, is it takes away protection for the athletic trainer or the physician after they have provided that health care in case something were to go wrong.

As I testified earlier, many medical malpractice carriers tie that malpractice coverage to that licensure link. And so of the major malpractice carriers that we surveyed, almost 30 percent said they wouldn't cover someone out of state regardless of licensure if they were out of state; 50 percent said they would cover them out of state only if they had a license in that second state; and there is 25 percent that wouldn't cover them regardless of what state they were in. So having the licensure piece overlooked or not married up will put physicians and athletic trainers and other providers that provide that care at potential great malpractice risk.

Mr. BILIRAKIS. Teams are having trouble hiring physicians for these positions because of the risk of lawsuits?

Dr. ASPLUND. I am not aware of any difficulty in hiring providers. It is nearly the provision of care and then the risk that that may involve.

Mr. BILIRAKIS. Very good. Thank you so much.

Dr. ASPLUND. Thank you.

Mr. BILIRAKIS. I appreciate it.

And I yield back, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentleman from New York, Mr. Engel, 5 minutes for questions.

Mr. ENGEL. Thank you very much, Mr. Chairman.

Dr. Breedlove, before I came, Mr. Pallone asked you a question about the rate of maternal mortality. I am wondering if we could come back to that because I wasn't quite sure—we were listening on the TV. I wasn't quite sure what the answers are.

The statistics I have is that it increased from 7.2 deaths per 100,000 births just in 1987, and it is more than double today, 17.8 deaths per 100,000 births in 2011. What is the reason for that? That is really alarming, or it seems alarming. What is the reason for that, and are other developed countries experiencing the same thing in mortality rates?

Dr. BREEDLOVE. I think from the data that is being collected by the CDC and the collaborative work groups related to maternal mortality in our country, we are finding that some of it does have to do with access to prenatal care and early assessment, the risk criteria during pregnancy, but some of it also has to do with care provision in the hospital systems themselves, whether that is the level of care provided, that the appropriate providers are in the right place for crisis management, or that those who are in hospital

facilities have adequate training and resources to provide the provisions they need for critical high-risk patients.

So, unfortunately, there are many variables, including the rising rate of cesarean section and the complications that come with that. So the effort that is occurring by many collaboratives, including ACOG, Society for Maternal-Fetal Medicine, AWHONN, the nursing organization, is to begin to implement care bundles that are hospital-based but also to define levels of maternal care which will have the right providers at the right facility for the need of the patient.

Mr. ENGEL. Is part of it that older women are having more babies than they were 30 years ago, or does that have nothing to do with it?

Dr. BREEDLOVE. I am not sure I could answer that question.

Perhaps my colleague, Dr. Gregg could, in terms of advanced maternal age and increased risk. Certainly, the increase in multiples can play a part in that, but I would defer to Dr. Gregg.

Mr. ENGEL. OK.

Dr. Gregg.

Dr. GREGG. I actually co-chair the Florida maternal mortality committee, which is recognized as one of the most thorough maternal mortality committees in the country. We review every maternal death in the state that has specific criteria.

Let me just say that a couple of things have happened. The way data on maternal mortality is ascertained has changed. So I heard somebody say there was a drop and somebody else say it is increasing. So all of that relates to who is obtaining the data. There were two entities within CDC both obtaining data, and now it is obtained across more states than ever before. So we are seeing what appears to be an increase in numbers are due to better ascertainment. And when that is compared worldwide, it looks like the U.S. does poorly. We have to remember that, worldwide, many countries don't collect any data or have very spotty data-collection capabilities. So I just want to put that out there.

There are increasingly—women of advanced maternal age are getting—not 35; to me, it is much higher than that—are getting pregnant. They have other associated medical conditions that go along with advanced age.

We have more women getting pregnant that in times past couldn't get pregnant because they had underlying medical conditions that did not support pregnancy well. We have interventions to help them get pregnant. So now we are seeing sicker patients enter pregnancy, and we are having to manage sick patients in a pregnancy that challenges their physiology, so—

Mr. ENGEL. Thank you. It makes sense. Since I have you, let me ask you another question not related to this, but I understand that, as drafted, the patient and provider education campaigns, including in H.R. 3441, would need to be funded using existing resources. So has any analysis been done to determine what the cost of these campaigns might be or where the funding might be pulled from to finance them?

Dr. GREGG. I am not aware of a financial analysis or financial analysis report and don't have the data on that. I apologize.

Mr. ENGEL. OK. Thank you.

Let me ask Dr. Reiner. In your testimony, you discuss the patchwork of laws that exist across 50 States with respect to liability for those who own or deploy automatic external defibrillators. And I would be interested to know what kinds of laws exist with regard to training and storage for these defibrillators. And the reason I am asking this is, while I take your points concerning liability, it occurs to me that we really should also be considering how we can enhance awareness and skill around these defibrillators. Obviously, they save lives. The usage rates might improve if defibrillators had to be stored, say, in permanent locations, and I know state laws vary. So if you could perhaps shed some light on how they vary in this respect. If you can—

Dr. REINER. Thank you for the question, Mr. Engle. I completely agree. Defibrillators work best when they are located in places where people congregate. And in a building like this, they are easy to find. But in other parts of busy cities, they are not. So part of the solution is education to the business community, community at large, educating people that these are easy to use, teaching kids—I love the idea to teach kids how to use these while they are in middle school and high school. But the other piece of this is removing the concern for liability, what I think is the unnecessary concern for liability that business owners do have for acquiring this technology. An AED cost about the same as a MacBook. It is cheap. This is decades-proven technology, but businesses are afraid of it.

Mr. ENGEL. Thank you. I want to just say in concluding that I always like when there are a bunch of doctors in the room, so I feel if anything happens to me, we can get good care.

Thank you all for testifying today. We really appreciate it.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the vice chairman of the subcommittee, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you very much. I appreciate all of you being here, but I want to focus on the Sports Medicine Licensure Clarity Act. That is the one that I am the sponsor of. I have a friend who is an emergency room physician, but he also is—I don't know if he is a team doctor or designated doctor. He is one of the doctors who travel with Auburn University. So I remember when I first came across this issue and got interested in it because of his experience, I said: Do you realize when you were at the BCS game in California and the Rose Bowl, as much fun as you were having, enjoying it, you were probably there with—you are unclear what your liability coverage would be if you are there?

And I know one of my colleagues was—I don't know where they were going with it—but talked about being a lawyer. This isn't preventing opportunities for people to bring malpractice suits. It just makes sure you are covered, your insurance is covered, so it is not taking away anybody's ability to move forward. It is just making sure that doctors have the surety that they are being covered.

And, also, I would just like to compliment Georgia Southern. I got to see you guys play a couple of years ago at Georgia Tech. I was there for a game. My son is there. And it was a closer game than some thought, and I think there was a controversial overturn that changed the game for Georgia Tech's behalf, and so a lot of fans get upset. But I remember walking out and going: Wow, Geor-

gia Southern handled everything with class and a lot of—great program, a lot to be proud in that program. And I know you are going to Mobile, so you are going to have to go to Alabama without a license, right, practicing license.

So that is the thing that we are trying to fix is that, you have got Western Kentucky University. You are playing Bowling Green. We are from Bowling Green. A lot of people think we are playing you guys, but we are Western Kentucky University, and we are going to Miami. And so I remember, last year, we actually went to the Bahamas Bowl, and it is amazing how many 18- to 22-year-old young men do not have passports. So my office actually spent about a month trying to get everybody cleared to go. So when these games happen and it is a single game somewhere, you just can't do paperwork for every scenario that you are moving forward.

So we just want to fix it. I think it just makes it smarter. I think everybody agrees that the team physician should be able to travel with the team—who knows the young men and women, and knows there may be a previous injury, what they are favoring. So instead of bringing a local physician there who doesn't know the history of each kid, it is important to do so.

So I just want to ask you about the licensing process for sportsmen and professionals at the state level, and I know it would be very expensive and cumbersome and maybe even impossible, from the time you get a full bid until you are ready to play a ball game, to get licensed as a sports professional in a state. So what is kind of the process currently to be licensed as a sports professional in Georgia or any other state you are familiar with?

Dr. ASPLUND. Mr. Guthrie, thank you for the question, and thank you for the support of our bill.

You are correct. All 50 states and territories have differing requirements or processes to get a medical license. They generally look at your educational background, your malpractice claims, your continuing medical education, and then they issue a license. And while each state has sort of an underlying—they are all similar, but yet they are different. And so we have been to Alabama twice, and we are going to go back a third time. And had I known with enough time to get a temporary 14-day license—which, according to the State of Alabama, would cost \$500 and would only last for 14 days. So on our initial trip to south Alabama, I could have paid \$500, gotten 14 days of coverage. Two months later, when we went to Troy, I would have to pay another \$500 to get 14 days of coverage and, now that we are returning to Mobile, another \$500 for this 14 days of coverage. So the temporary medical licensing may work on occasion when you know that you have—when you know where you are going.

Mr. GUTHRIE. But even if you are licensed there, there is no guarantee that your malpractice insurance recognizes that, right? That is what we are trying to clarify as well.

Dr. ASPLUND. That is correct. And in a study that we talked about, malpractice carriers sometimes tie their coverage to your state of license. So each state is different. The process is costly, anywhere from \$150 to \$900 per state, and the timeframe on that is anywhere from 2 to 6 months until that paperwork can process.

Mr. GUTHRIE. I want to get to a couple of other questions. So the bill doesn't restrict what you can do. You couldn't have gone to Troy hospital—or if you went to Montgomery or wherever you went or Birmingham—and performed an orthopedic surgery on a player that was hurt?

Dr. ASPLUND. Correct.

Mr. GUTHRIE. And it does restrict what you can do. So pretty much what we understand is on-the-field coverage?

Dr. ASPLUND. Yes. It restricts it to on-the-field or in-the-training-room type coverage. Any coverage that would occur in a medical facility, like a hospital or a clinic, would not be covered by this bill. It is typical stuff that you would do on the sidelines, in the training room, underneath the stadium.

Mr. GUTHRIE. And why is that important? I have got just a couple of seconds, so I want to make sure. Why is it important? Because I know my friend was telling me that, you know, this person has a sore ankle; this person has done it before; if he hurts it again in the game, I know where to go. Why is it better to have—I guess I am answering it—but why is it better to have you with your team than just hire a local doctor to come cover the game?

Dr. ASPLUND. Well, you highlight some of the concerns with the orthopedic issues, but we are seeing more and more young people with complex medical issues that are playing sports at the highest level. We have several asthmatics, several diabetics. We have two athletes who have no colon at all. And so there are complex medical issues that also come into play. The example I highlighted in my testimony of a spinal cord care, that process is practiced and rehearsed weekly with our team, and so if a new doctor were just to fall in on our team, there may be some miscommunication and a potential catastrophic injury if the neck was turned too soon or the back was turned too soon, rendering an athlete paralyzed.

Mr. GUTHRIE. Are you employed by the school, or are you a private physician who travels with the team?

Dr. ASPLUND. In this particular job, I am employed by the school and, hence, the state, and so would likely be covered by the Georgia Tort Act for performing my job, but when I was at Ohio State, I was a private practice contract.

Mr. GUTHRIE. That is what my friend is. So you would be in the same situation, so not everybody is covered?

I am running over time.

Dr. ASPLUND. Correct.

Mr. GUTHRIE. So it is important that we do this. And I appreciate being involved in it.

Dr. ASPLUND. Thank you very much.

Mr. GUTHRIE. Thank you.

Mr. PITTS. The chair thanks the gentleman.

I now recognize the gentlelady from North Carolina, Mrs. Ellmers, 5 minutes for questions.

Mrs. ELLMERS. Thank you, Mr. Chairman.

Again, thank you to our panel. This has been a very good subcommittee hearing, and the testimony has been wonderful.

Dr. Bermudez, my questioning is primarily for you on our bill, on our eating disorders bill. And I would just like to ask you, you mentioned some of the myths that are associated with eating dis-

orders. Can you just expand a little bit on what some of those myths are?

Dr. BERMUDEZ. Absolutely, and thank you. The reality is that eating disorders affect everybody. Everybody is at risk.

Mrs. ELLMERS. It is not just young females.

Dr. BERMUDEZ. Yes. If you have sons and daughters and if you have nieces and nephews and if you have grandchildren, they are all at risk in a societal context like ours. So the key is to take it away from the concept of choice, such as people choose to do this and this is about lookism, and take it into the context of this is a brain-based mental illness that profoundly affects the lives of not only the person who is identified with the illness but all of those affected and surrounding them as well. So that is one important shift.

The other important shift is it is everybody's disease, every gender, every race, every ethnicity, every socioeconomic status, and so that no one is exempt because of who they are or what they look like. Those are, I think, the two important distinctions in dispelling the myths.

Mrs. ELLMERS. Now, as far as the most common eating disorders, I know we talked a little about anorexia. We talked about binge eating, which certainly, we know that that is part of the bulimia nervosa. Do you also consider, kind of along the line of the binge eating, those who are overweight and eating disorders associated with, maybe not the binge side of it but the eating—we know that we have kind of an epidemic in this country of obesity. Would you consider that part of this too or no?

Dr. BERMUDEZ. So I think we need to make some distinctions and highlight some similarities. I think the main distinction that is really important, I think, for the public to understand is that obesity is a real problem in our country, but obesity, in and of itself, is not a mental health illness.

Mrs. ELLMERS. Correct. And that would be one of the clarifications that would be made in the process of treatment?

Dr. BERMUDEZ. Absolutely.

And so the other distinction that, to me, is really important, though, is that there are similarities. There are potential advantages here. There is potential value to better understand and address some of the issues with obesity because at the end of the day, in a stressful living situation, in a complex society like ours, which really means that kids grow up with significant perceived stress, we tend to either eat too little or eat too much. The reality is that the relationship between our developmental stance, our constant concept of self or self-view, and our relationship with food are integrally tied. So as we learn about prevention, as we better understand how to do early intervention and teach the front line, parents, teachers, about what to recognize and the steps to take to secure more adequate next-step assessments, not only would we be protecting the most vulnerable, but we will learn a whole lot about the resiliency factors that keep those that stay well. So we may very well learn how to keep them well. And along those lines, we may very well learn what happens when the eating goes not just toward bingeing or purging or anorexia but simply eating too much and ending on the side of obesity.

Mrs. ELLMERS. Which leads to its own set of—

Dr. BERMUDEZ. Right.

Mrs. ELLMERS. You did mention that we have seen this in children as young as 7 or 8. So I have a very basic question. We are looking at middle school as starting the pilot program. Do you think maybe we should rethink that and maybe start it earlier?

Dr. BERMUDEZ. I think, based on the information we know, the demographics of eating-related pathology that we know today, middle school is a critical place to start.

Mrs. ELLMERS. OK.

Dr. BERMUDEZ. It is a vulnerable time of life. It is a time when, in the normal process of separation, individuation, kids are beginning to sort of find their own path. Peer influence and cultural influences sort of are highlighted. So it is really a vulnerable time of life. Statistically speaking, I think this is really where the payoff is.

Mrs. ELLMERS. The best—

Dr. BERMUDEZ. But we should not ignore the fact that younger children may also be affected.

Mrs. ELLMERS. Very good.

And I have one last question with 30 seconds left. I want to target where we were going with the eating disorder and early intervention and possibly not being able to make the goals that we want and leading to some of the physical illnesses that end up happening. And I know, in your testimony, you basically said eating disorders are serious, potentially life-threatening conditions that affect a person's emotional and physical health. And it goes on to say that it could affect your organs, going on to heart, brain, other vital organs, retarded growth, osteoporosis, kidney problems, gastrointestinal dysfunction, and even heart failure.

With that in mind—and one of our biggest challenges here in Washington is being able to put forward legislation with funding, moving forward so that we can actually show that there is going to be progress made into the future, which will eventually lead to fiscal savings when we are talking about things like Medicaid, Medicare coverage. Now, I know you are in eating disorders, and that is your specialty. But in your medical background, would you not say that if we could prevent this and keep this person healthier as a result of intervention, that this will help to save that person from having lifelong or end-of-life issues that would affect them and the cost of health care?

Dr. BERMUDEZ. Representative Ellmers, I think that is a key point of H.R. 4153. We are talking about not just saving lives and saving people from suffering, but this is an area in which an ounce of prevention is worth many, many, many pounds of cure. So these are expensive illnesses to treat. These take a significant toll on a very important sector of our society, which is our bright, otherwise healthy young people. And my sense is that what we will learn from this pilot program is that this is really where the future is to say: Let's get ahead of the curve here and not just continue to sort of do the remedial care that we have been focused on.

Mrs. ELLMERS. Yes. Focus on prevention.

Well, thank you, again, so much.

And, again, thank you to our panel. This has been a very, very good subcommittee hearing, but I have learned a lot as well. So thank you.

Mr. PITTS. The chair thanks the gentlelady.

We have a UC request?

Mr. GUTHRIE. Thank you, Mr. Chairman.

I do have a unanimous consent to add into the record or put into the record several letters, one from a coalition of healthcare providers supporting the bill, a letter of support from the American Association of Orthopaedic Surgeons, a letter of support from the American Medical Association, also from the American Osteopathic Association, from the National Athletic Trainers' Association.

And I know we were discussing how this affects college football more than anything because of your role, but this is also one from Major League Baseball, the NBA, the NCAA, NHL, NFL, and the Olympic and Paralympic Committees. And I will ask unanimous consent they be put into the record.

Mr. PITTS. Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. That concludes our time of questioning.

I will have some followups, so I will send those to you in writing. We ask that you, please, respond promptly.

I remind members that they have 10 business days to submit questions for the record. Members should submit their questions by the close of business on Wednesday, December 23.

Really a very, very excellent hearing, very informative, very high-quality testimony. Thank you very much for coming and speaking to the subcommittee today.

Without objection, the subcommittee stands adjourned.

[Whereupon, at 12:26 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. DORIS O. MATSUI

Thank you, Mr. Chairman for holding this hearing today. I look forward to hearing from each of the witnesses about the targeted public health problems we are aiming to address, and your thoughts on the best solutions to these challenges.

In particular, I would like to highlight my support for the Nursing Workforce Reauthorization Act, and I thank my colleague Representative Capps for her leadership on that issue.

Additionally, I would like to thank my colleague, Representative Ellmers for her work on the eating disorders legislation we are discussing today.

As many as 30 million Americans suffer from an eating disorder, but only 1 in 10 ever receives treatment. Eating disorders can have severe consequences and medical complications such as heart failure, organ failure, malnutrition, and suicide.

That is why I support the Anna Westin Act, which I have worked on with my colleague Representative Lance as well as the coauthors Representatives Deutch and Ros-Lehtinen.

The Anna Westin Act would train doctors and teachers to recognize at-risk behaviors in order to ensure earlier diagnosis and treatment, and it would clarify mental health parity for eating disorders so that insurers can't pick and choose mental disorders to exclude from coverage.

The pilot project in the legislation we are discussing today would test the impact of early intervention on the prevention, management, and course of eating disorders in grades 6 through 8. This is certainly a project that we should undertake.

I encourage support of this legislation, and I also encourage the Committee to take our work on eating disorder prevention a step farther by reviewing the Anna Westin Act as well. Thank you.

Energy and Commerce Subcommittee on Health
Examining Legislation to Improve Health Care and Treatment
Wednesday, December 9, 2015
Congresswoman Jaime Herrera Beutler

Thank you, Chairman Pitts, Ranking Member Green, and members of the Energy & Commerce Health Subcommittee for opportunity to advocate for parents with H.R. 3441, *The Accurate Education for Prenatal Screenings Act*.

Today, if you are an expectant mom, you are likely to be offered a non-invasive prenatal screening by your doctor— a screening that, its developers claim, can tell you if your baby has Down syndrome or other genetic conditions with “no confusion. Just simple clear results.”

The problem is that these screenings are not diagnostic tests – they have false positives and false negatives. In fact, studies have found that positive results are false up to half the time!

These screening are not regulated by the FDA and there are no requirements about what information is provided to doctors and parents.

A study that included information available online in the U.S. found that parents are receiving inadequate information about cell-free DNA prenatal screenings. Only 15% of the screenings’ websites pointed out that the test cannot rule out all fetal abnormalities. Some sites even stated that the test guarantees a healthy baby. Just over half the websites stated that an invasive test is required to confirm a positive non-invasive screening result, and only a quarter mentioned the importance of pre-test counseling with a health care professional.

Families are empowered when provided clear, accurate and up-to-date information. When that information is limited, unreliable or inaccurate, families are placed at a dangerous disadvantage.

The bill requires the appropriate HHS agency to develop unbiased, evidence-based education materials for providers and expectant parents that help them better understand cell-free DNA prenatal screenings.

Thank you again for the opportunity to advocate for parents and doctors to have complete and correct information about the advantages – and limitations – of prenatal screenings. I respectfully urge the committee to act expeditiously on H.R. 3441, *The Accurate Education for Prenatal Screenings Act*.

Written Testimony

Of

The American Congress of Obstetricians and Gynecologists

Submitted by:

Mark DeFrancesco, MD, MBA, FACOG

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.

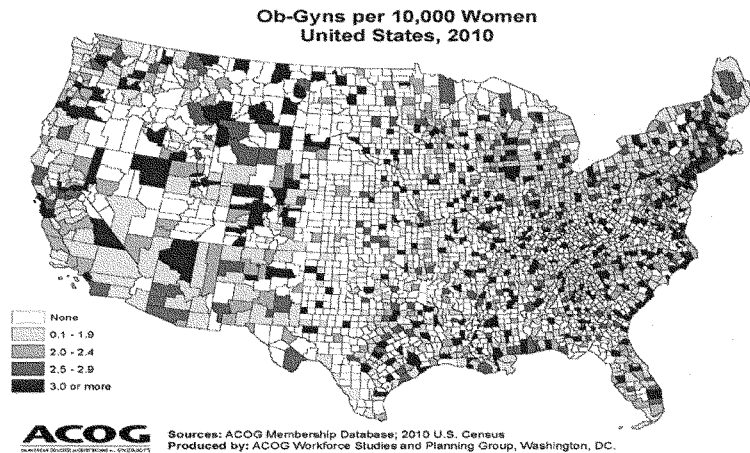
Background

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.¹ 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.

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

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.

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.

¹⁰ Based on ACOG Fellow and member statistics. ACOG represents about 90% of all board certified obstetricians and gynecologists in the United States.

¹¹ 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/>

¹² Markus, Anne Rossier., Andres, Ellie., et al. "Medicaid Covered Births, 2008 Through 2010, in the Context of the Implementation of Health Reform." *Women's Health Issues Journal*. 2013. 23(5); e273-3280. DOI: <http://dx.doi.org/10.1016/j.whi.2013.06.006>

¹³ Rayburn, William F. "The Obstetrician/Gynecologist Workforce in the United States: Facts, Figures, and Implications 2011." Developed by the American Congress of Obstetricians and Gynecologists. Washington, DC: American Congress of Obstetricians and Gynecologists; 2011.

¹⁴ Cell-free DNA screening for fetal aneuploidy. Committee Opinion No. 640. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;126:e31-7.

¹⁵ Ibid.

¹⁶ 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/>

¹⁷ Prenatal Cell-free DNA Screening [PDF]. National Society of Genetic Counselors (NSGC), November 2014. (Endorsed October 2015)

¹⁸ 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>

¹⁹ 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>

²⁰ 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/>



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December 8, 2015

Written Testimony for the Record

Submitted electronically to Graham Pittman at graham.pittman@mail.house.gov.

Re: House Energy and Commerce, Subcommittee on Health Hearing "Examining Legislation to Improve Health Care and Treatment."

I. Summary of testimony and key points:

The National Nursing Centers Consortium (NNCC) is a 501 (c) non-profit organization representing nurse-managed health clinics (NMHC) across the country, of which there are approximately 500. These clinics, which are led by advanced practice nurses, typically nurse practitioners, offer accessible, high quality, cost effective care to thousands of medically underserved patients each year.

NNCC respectfully requests that the Subcommittee advance the Title VIII Nursing Workforce Reauthorization Act of 2015 (H.R. 2713) for the following reasons:

- Many NMHCs are affiliated with academic Schools of Nursing, and each academically affiliated NMHC provides clinical placements for an average of 50 to 60 students annually. The Title VIII Nurse Education, Practice, Quality, and Retention Program (NEPQR) program is a critical source of funding for these clinics.
- HR 2713 includes a technical change adding NMHCs to the list of eligible entities in the definition section of the Title VIII statute. The change increases the visibility of NMHCs and could potentially open up new funding sources for the clinics.

II. Full Testimony

Dear Chairman Pitts, Vice Chairman Guthrie, and Ranking Member Greene:

On behalf of the National Nursing Centers Consortium (NNCC), I am pleased to present the House Committee on Energy and Commerce, Subcommittee on Health with the following testimony for the record regarding H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act of 2015. In addition to reauthorizing the Nursing Workforce Development programs (Title VIII of the Public Health Service Act); the legislation proposes four technical changes to modernize the programs. One of these technical changes would add Nurse-Managed Health Clinics (NMHCs) to the list of eligible entities in the definition section of the Title VIII statute [42 U.S.C. S 296]. As the Chief Executive Officer of the organization that represents NMHCs nationally, I urge the Subcommittee to advance H.R. 2713 with this important change. To demonstrate the significance of this change, I will first provide some background on NNCC and NMHCs.

The NNCC is a 501(c)(3) nonprofit member organization representing nurse-managed health clinics (sometimes called nurse-managed health centers or NMHCs). Section 254c-1a of the Public Health Service Act defines the term 'nurse-managed health clinic' as a "nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center (FQHC), or independent nonprofit health or social services agency."¹ Recent estimates indicate that there are approximately 500 nurse-managed clinics nationwide, including birthing centers and school-based clinics. NMHC care is directed by nurse practitioners and other advanced practice nurses offering a wide range of primary care, health promotion, and disease prevention services to low-income, vulnerable patients living in medically underserved areas. Nationally, NMHCs record

¹ 42 U.S.C.A. § 254c-1a(a)(2) (West 2012).

about 250,000 patient encounters each year. The majority of NMHC patients are either Medicaid recipients, uninsured or self-pay.

Because many NMHCs are affiliated with schools of nursing, NMHCs also help to build the capacity of the community-based health care workforce by acting as teaching and practice sites for nursing students and other health professionals. Each academically-affiliated NMHC provides clinical placements for an average of 50 to 60 students a year.² These students include graduate and undergraduate nursing students, as well as medical, physician assistant, and social work students among others. Students participating in post-clinical focus groups express a high level of satisfaction with NMHC-based clinical placements, commenting that their experience in NMHCs highlighted the need to reduce health care disparities and respect patient diversity.³ A large percentage of the federal funding for academically-affiliated NMHCs comes from the Title VIII Nurse Education, Practice, Quality, and Retention Program (NEPQR) program. Reauthorizing NEPQR would allow academic NMHCs to expand their dual role of providing quality care to the medically underserved and educating the next generation of nurses.

Outcome data from managed care organizations and academic research journals show that NMHCs provide accessible high quality care that is also cost effective. The nurse practitioners in NMHCs can manage 80 to 90 percent of the care provided by primary care physicians without referral or consultation.⁴ According to a 2011 meta-analysis of peer-reviewed articles regarding the quality of nurse practitioner-provided care, primary care nurse practitioners continually produced patient health outcomes comparable to those of primary care physicians.⁵ With respect to cost, NMHC patients typically have higher rates of generic

² NNCC, 2012 NNCC Membership Survey (2012)

³ Institute for Nursing Centers, Feedback From Student Focus Group Surveys Administered by the Institute for Nursing Centers in 2009 (2009).

⁴ Munding, M.O. (1994). Advanced-practice nursing -- good medicine for physicians? *New England Journal of Medicine*, 330(3), 211-214.

⁵ Newhouse N.P., Stanik-Hutt J., White, K.M., Johantgen, M., Bass E.B., Zangaro G., Wilson R.F., Fountain L., Steinwachs D.M., Heindel L., Weiner J.P. (2011). Advanced practice nurse outcomes 1990-2008: a systemic review.

medication fills and lower hospitalization rates than patients of similar providers.⁶ Additionally, elderly and disabled people with access to NMHCs visit emergency rooms less often than those without access.⁷

Specific Comments:

Although some NMHCs receive stable federal funding as part of the federally qualified health center program, the majority of NMHCs rely on a mix government and foundation grants to sustain their health services and clinical training programs. As stated above, the NEPQR program is critical to NMHC sustainability efforts. Failure to reauthorize this Title VIII program would cause NMHCs around the nation to severely curtail or eliminate needed services and training programs. I urge the Subcommittee to advance H.R. 2713 to ensure the continued availability of funding to NMHCs.

Additionally, NMHCs face a host of challenges related to reimbursement, scope of practice, and provider credentialing. For example, a recent survey revealed that 25% of those managed care organizations participating in the healthcare marketplaces will not contract with nurse practitioners as primary care providers, which includes those nurse practitioners working in NMHCs. Similarly, some NMHC providers are not able to take full advantage of telehealth technology due to restrictions in state scope of practice or telehealth statutes. These limitations not only affect the financial resources available to NMHCs, they also restrict access to care for the underserved, drive up the cost of care and deny consumers the right to choose the primary care provider of their choice.

H.R. 2713 seeks to address these challenges by adding Nurse-Managed Health Clinics (NMHCs) to the list of eligible entities in the definition section of the Title VIII statute. This

Nursing Economics, 29(5) Published Online Before Release, available at: <http://www.nursingeconomics.net/cgi-bin/WebObjects/NECJournal.woa>

⁶ Hansen-Turton, T. (2005). The nurse-managed health center safety net: a policy solution to reducing health disparities. *Nursing Clinics of North America*, 40, 729-738.

⁷ Glick, D. F., Thompson, K. M., & Ridge, R. A. (1999). Population-based research: The foundation for development, management, and evaluation of a community nursing center. *Family & Community Health*, 21(4), 41-50.

addition brings greater visibility to the benefits of the NMHC model and possibly opens up new funding opportunities for NMHCs by placing the centers on equal footing with other models of care. Again, I urge the Subcommittee to move H.R. 2716 to the next stage in the legislative process with this important technical change.

I appreciate the opportunity to testify. Please feel free to contact me at (215) 731-7140 or tine@nncc.us with any questions.

Very truly yours,

A handwritten signature in black ink, appearing to read "Tine Hansen-Turton".

Tine Hansen-Turton, MGA, JD, FAAN, FCPP

Chief Executive Officer

National Nursing Centers Consortium



SUMMARY

Testimony Regarding H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act of 2015

- Adopt the CNS-related amendments contained in H.R. 2713, the *Title VIII Nursing Workforce Reauthorization Act of 2015*.
- Changes include:
 - ❖ Inserting a definition of the clinical nurse specialist (CNS) in the Advanced Education Nursing Grants program [42 U.S.C. S 296j]
 - ❖ Adding the CNS to the list of nursing specialties that can serve on the National Advisory Council on Nurse Education and Practice [42 U.S.C. S 297t].



**Testimony Regarding H.R. 2713, the Title VIII Nursing
Workforce Reauthorization Act of 2015
November 8, 2015**

To: Subcommittee on Health, Committee on Energy and Commerce
U.S. House of Representatives

Submitted by: Peggy Barksdale, MSN, RN, OCNS-C, CNS-BC, President, National Association of
Clinical Nurse Specialists

The National Association of Clinical Nurse Specialists (NACNS) is the voice of more than 70,000 clinical nurse specialists (CNSs). CNSs are licensed registered nurses who have graduate preparation (master's or doctorate) in nursing as a clinical nurse specialist. They have unique and advanced level competencies that meet the increased needs of improving quality and reducing costs in today's healthcare system. CNSs provide direct patient care, including assessment, diagnosis, and management of patient healthcare issues. They are leaders of change in health organizations, developers of scientific evidence-based programs to prevent avoidable complications, and coaches of those with chronic diseases to prevent hospital readmissions. CNSs are facilitators of multidisciplinary teams in acute and chronic care facilities to improve the quality and safety of care, including preventing hospital acquired infections, reducing length of stays, and preventing hospital readmissions.

The NACNS urges the subcommittee to adopt the CNS-related amendments contained in H.R. 2713, the *Title VIII Nursing Workforce Reauthorization Act of 2015*, which would align with current nursing roles and practice. These changes include inserting a definition of the clinical

nurse specialist in the Advanced Education Nursing Grants program [42 U.S.C. S 296j] and adding the CNS to the list of nursing specialties that can serve on the National Advisory Council on Nurse Education and Practice [42 U.S.C. S 297t]. As one of the four advanced practice registered nurse (APRN) roles, these changes regarding CNSs would align with the APRN Consensus Model.

The Title VIII Nursing Workforce Development Programs provide training for entry-level and advanced degree nurses to improve the access to, and quality of, health care in underserved areas. They are fundamental to the infrastructure delivering quality, cost-effective health care. NACNS believes that the deepening health inequities, inflated costs, and poor quality of healthcare outcomes in this country will not be reversed until the concurrent shortages of nurses, advanced practice registered nurses, and qualified nurse educators are addressed.

Your support of S. 2713 will help ensure that future nurses exist who are prepared and qualified to take care of you, your family, and all those who will need our care. Without national efforts of some magnitude to match the healthcare reality facing the nation today, an under resourced nurse education and its adverse effect in health care generally will be difficult to avoid.

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WRITTEN TESTIMONY FOR THE RECORD

HOUSE ENERGY AND COMMERCE, SUBCOMMITTEE ON HEALTH HEARING
“EXAMINING LEGISLATION TO IMPROVE HEALTH CARE AND TREATMENT”

SUBMITTED BY: SUZANNE MIYAMOTO, PhD, RN, FAAN
ON BEHALF OF THE NURSING COMMUNITY COALITION

DECEMBER 9, 2015

On behalf of the 55 undersigned national professional nursing organizations representing the Nursing Community coalition, we respectfully submit this testimony for the record regarding H.R. 2713, the Title VIII Nursing Workforce Reauthorization Act of 2015, to the House Committee on Energy and Commerce, Subcommittee on Health. This legislation would reauthorize the Nursing Workforce Development programs (Title VIII of the Public Health Service Act) and propose four technical changes to modernize the programs. The Nursing Community represents nearly one million practicing nurses, nursing students, and nursing faculty, and is committed to improving the health and health care of our nation by collaborating to support the education, practice, and research of registered nurses (RNs) and advanced practice registered nurses (APRNs).

For over five decades, the Title VIII programs have helped to build the supply and distribution of qualified nurses to meet our nation’s healthcare needs. As the largest dedicated source of federal funding for nursing education, these programs bolster nursing education at all levels, support nurses in the workforce, and provide assistance for institutions involved in the education and training of these clinicians. Regional demands for nursing services, coupled with an aging

nursing workforce, contribute to a projected need that will outweigh supply if current entry rates into the profession continue.¹ Therefore, it is essential that our nursing pipeline has the support of Title VIII programs to address these workforce challenges and increase the number of individuals entering into the registered nursing workforce. Our organizations' members deeply rely on these programs to foster high-quality care delivery in the wide range of settings where they practice, teach, and lead in improving health care.

Moreover, Title VIII programs are specifically designed to help address challenges and barriers to educating a greater number of RNs, APRNs, and other nurses with advanced degrees. For example, the Nurse Education, Practice, Quality, and Retention (NEPQR) Program supported 9,448 nursing students in Academic Year 2013-2014.² NEPQR helps schools of nursing, academic health centers, nurse managed health clinics, and healthcare facilities strengthen the RN workforce. NEPQR also allows for programs to be created that are reflective of emerging priorities. For example, in FY 2015, NEPQR funded a number of schools through the Veterans' Bachelor of Science in Nursing program.³ Designed to assist Veterans in achieving their nursing degree, this program allows these Servicemen and Servicewomen to matriculate into the nursing workforce building upon their experience and training from their military careers. This is timely as our nation identifies ways to help improve care for Veterans and strengthens a health professions workforce that understands the unique needs of Veterans and their caregivers.

¹ Auerbach, D. I., Buerhaus, P., & Staiger, D. O. (2015). Will the nursing workforce weather the retirement of the baby boomers? *Medical Care*, 53(10), 850-856.

² U.S. Department of Health and Human Services. (2015). *Health Resources and Services Administration Fiscal Year 2016 Justification of Estimates for Appropriations Committees*.

³ U.S. Department of Health and Human Services. Health Resources and Services Administration Data Warehouse. Retrieved from:
https://ersrs.hrsa.gov/ReportServer/Pages/ReportViewer.aspx?/HGDW_Reports/FindGrants/GRANT_FIND&ACTIVITY=UFI&rs:Format=HTML4.0.

H.R. 2713 would amend the statute to allow for four technical modernizations that would align with current nursing roles and practice. The first and second changes would include a definition of the Clinical Nurse Specialist (CNS) in the Advanced Education Nursing (AEN) Grants program [42 U.S.C. S 296j] and add the CNS among the list of nursing specialties to serve on the National Advisory Council on Nurse Education and Practice [42 U.S.C. S 297t]. CNSs are graduate-prepared nurses who specialize in a specific area of practice defined by a population, setting, or disease type. As one of the four APRN roles, these two changes would align with the APRN Consensus Model and create parity in statute.⁴

The third technical change would amend the AEN Grants program [42 U.S.C. S 296j] to include the Clinical Nurse Leader (CNL) in the definition of advanced education nurses. CNLs are graduate-prepared nurses who lead in the coordination of patient care by evaluating patient outcomes, assessing cohort risk, and redirecting patient care plans as necessary. Including CNLs would provide them equal opportunity to participate in the AEN Grants program with other graduate degree programs that can apply for these dollars.

The fourth technical change would add Nurse-Managed Health Clinics (NMHCs) to the list of eligible entities in the definition section of the Title VIII statute [42 U.S.C. S 296]. NMHCs are recognized as a key example of efficient and cost-effective health care. NMHCs are successful in providing individualized primary care that includes health promotion, disease prevention and

⁴ APRN Consensus Work Group. (July 7, 2008). Consensus Model for APRN Regulation: Licensure, Accreditation, Certification & Education. Retrieved from: https://ncsbn.org/Consensus_Model_for_APRN_Regulation_July_2008.pdf.

early detection, health screenings and teaching, management of chronic and acute care, and counseling. These care sites often focus on populations that face provider or service shortages and also serve as clinical training sites for nursing and other health professions students.

As our healthcare system continues to undergo transformations that necessitate a more highly-educated nursing workforce, it is critical that Title VIII programs are sustained through reauthorization so their impact on our nation's health is not interrupted. The Nursing Community thanks the Subcommittee for the opportunity to provide insight on the importance of the Title VIII Nursing Workforce Development programs and why the Title VIII Nursing Workforce Reauthorization Act of 2015 is critical to their future sustainability. We urge the Subcommittee and full Committee to advance this valuable legislation. If the Nursing Community can be of assistance, please contact Dr. Suzanne Miyamoto at 202-463-6930, or Smiyamoto@aacn.nche.edu.

Sincerely,

Academy of Medical-Surgical Nurses
 American Academy of Ambulatory Care Nursing
 American Academy of Nursing
 American Assembly for Men in Nursing
 American Association of Colleges of Nursing
 American Association of Critical-Care Nurses
 American Association of Neuroscience Nurses
 American Association of Nurse Anesthetists
 American Association of Occupational Health Nurses
 American Association of Nurse Practitioners
 American College of Nurse-Midwives
 American Nephrology Nurses' Association
 American Nurses Association
 American Organization of Nurse Executives
 American Pediatric Surgical Nurses Association
 American Psychiatric Nurses Association

American Society for Pain Management Nursing
 American Society of PeriAnesthesia Nurses
 Association for Radiologic and Imaging Nursing
 Association of Community Health Nursing Educators
 Association of Nurses in AIDS Care
 Association of Pediatric Hematology/Oncology Nurses
 Association of periOperative Registered Nurses
 Association of Public Health Nurses
 Association of Rehabilitation Nurses
 Association of Women's Health, Obstetric and Neonatal Nurses
 Commissioned Officers Association of the U.S. Public Health Service
 Dermatology Nurses' Association
 Emergency Nurses Association
 Gerontological Advanced Practice Nurses Association
 Hospice and Palliative Nurses Association
 Infusion Nurses Society
 International Association of Forensic Nurses
 International Society of Psychiatric-Mental Health Nurses
 National American Arab Nurses Association
 National Association of Clinical Nurse Specialists
 National Association of Hispanic Nurses
 National Association of Neonatal Nurse Practitioners
 National Association of Neonatal Nurses
 National Association of Pediatric Nurse Practitioners
 National Association of School Nurses
 National Black Nurses Association
 National Council of State Boards of Nursing
 National Gerontological Nursing Association
 National League for Nursing
 National Nursing Centers Consortium
 National Organization of Nurse Practitioner Faculties
 Nurses Organization of Veterans Affairs
 Oncology Nursing Society
 Organization for Associate Degree Nursing
 Pediatric Endocrinology Nursing Society
 Preventive Cardiovascular Nurses Association
 Public Health Nursing Section, American Public Health Association
 Society of Urologic Nurses and Associates
 The Quad Council of Public Health Nursing Organizations

Society for Maternal-Fetal Medicine
Written Public Testimony
Energy & Commerce Subcommittee on Health
“Examining Legislation to Improve Health Care and Treatment”
Submitted by Laura Riley, MD; President, Society for Maternal-Fetal Medicine

My name is Dr. Laura Riley, and I currently serve as President of the Society for Maternal-Fetal Medicine. I am the Medical Director of Labor and Delivery at Massachusetts General Hospital in Boston, MA. 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. 1209, the Improving Access to Maternity Care Act and H.R. 3441, the Accurate Education for Prenatal Screenings Act.

The Society for Maternal-Fetal Medicine (SMFM) was established in 1977 to give Maternal-Fetal Medicine (MFM) physicians and scientists a place to share knowledge, research and clinical best practices in order to improve care for moms and babies. Maternal-Fetal physicians are obstetricians with additional training in the area of high-risk pregnancies. We specialize in treating the un-routine. Because of our additional training, we are involved in the latest advancements in maternal and fetal care. We are dedicated to improving maternal and child outcomes and to raising the standards of prevention, diagnosis and treatment of maternal and fetal disease. Our members also contribute to a large proportion of research and training in the Obstetrical field.

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

SMFM has proudly endorsed H.R. 1209, the Improving Access to Maternity Care Act, introduced by Rep. Michael Burgess, M.D. As you know, this important legislation would require the Health Resources and Services Administration to designate maternity care health professional shortage areas and review those designations on an annual basis. It would also require the Department of Health and Human Services to collect and publish data on these shortage areas.

Although MFMs deal primarily with high-risk pregnancies, access to maternity care is key to ensuring good outcomes for both mother and baby, regardless of whether their pregnancy is high risk or not. Unfortunately many women in underserved areas of the country may feel the brunt of shortages of qualified maternity providers – including MFMs. This legislation will improve access to maternity providers in underserved areas, ensuring that pregnant women receive the care they deserve, and lead to better outcomes.

We feel that highlighting the critical need for maternity care providers in a specific area and designating it as a maternity care shortage area will attract more qualified maternity care providers to these areas, and improve access of pregnant women to high quality care. These designations already exist for

primary care, dental and mental health, and it only makes sense to add maternal health to the list. This will go a long way to improving the health of both mothers and babies in our country.

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

SMFM has some concerns with H.R. 3441, and has previously expressed these to the champions of this legislation. While we agree that prenatal screening is very important, this is a very complex area that requires expertise and is a very rapidly evolving technology. SMFM and ACOG issued a 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 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 feel that while materials certainly need to be created, the environment or circumstances under which such materials should be developed and disseminated is still unclear. The material produced will have to be updated frequently as knowledge and practice in this field is evolving rapidly. We anxiously await a previously requested report from the CDC about the gaps in materials and a recommended path forward.

We would also 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 and would have a wider impact on public health. Prenatal cell free DNA screening is performed in the context of other screening and diagnostic tests, therefore accurate education requires equally accurate discussion of the alternative options.

Finally, the Perinatal Quality Foundation earlier this year partnered with Quest Diagnostics, LabCorp, Illumina and Sequenom to create a program 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.” This important initiative, supported by SMFM, is already underway to create a comprehensive education and quality-tracking program and aims to close knowledge gaps among consumers and providers about this new technology. It 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.

Specifically under this initiative, the PQF will develop educational materials and tools, including a website and event forums, for patients, clinicians, and other healthcare personnel. The materials will focus on the types of prenatal screening tests, their strengths and limitations, test results interpretation, and actions to consider based on results. 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. All of these important activities are expected in early 2016.

Given this project's current status, we believe that H.R. 3441 would create duplicative activities related to this space, and aims to achieve similar goals.

Conclusion

On behalf of the Society for Maternal-Fetal Medicine, 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 our Washington Representative, Katie Schubert, with any questions you may have, at (202) 484-1100 or kschubert@dc-crd.com.



Written Testimony for the Record
House Energy and Commerce, Subcommittee on Health Hearing
"Examining Legislation to Improve Health Care and Treatment"

Submitted by: Beverly Malone, PhD, RN, FAAN, Chief Executive Officer,
National League for Nursing

December 9, 2015

On behalf of the National League for Nursing (NLN), I respectfully submit this testimony for the record regarding H.R. 2713, the *Title VIII Nursing Workforce Reauthorization Act of 2015*, to the House Committee on Energy and Commerce, Subcommittee on Health. H.R. 2713 reauthorizes the Title VIII nursing workforce development programs at the Health Resources and Services Administration (HRSA). The NLN promotes excellence in nursing education to build a strong and diverse nursing workforce to advance the health of the nation and the global community. The League represents more than 1,200 nursing schools, 40,000 members, and 26 regional constituent leagues.

NURSING EDUCATION

For the last 50 years, the Title VIII nursing workforce development programs have provided education and training for entry-level and advanced practice registered nurses (APRNs) to improve the access to, and quality of, health care in underserved communities. The Title VIII programs are the largest dedicated source of federal funding for nursing education and training. These programs are fundamental to a strong nursing workforce infrastructure delivering quality and cost-effective health care. Due to growth and retirements from 2012 – 2022, the Bureau of Labor Statistics (BLS) projects 34,200 or 35 percent new nursing faculty needed, 124,600 or 31 percent new

APRNs needed, 363,100 or 25 percent new LPNs/LVNs needed, and 1.1 million or 19 percent new RNs needed.¹

THE NURSE PIPELINE AND EDUCATION CAPACITY

Although the recession resulted in some stability in the short-term for the nurse workforce, policy makers must not lose sight of the long-term growing demand for nurses in their districts and states. As the United States tackles the workforce shortage that exacerbates the stress in the health care system, nursing programs across the country are rejecting qualified candidates because there is not enough faculty to teach them.

The NLN Biennial Survey Of Schools Of Nursing Academic Year 2013-2014 found that the percentage of PN/VN, ADN and diploma (RN) pre-licensure programs that turned away qualified applicants dropped in 2014, the percentage for BSN programs remained unchanged between 2012 and 2014, while the percentage for BSRN (RN to BSN), MSN, and doctorate programs increased by 6 percent, 8 percent, and 4 percent, respectively.² If the trend in the number of qualified applicants turned away from BSN programs remains the same as from 2012 to 2014, this could have a potential impact on the IOM's recommendation in *The Future of Nursing: Leading Change, Advancing Health* (2011) for an increase in the proportion of nurses with baccalaureate degrees from 50 to 80 percent by 2020.³ NLN research shows that a lack of faculty also remains a key obstacle to expanding the capacity of nursing programs in almost all

¹ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook, 2014-15 Edition*

² National League for Nursing (2015). Findings From The 2014 NLN Biennial Survey Of Schools Of Nursing Academic Year 2013-2014 Executive Summary. *NLN DataView*SM. Retrieved from <http://www.nln.org/docs/default-source/newsroom/nursing-education-statistics/2014-survey-of-schools---executive-summary.pdf?sfvrsn=0>.

³ Institute of Medicine. (2011). *The Future of Nursing: Leading Change, Advancing Health*. Washington, DC: National Academies Press.

programs. The lack of faculty is more noticeable for doctoral programs; more than half of the doctoral programs (53 percent) reported lack of faculty as the main obstacles.⁴

EQUALLY PRESSING IS LACK OF DIVERSITY

Health disparities are multi-dimensional and exist throughout the United States. Besides representing an untapped talent pool to remedy the nationwide nursing shortage, diversity in nursing is essential to developing a health care system that understands and addresses the needs of our rapidly changing population. Our nation is enriched by cultural complexity – 37 percent of our population identify as racial and ethnic minorities. Yet diversity eludes the nursing student and nurse educator populations. Minorities only constitute 28 percent of the student population and males only 15 percent of pre-licensure RN students.⁵ In fiscal year 2013, 36 percent of nursing students trained in the Advanced Nursing Education Title VIII program were underrepresented minorities and/or from disadvantaged backgrounds.

A survey of nurse educators conducted by the NLN and the Carnegie Foundation's Preparation for the Professions Program found that only 7 percent of nurse educators were minorities compared with 16 percent of all U.S. faculty. The lack of faculty diversity limits nursing schools' ability to deliver culturally appropriate nursing education.

⁴ National League for Nursing (2015). Findings From The 2014 NLN Biennial Survey Of Schools Of Nursing Academic Year 2013-2014 Executive Summary. *NLN DataView™*. Retrieved from <http://www.nln.org/docs/default-source/newsroom/nursing-education-statistics/2014-survey-of-schools---executive-summary.pdf?sfvrsn=0>.

⁵ National League for Nursing (2015). Findings From The 2014 NLN Biennial Survey Of Schools Of Nursing Academic Year 2013-2014 Executive Summary. *NLN DataView™*. Retrieved from <http://www.nln.org/docs/default-source/newsroom/nursing-education-statistics/2014-survey-of-schools---executive-summary.pdf?sfvrsn=0>.

H.R. 2713 UPDATES

H.R. 2713 would amend the statute to allow for four technical modernizations that would align with current nursing roles and practice. The first two changes would include a definition of the Clinical Nurse Specialist (CNS) in the Advanced Education Nursing Grants program [42 U.S.C. S 296j] and add the CNS among the list of nursing specialties to serve on the National Advisory Council on Nurse Education and Practice [42 U.S.C. S 297t]. CNSs are graduate-prepared nurses who specialize in a specific area of practice defined by a population, setting, or disease type. As one of the four APRN roles, these changes would align with the APRN Consensus Model.

The third technical change would amend the Advanced Education Nursing grants program [42 U.S.C. S 296j] to include the Clinical Nurse Leader (CNL) in the definition of advanced education nurses. CNLs are graduate-prepared nurses who lead in the coordination of patient care by evaluating patient outcomes, assessing cohort risk, and redirecting patient care plans as necessary. Including CNLs would provide them equal opportunity to participate in the AEN grants program with other graduate degree programs that can apply for these dollars.

The fourth technical change would add Nurse-Managed Health Clinics (NMHCs) to the list of eligible entities in the definition section of the Title VIII statute [42 U.S.C. S 296]. NMHCs are recognized as a key example of efficient and cost-effective healthcare. NMHCs are effective in providing individualized primary care that includes health promotion, disease prevention and early detection, health screenings and teaching, management of chronic and acute care, and counseling. These care sites

often focus on populations that face provider or service shortages and also serve as clinical training sites for nursing and other health professions students.

H.R. 2713 ensures the Title VIII nursing workforce development programs will continue to address the specific needs of the nursing and nurse faculty workforces as well as patients in our communities. The NLN thanks the Subcommittee for the opportunity to provide insight on the importance of the Title VIII programs and why the *Title VIII Nursing Workforce Reauthorization Act of 2015* is critical to their future sustainability. We urge the Subcommittee and full Committee to advance H.R. 2713. If the NLN can be of assistance, please contact Christine Murphy, Director of Public Policy and Advocacy at 202-909-2533.

Testimony of the National Athletic Trainers' Association (NATA)
U.S. House Energy and Commerce Committee
Hearing on Examining Legislation to Improve Health Care and Treatment
Submitted on December 9, 2015 by NATA President, Scott Sailor, EdD, ATC

On behalf of the National Athletic Trainers' Association (NATA), I am pleased to have the opportunity to provide written testimony to the House Energy and Commerce Health Subcommittee hearing titled "Examining Legislation to Improve Health Care and Treatment." Specifically, NATA is supportive of the *Sports Medicine Licensure Clarity Act of 2015* (H.R. 921).

As you may know, NATA is a professional organization serving more than 43,000 certified athletic trainers, students of athletic training, and other health care professionals. Our mission is to represent, engage, and foster the continued growth and development of the athletic training profession and athletic trainers as unique health care providers. Athletic trainers are health care professionals who collaborate with physicians to provide preventative services, emergency care, clinical diagnosis, therapeutic intervention, and rehabilitation of injuries. As the leading organization representing athletic trainers, NATA is in full support of the *Sports Medicine Licensure Clarity Act of 2015*.

Athletic trainers and other sports medicine professionals care for individual athletes and entire athletic teams at the professional and collegiate levels. However, in many states no legal protection is provided for athletic trainers or sports medicine professionals whose job requires travel outside of their home state (where they are licensed) with an athletic team for the purpose of providing health care coverage for their team. Medical liability insurance carriers do not cover such health care

professionals when they travel with their team to states where they are not licensed to practice. Consequently, they must choose between either treating injured athletes at great professional risk or abandoning the athletes to whom they provide care.

The *Sports Medicine Licensure Clarity Act of 2015* will provide legal protection for athletic trainers and sports medicine professionals who must travel to other states with an athletic team to provide care for the members of that team. For the purposes of liability, health care services provided by a covered athletic trainer or sports medicine professional to an athlete, an athletic team, or a staff member of the team outside of his or her home state will be deemed to have occurred in the professional's primary state of licensure. The legislation also allows athletic trainers and other sports medicine professionals to engage in the treatment of injured athletes across state lines without the fear of great professional harm, such as loss of license to practice, while protected from financial loss with professional liability insurance. The legislation aims to preserve athletes and athletic teams' access to high-quality health care services provided by athletic trainers and other sports medicine professionals.

Thank you for this opportunity to present our views. We look forward to working with you to address these and other important issues. Should you have any questions or require any additional resources, please feel free to contact NATA.

Scott Sailor, EdD, ATC
NATA President

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.

December 8, 2015

The Honorable Joe Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
420 Cannon House Office Building
Washington, D.C. 20515-6065

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2470 Rayburn House Office Building
Washington, D.C. 20515-6065

Dear Chairman Pitts and Ranking Member Green:

We, the undersigned organizations, would like to thank you for holding a legislative hearing for H.R. 921, the *Sports Medicine Licensure Clarity Act of 2015*. This bill would ensure sports medicine providers' ability to provide timely, high-quality health care services to injured athletes and team staff without the fear of incurring great professional loss.

As you are aware, many states do not provide legal protection for sports medicine professionals who travel to another state with an athletic team solely to provide care for that team. Compounding this problem, medical professional liability insurance carriers are not required to cover sports medicine professionals who deliver care to a member of their team during away games outside the insurance policy coverage area. As a result, these sports medicine providers must choose to either treat injured athletes at great professional risk, or turn the injured athlete over to local physicians who are not familiar with the athlete's medical history. Lastly, this bill preserves athletes' continuity of care and access to their team's health care providers where there is an established relationship that can continue post-injury. Your leadership on H.R. 921 will allow sports medicine providers to provide continued, high-quality health care services to injured athletes and team staff without the fear of violating local and state laws.

The undersigned organizations fully support this important piece of legislation and we look forward to working with you to pass this bill.

Sincerely,

American Academy of Neurology
American Association of Orthopaedic Surgeons
American College of Surgeons
American Medical Association
American Medical Society for Sports Medicine
American Orthopaedic Society for Sports Medicine
American Osteopathic Association
Congress of Neurological Surgeons
North American Spine Society
National Athletic Trainers Association



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 Suite 100
 Washington, D.C. 20002-5701

P. 202.546.4430
 F. 202.546.5051

www.aaos.org/dc

On behalf of over 18,000 board-certified orthopaedic surgeons, the American Association of Orthopaedic Surgeons (AAOS) would like to commend Chairman Joe Pitts (R-PA) and Ranking Member Gene Green (D-TX) for holding the Energy and Commerce Subcommittee on Health hearing titled, "Examining Legislation to Improve Health Care and Treatment." Specifically, the AAOS would like to thank the Chairman, the Ranking Member, and the entire subcommittee for considering H.R. 921, the Sports Medicine Licensure Clarity Act of 2015, at this time.

Sports medicine professionals are responsible for the organization, management, and provision of care for athletes in individual, team, and mass participation sporting events. These professionals include both physicians and athletic trainers who are specifically trained in identification, prevention, treatment, and rehabilitation of sports injuries and have a fundamental knowledge of on-field medical emergency care and of musculoskeletal injuries, medical conditions, and psychological issues affecting athletes.

While over fifteen percent of the AAOS' members practice sports medicine as their primary specialty, a large majority are involved in the care of athletes engaged in sports activities across state lines. In addition to their orthopaedic surgery residency, these medical professionals must also complete a surgical sports medicine fellowship, which lasts anywhere from twelve to twenty four months. Such fellowships allow orthopaedic surgeons to gain more experience and knowledge dealing with the treatment and care of sports-related injuries.

As part of their job, sports medicine professionals who work with athletic teams often travel across state lines when teams play away games. In the NFL, the Pennsylvania-based Philadelphia Eagles team traveled to Texas, California,

Arizona, Wisconsin, and New York over the course of their 2014 season.¹ In the NCAA, a basketball player at West Virginia University might travel to Iowa, Oklahoma, Kansas, or Texas for in-conference games as part of the BIG 12 Athletic Conference, and may travel to other schools for out-of-conference games, as well.²

However, as you are aware, many states do not provide legal protection for sports medicine professionals who travel to another state with an athletic team solely to provide care for that team. Compounding this problem, medical professional liability insurance carriers are not required to cover sports medicine professionals who deliver care to a member of their team during away games outside the insurance policy coverage area.

Athletic groups of all levels contract with teams of sports medicine professionals to ensure that the athletes receive high quality, timely, and expert care in dealing with sports-related injuries. Professional sports teams such as those in the National Football League (NFL), National Hockey League (NHL), and National Basketball Association (NBA), often contract with one or more team physicians and other sports medicine professionals to care for their athletes. College sports teams that are part of the National Collegiate Athletic Association (NCAA) also have sports medicine teams comprised of dedicated sports medicine professionals that care for the athletes.

Sports medicine professionals provide the highest quality, expert sports-related health care to hundreds of thousands of professional, semi-professional, and amateur athletes across the United States. At the NCAA Division 1 level alone, there are over 6,000 teams and over 170,000 athletes.³ Over time—through off-

¹ <http://www.nfl.com/schedules/2014/REG/EAGLES>

² <http://www.wvusports.com/schedules.cfm?sport=mbball>

³ <http://www.ncaa.org/about?division=d1>

seasons, practices, and game-time injuries—these team physicians and sports medicine professionals develop a trusting rapport with the athletes for whom they provide care.

The NCAA's partnership with the Datalys Center and the National Center for Catastrophic Sports Injury Research provides great insight into how often athletes need the care of a sports medicine professional. Data from 2004 through 2009 suggests that the overall injury rate in NCAA football is 8.1 injuries per 1,000 athlete exposures (games and practices combined). In football, there were over 41,000 injuries, with ligament sprains being the most common injury reported.⁴ In NCAA women's volleyball, the overall rate of injury was 4.3 per 1,000 athlete exposures (games and practices combined) between 2004 and 2009. There were more than 26,000 injuries reported and the data suggests volleyball players were just as likely to become injured in a game as in practice.⁵ For these athletes, and all others, sports medicine professionals would be called on to evaluate, diagnose, treat, and follow-up to any and all injuries or suspected injuries obtained.

These athletes deserve the same high-quality care when they are on the road as they do when they are at home. In the case of traveling sports teams, the highest-quality care possible would be provided by their own team's sports medicine professionals. These are the providers who best understand the athletes' medical history, and can provide the most seamless and effective continuity of care from initial evaluation and treatment, to recovery, rehabilitation, and follow-up care.

⁴

http://www.datalyscenter.org/6ac981a4eb_sites/datalyscenter.org/files/NCAA_Football_Injury_WEB_1_.pdf

⁵

http://www.datalyscenter.org/6ac981a4eb_sites/datalyscenter.org/files/NCAA_W_Volleyball_Injuries_HiRes.pdf

For sports medicine professionals who travel into multiple states, obtaining and maintaining licensure in each state – especially under a scenario where they are not even providing medical care to the residents of the secondary state – constitutes an excessively high administrative, cost, and risk management burden.

As a result, the sports medicine professional must choose between treating injured athletes at great professional risk, or handing over the care of an injured player to another professional who is not familiar with the athlete's medical history, and therefore approaches the injured athlete with a distinct disadvantage.

The Sports Medicine Licensure Clarity Act would remedy this problem by clarifying medical liability rules for sports medicine professionals to ensure they are properly covered by their professional liability insurance while traveling with athletic teams in another state. Specifically, the legislation, which enjoys bipartisan support, stipulates that for the purposes of liability, healthcare services provided by a covered sports medicine professional to an athlete, an athletic team, or a staff member of an athlete or athletic team in a secondary state will be deemed to have been provided in the professional's primary state of licensure.

By specifying that healthcare services provided by a covered sports medicine professional outside the state of licensure will be covered, the bill removes questions about licensing jurisdiction and eliminates ambiguity about coverage when a provider cares for players during competitions across state lines. This bill helps ensure that injured athletes have timely access to healthcare professionals who best know their medical histories and can provide seamless, expert, and efficient continuity of care through the duration of their injury.

The AAOS strongly believes that sports medicine providers should not have to choose between treating injured athletes at great professional and financial risk,

and reducing athletes' access to quality health care services. Therefore, the AAOS urges you and your colleagues to report this bill favorably out of subcommittee.

Thank you for your consideration of this important piece of legislation that would allow the highest level of care for athletes across the United States.



JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

April 28, 2015

The Honorable Brett Guthrie
U.S. House of Representatives
2434 Rayburn House Office Building
Washington, DC 20515

Dear Representative Guthrie:

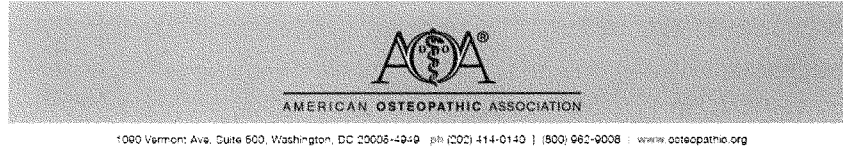
On behalf of the physician and medical student members of the American Medical Association (AMA), I am writing in support of H.R. 921, the "Sports Medicine Licensure Clarity Act of 2015." If enacted, this bill would provide key protections for sports medicine professionals, including physicians, who provide medical services in a secondary state.

Liability insurance does not typically provide coverage outside the state where a physician is licensed to practice. This means that when physicians or other sports medicine professionals travel with their athletes they may not be covered. To remedy this problem, your bill would deem services provided in a non-covered state to have been provided in the physician's primary state of licensure when determining applicable liability laws and the professional's liability insurance coverage. This deeming authority is only for care given to the team's athletes or staff and would not include services provided at a health care facility in a non-covered state. H.R. 921 is therefore a common sense approach that would ensure reasonable protections for these care providers.

We thank you for introducing H.R. 921, and look forward to working with you on this important legislation.

Sincerely,

James L. Madara, MD



December 4, 2015

The Honorable Brett Guthrie
 United States House of Representatives
 2434 Rayburn House Office Building
 Washington, D.C. 20515

Dear Representative Guthrie:

On behalf of the American Osteopathic Association (AOA) and the more than 122,000 osteopathic physicians and osteopathic medical students we represent, we thank you for introducing the "Sports Medicine Licensure Clarity Act" (H.R. 921). We support your efforts to provide liability protection for sports medicine professionals who provide medical services in a secondary state.

The current medical liability system presents a significant challenge to our nation's health care delivery system. Currently, many states do not provide legal protection for sports medicine professionals who travel to another state with an athletic team solely to provide care for that team. In addition, medical liability insurance carriers do not cover sports medicine professionals when they travel with their team to states where they are not licensed to practice medicine. Consequently, these sports medicine providers must choose between either treating injured athletes at great professional risk, or abandoning the teams to whom they provide medical care.

Under your legislation, legal protection is provided for sports medicine professionals who travel to other states with an athletic team to provide care for that team. The AOA remains committed to enacting legislation that would create a more balanced liability system.

Again, thank you for your steadfast leadership on this issue. Please do not hesitate to call upon the AOA or our members for assistance on this priority issue.

Sincerely,

A handwritten signature in black ink, which appears to read 'John W. Becher, DO'.

John W. Becher, DO
 President



April 23, 2015

The Honorable Brett Guthrie
 United States House of Representatives
 2217 Rayburn House Office Building
 Washington DC 20510

The Honorable Cedric Richmond
 United States House of Representatives
 240 Cannon House Office Building
 Washington DC 20510

Dear Reps. Guthrie and Richmond:

We, the undersigned sports leagues and organizations, write to express our strong support for the Sports Medicine Licensure Clarity Act, which would provide protections for certain sports medicine professionals.

Each day, thousands of amateur and professional athletes all over the country place their well-being in the hands of highly qualified physicians and athletic trainers employed by their team. However, these medical professionals, who are generally licensed to practice in one state, may be prevented from providing that same care when their team travels to play out-of-state opponents.

By providing temporary and limited licensing protections, H.R. 921 will help ensure these professionals can continue to provide high quality medical services to athletes under their care, regardless of whether they are playing at home or "on the road."

We thank you for your leadership on this important issue.

Major League Baseball
 National Basketball Association
 National Collegiate Athletic Association
 National Hockey League
 National Football League
 U.S. Olympic Committee

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-2927
Minority (202) 225-3641

January 12, 2016

Dr. Ovidio Bermudez
Chief Clinical Officer and Medical Director of
Child and Adolescent Services
Eating Recovery Center
7351 East Lowry Boulevard
Denver, CO 80230

Dear Dr. Bermudez:

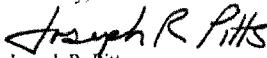
Thank you for appearing before the Subcommittee on Health on December 9, 2015, to testify at the hearing entitled "Examining Legislation to Improve Health Care and Treatment."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on January 26, 2016. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to graham.pittman@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

1. Can you describe for the committee what treatment looks like for a person experiencing a severe eating disorder?

Most individuals with an eating disorder respond best to treatment involving a multidisciplinary team, including but not limited to a primary care physician, dietitian, and a psychotherapist who are knowledgeable about eating disorders. The most effective and long-lasting treatment for an eating disorder is some form of psychotherapy or counseling, coupled with careful attention to medical and nutritional needs.

2. What are some typical signs and symptoms that would likely trigger intervention?

Eating disorders can be diagnosed based on weight changes, but also based on behaviors, attitudes and mindset. Some of the earliest signs of an eating disorder could include a variety of emotional, physical, and behavioral changes. While these changes may seem like harmless and typical adolescent behavior, taken together they can indicate a serious, life-threatening eating disorder. These changes can include:

Emotional

- Change in attitude/performance
- Expresses body image complaints/concerns: being too fat even though normal or thin; unable to accept compliments; mood affected by thoughts about appearance; constantly compares self to others; self-disparaging; refers to self as fat, gross, ugly; overestimates body size; strives to create a "perfect" image; seeks constant outside reassurance about looks
- Incessant talk about food, weight, shape, exercise, cooking, etc.
- Appears sad/depressed/anxious/expresses feelings of worthlessness
- Emotions are flat or absent
- Intolerance for imperfections in academics, eating, social life, etc.
- Is target of body or weight bullying currently or in the past
- Spends increasing amounts of time alone; pulls back from friends
- Is obsessed with maintaining unhealthy eating habits to enhance performance in sports, dance, acting, or modeling
- Overvalues self-sufficiency; reluctant to ask for help
- Unable or unwilling to acknowledge recent changes

Physical

- Sudden weight loss, gain, or fluctuation in short time
- Complaints of abdominal pain
- Feeling full or "bloated"
- Feeling faint, cold, or tired
- Dark circles under the eyes
- Calluses on the knuckles from self-induced vomiting
- Dry hair or skin, dehydration, blue hands/feet

- Lanugo hair (fine body hair)
- Fainting or dizziness upon standing
- Thinning, dry hair

Behavioral

- Diets or chaotic food intake; pretends to eat, then throws away food; skips meals
- Exercises for long periods; exercises excessively every day (can't miss a day)
- Constantly talks about food
- Difficulty sitting still: hovers over chair instead of sitting, constantly jiggles legs, gets up from desk at every opportunity, offers to run errands
- Makes frequent trips to the bathroom
- Makes lists of foods and calories eaten
- Wears very baggy clothes to hide a very thin body (anorexia) or weight gain (binge eating disorder) or hide "normal" body because of disease about body shape/size
- Is fatigued; gets dizzy
- Avoids cafeteria, works through lunch, eats alone
- Carries own food in backpack or purse
- Shows some type of compulsive behavior
- Denies difficulty

3. What would be the consequences if that person would not be able to access treatment?

If left untreated, eating disorders can be life-threatening. They are serious illnesses that can damage the brain, liver, kidneys, GI tract, teeth, skin, hair, bones, and heart. They can result in such serious medical conditions as retarded growth, osteoporosis, kidney problems, gastrointestinal dysfunction, and even heart failure. That is why it is so important to identify the illness in its earliest stages. The quicker an individual gets into treatment, the more likely they will be to recover.

4. What are the most common barriers to treatment? In your experience, do people with eating disorders have appropriate access to treatment through their health insurance, specifically as it relates to residential eating disorder services?

The cost of residential treatment for eating disorders can be upwards of \$30,000 a month. Many insurance companies do not provide full coverage for this treatment. This is why it is so important for school professionals and parents to be able to recognize the signs and symptoms of eating disorders to help identify individuals in the earliest stage of their illness. By preventing the development of full syndrome disorders and the chronic health problems they cause, early detection and intervention through this pilot program for school screenings would significantly reduce treatment costs and could even save lives.