Mandating QIOs' Standard-setting

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- My name is Jim Blumstein. I am a professor at Vanderbilt – Law School and Medical School. I am with Dr. Alan Storrow, who is co-principal Investigator on the project I will be discussing.

- I want to thank Sen. Haile, who was kind enough to meet with me. We had a good meeting, and he encouraged me to continue working on our idea about medical malpractice and defensive medicine.

- Sen. Haile was instrumental in my invitation to appear before this Committee today. I owe such a debt of gratitude to him and to his extraordinary staff person, Jinny Benedetti, and also to the Committee's lead contact staff person – Jenny Ritchey.

- Thank you for giving me this opportunity to appear before you and to present some thoughts about defensive medicine and an eventual proposal for your consideration -- a proposal for targeted legislation that, I believe, could cut costs of health care while still maintaining high standards for the quality of care.

- The ideas and the proposal are the result of several years of investigation and research that collleagues and I (re-introduce Dr. Alan Storrow) have conducted on a project funded by a federal grant.

- It is no secret that to protect themselves from medical malpractice claims, doctors—understandably—practice **"defensive medicine."** It is also no secret—studies show—that **defensive medicine** can raise health care costs substantially without increasing the quality of care and may even impose

additional, unnecessary risks to patients such as excessive exposure to radiation from unneeded x-rays or imaging .

- The traditional structure of medical malpractice litigation is what gives doctors an incentive to practice defensive medicine. A doctor has a legal duty to a patient to render treatment that complies with the "standard of care" for that treatment. To win a medical malpractice suit against a doctor, the patient must prove that the doctor breached that duty. The patient must (1) establish—using qualified medical experts—what that standard of care is, (2) show that the doctor's treatment did not meet that standard of care, and (3) show that the doctor's failure to meet the standard of care caused the injury.

- This structure assumes that there is a scientifically validated, professionally implemented consensus in the medical community as to what the standard of care is. It is designed to rely on professionals to determine the appropriate standard of care.

- But there is now substantial evidence that, in many circumstances, no such consensus exists, not even for many everyday procedures and diagnoses. This evidence is presented in the Dartmouth Atlas

    - This work was pioneered by Dr. Jack Wennberg at Dartmouth
    - It showed wide variations in procedure rates in New England towns on various ectomies -- tonsillectomies, adenoidectomies, hysterectomies
    - And no medical basis for the variations – just where the doctor did his or her training
    - And organized medicine initiated a program, called **Choosing Wisely**, to identify areas of practice that suffer from potentially risky overutilization with resulting increased costs and risks to patients
    - This evidence is what triggered our research project and persuaded a federal agency to support our work.

- The result of all this uncertainty is that doctors very often can't know at the time of treatment exactly what standard to follow. They don't know until an injury has occurred and the jury in a medical malpractice case hears competing testimony from the plaintiff's and defendant's medical experts and determines—after the fact—what the standard of care was and what the doctor needed to have done to meet the standard of care.

- This after-the-fact determination of the standard of care results in clinical uncertainty for doctors when they render care. No wonder, then, that faced with the ever-increasing prospect of legal action, doctors are incentivized to go overboard in treating patients. They can't be certain what will be deemed legally sufficient, so they do more than what is medically called for. They

are often led to provide care that is unnecessary medically, just to be able to protect against a later jury finding of an expansive standard of care.

- This is what is meant by "defensive medicine." It obviously results in higher treatment costs without necessarily increasing the quality of care. Worse, defensive medicine can increase the risk to the patient and thereby actually lower the quality of care. Our primary focus in our work has been on the risk of excessive exposure to radiation from unwarranted x-rays---unnecessary imaging or testing.

- To begin to address this problem facing patients, doctors, and payors (like TennCare) we set out to identify (following several of the Choosing Widely areas) specific areas of medical practice in which defensive medicine is most likely to occur and then to develop appropriate "safe harbors" that establish in advance what the standard of care is in those areas, providing a protocol for the treatment that meets the standard of care.

    - Dr. Storrow convened panels of medical experts in each of three areas – lower back pain, headache, mild head injury
    - They worked hard to demonstrate that the concept of a safe harbor was doable – not in all cases but in appropriate and carefully defined areas

- The creation of a safe harbor would preserve quality of care while letting the doctor know in advance what is expected.

- Any such safe harbor must be prescriptive and precise. Creation of any safe harbor must be based on clinical evidence, of course, and the safe harbor would be available only in carefully defined circumstances. It must provide a clear guideline on which a doctor can rely. It must be narrowly focused in design and limited in scope. It must target specific circumstances and practice areas in which high-cost and potentially harmful defensive medicine currently thrives.

- And—this is where **you** come in—such a safe harbor must have the force of law so that the doctor knows that compliance with the safe harbor protocol will satisfy the doctor's legal duty of care. In other words, the doctor who complies with the applicable safe harbor protocol will be deemed to have satisfied the standard of care as a matter of law.

- Establishing safe harbors with the force of law will accomplish at least 4 things:
    1. eliminate the costly battle of the medical experts in any ensuing medical malpractice suit
    2. reduce the incentive to practice defensive medicine and thereby

3. reduce costs of care
4. reduce extra risk to the patient

- An injured patient would still have a meaningful pathway to an award of damages for the injury by showing that the doctor was negligent in complying with the safe-harbor standard of care and that the doctor's negligence caused the injury.

- The difficulty—you will be quick to perceive—is in developing and implementing appropriate safe harbors. Our project has investigated and developed 3 potential "sample" safe harbors derived from the Choosing Wisely initiative: (i) lower back pain; (ii) headache; (iii) mild head injury

- There is at the federal level a structure that could be used to achieve the goal of establishing appropriate safe harbors with the force of law. You may have heard of QIOs—Quality Improvement Organizations. They are private entities that contract with the feds regarding Medicare quality and which are authorized to adopt standards of care that, if met, would satisfy a doctor's obligation in the medical malpractice context. But QIOs have not yet exercised that authority.

- So what we would like to propose—and help develop and implement—is that Tennessee consider enacting legislation to require a QIO within its jurisdiction and doing business in Tennessee to exercise its standard-setting authority in Tennessee. That way, Tennessee would be on the forefront—and be an example to other States—of giving carefully developed safe harbors the force of law and thus reducing the clinical uncertainty that drives the current, costly practice of defensive medicine.

- To that end, we have been working on a draft statute. We hope that this meeting today has at least piqued your interest in pursuing our proposal. We are happy to provide any further information and to have further discussions between now and next year's Session as we work on the proposed law. We especially welcome your questions and concerns so that we may work them out as we refine the proposed statute. To give you a bit more detail and some additional perspectives on the issues, we have prepared a handout for you for ease of reference.

We truly appreciate your time and consideration of this proposal.