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Invited Testimony of

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Senator Mikulski and Members of HELP, thank you for the opportunity to talk to you about this important topic.

A few years ago, 18-month-old Josie King died from preventable mistakes at one of the world's best hospitals: my hospital, Johns Hopkins. On the four-year anniversary of her daughter's death, her mother, Sorrel, looked me in the eye and asked: If Josie was admitted to Johns Hopkins today, would she be less likely to die today than she was four years ago?"

I started telling her about our commitment to safety, listing all the quality and patient safety projects we were doing. She abruptly and appropriately cut me off. She did not care what we were doing. She wanted to know if care was safer. She wanted science. Unfortunately, at the time, we could not give her an answer.

We know precious little about healthcare quality and patient safety. We *do know* healthcare is increasingly expensive; we can give you detailed cost reports, because we have standardized measures and regulated practices for reporting financial performance. We cannot tell Sorrel that Josie is less likely to die. The national report on healthcare quality is less informative. In the ten years since the IOM report *To Err is Human* raised healthcare quality and patient safety to the level of national priority, we have made only minimal progress, and for most areas, we do not even measure performance.

Yet at the same time, advances in biomedical sciences have been astounding. Thanks to recent science, AIDS is now a chronic disease and we have cured many childhood cancers. In just 13 years, an international collaboration between governments, scientists and private industries sequenced the entire human genome, all 3.2 billion letters with 99.99% accuracy. The results are publically available so that scientists around the world can use the information to develop new therapies.

How do we explain this dichotomy between the success of biomedical science and the failure of patient care? It is because we have failed to view the delivery of healthcare as a science.

For every dollar of federal health care research funding that goes towards learning how to better treat and understand disease, only one penny goes towards learning how to better care for patients. While it is essential that we continue to enhance funding for basic and clinical research, we need a more balanced research portfolio -- a portfolio in which we view quality and safety research as *essential to,* rather than separate from, basic and clinical research. We need to eliminate the gap that exists between what we learn in a lab and what actually reaches the patient. We must have a method to create standards and to measure and track our progress with measures that are meaningful and valid to those providing care, to those receiving care and to those paying for care, for resources are too scarce and patient safety is too precious to ignore.

Five years ago, wrong-site surgery – one of the most visible and troubling errors -- was incorporated into the National Quality Forum "Never Events" list, reducing these errors became a national patient safety goal, and hospital accreditation standards were established to guide local hospital efforts. Yet these standards were developed based on common sense, not science, without evidence of their benefit or costs, and without a valid method to monitor their effectiveness. Since the standards were put in place, reports of wrong site surgery have increased yearly. We do not know if this is due to better reporting, if the interventions do not work, or if they are not used correctly. However, the results are not encouraging, and the public, the payers of healthcare and the providers of care deserve better.

We need to approach patient safety the same way we approach curing a disease, through rigorous scientific research that produces hard data with clear measurable results. We need to summarize evidence into clear standards, develop measures and monitor performance with valid, reliable data, and work to improve teamwork and communication so evidence can be implemented.

We applied the model to tackle catheter related blood stream infections -- a type of infection that kills between 30,000 and 62,000 people a year and results in nearly 3 billion in excess costs. Prior to our study, little was known regarding how many of these infections were preventable.

We approached the problem scientifically. In phase 1, we reviewed existing data and selected five key procedures that would most likely prevent these infections. We compiled these procedures into an easy to follow checklist. We identified potential barriers to using the checklist and developed tactics to overcome those barriers so we could optimize compliance. We then pilot tested the intervention at Johns Hopkins and measured performance. The result, we nearly eliminated these infections.

In phase 2, AHRQ provided a matching grant to help us pilot test the program in the state of Michigan. Within three months of implementing the interventions, the median rate of infection in the 103 participating ICUs plummeted to 0, and has stayed at 0 for 4 years. These infections were reduced by 66%. The work was not easy; it required hospital leaders, doctors and nurses to implement interventions, improve teamwork, and monitor performance. But the results were well worth the investment. In just one year, the reduction in infections were estimated to have saved the hospital system millions of dollars and thousands of lives

In phase 3, we are trying to implement this program across the U.S., state by state, hospital by hospital. Thanks to funding from AHRQ we partnered with the American Hospital Association to implement this life saving program in 10 hospital systems in 10 states. Additional philanthropic support donated to my research team at Hopkins will permit us to reach another group of states. Most states are trying to reduce these infections, but they need support in order to be efficient, and to rigorously measure and improve performance.

Similarly, the National Association of Childrens Hospitals and Related Institutions is developing efforts to bring this same program to pediatric centers in the United States. Indeed, my wife,

Marlene Miller, is leading these efforts. They used the same model, developed pediatric specific standards and have impressive results in reducing infections in pediatric ICU's. Just as with our adult program, they struggle to fund, organize, implement and measure improvement.

There are many ills that befall the U.S. healthcare system; CLABSI is but one. The fragmented approach to reducing these infections points to a deep problem with our healthcare system; vague or non-existent performance standards, poor or absent and often invisible measures of performance, misaligned financial incentives, fragmented and under resourced labors all cripple efforts to improve quality, reduce costs and implement health information technology.

Our ability to produce measured and sustained reductions in infections and costs, point to a possible way forward.

Reducing these infections could be a polio campaign for the 21st century ~ and we need one. These infections are common, costly, and often lethal. We know how to reduce them, yet support for this improvement has been left to a haphazard patchwork of local, regional and national efforts involving clinical, operational and policy levers. No one could argue that whatever the clinical effectiveness of such efforts, the inefficiency is glaring. A coordinated national effort to eradicate these infections should be an immediate priority.

Beyond these infections, however, I believe a closer look at our model offers tremendous potential for use on a broad scale. In the model, we centralize development of evidence-based standards, measures and data collection standards for a nationally relevant set of patient safety goals. We hold healthcare organizations accountable for improving quality, and we advance the science needed to improve healthcare delivery, so that learning does not need to take place one patient, one physician, one hospital at a time. In this model, payers, consumers, insurers, administrators, clinicians and regulators, work together to solve the problem. Now that we have a proven system that can measure and prevent harm we should align payment policies to support safe care.

Our national failure to view the delivery of healthcare as a science is also a significant factor in our limited success in learning from mistakes that do occur.

Though it took over nine years, we are now close to having a voluntary mechanism for reporting healthcare errors at a national level. Yet we do not know how to learn from the errors that will be reported. There is no national infrastructure to learn from common, costly and lethal mistakes that are beyond the capacity of any single health system to fix. For example, in all of the 6,000 U.S. hospitals, patients sometimes get epidural pain medicine connected to an intravenous catheter, a potentially lethal error. The intervention to prevent this error is to encourage doctors and nurses to be more careful, to reeducate staff. Assume this education takes one hour: imagine the costs of reeducating all the doctors and nurses in the country and now imagine the probability that the education will work. Current methods for learning from this type of mistake are form

over substance. They waste time, money, energy and the good will of caregivers who know they are human and will likely make the mistake again.

There is a better way. We learned it from aviation. In aviation they recognized that is foolish to have individual airlines investigate and learn from mistakes in isolation. They formed a public private partnership called The CAST (The Commercial Aviation Safety Team). The industry works together to prioritize the greatest risks, investigate them thoroughly and implement interventions that work. Most of the interventions are product redesign. We need cast in healthcare. We need to get the manufacturers to design the catheters so that the epidural and intravenous catheters do not fit together. We need to eliminate the possibility of making this mistake rather than hoping that re-education will work. Yet there is no mechanism to bring administrators, clinicians, regulators, and device makers together in healthcare to accomplish this. We have a small planning grant from the Robert Woods Johnson Foundation (RWJF) to pilot this concept. All parties are eager to participate. Yet we need federal leadership. We need your wisdom, your expertise and your support.

Through our work, we have learned that we can improve quality and reduce costs. Current efforts are too isolated, too weak on science, and too limited in focus. This will not get us where we need to go. There is something we can do to change this: to we can save lives and dollars, we can provide Sorrel an answer: are the Josie's in the world less likely to die?

Specific suggestions for Improving Healthcare Quality and Patient Safety:

1. **Advance and invest in the science of health care delivery**
   Fund research under AHRQ so that rather investing a penny in quality for every dollar in basic and clinical research we have a more balanced portfolio; Imagine the gains in quality and reduced costs if we increased the ratio to a quarter for every dollar.

2. **Create an Institute for Healthcare Delivery**
   This institute, similar to the human genome project, should link provider organizations, insurers, payers, and regulators to design, implement, and evaluate interventions to improve quality, reduce costs of care, and implement Health Information Technology. The products from this group can inform payment policies

3. **Coordinate public and private efforts to improve quality of care**
   A "supra agency" should be established to facilitate and monitor integration of inter-agency activities to address deficits in the quality of U.S. healthcare. The agency should report directly to the Secretary of HHS.

4. **Invest in Healthcare information technology (HIT)**
   HIT is essential for monitoring and improving quality and reducing costs of care. Efforts to improve HIT need to be linked with efforts to improve quality and reduce cots; to date they have not. Such efforts should provide, at a minimum:
   a. A database of evidence-based standards

b. A database to monitor and report performance measures to the public, clinicians, healthcare leaders and government officials.
c. Decision support tools to ensure patients receive the correct therapies.
d. Tools to help educate patients, families, and clinicians.

5. **Build capacity**
   Support training in quality improvement methods for physicians, nurses other clinicians and administrators in order to improve the delivery of healthcare across the U.S. At most academic medical centers, there are hundreds of faculty who can teach genetics, hundreds who can teach physiology, yet a precious few, if any, who can teach safety. This needs to change if we are to make and sustain progress.

6. **Support completion and rigorous evaluation of the national program to eliminate central line associated blood stream infections (CLABSI) and Support a new Program for MRSA**
   Patients in all states ought to have access to safe ICU care and reduced CLABSI. MRSA has become the most common pathogen causing hospital acquired infections (HAIs) in healthcare facilities in the United States and throughout the world. Researchers at the Centers for Disease Control and Prevention examined MRSA data from more than 1,200 intensive care units (ICUs) from 1992 to 2003. They found that in 1992, 36 percent of S. aureus isolates were drug-resistant; but in 2003, 64 percent of isolates were MRSA, an increase of about 3 percentage points per year.

President Obama suggested the new administration would restore science to its rightful place… raise health care's quality... and lower its costs. To achieve this goal, programs that work -- such as the model to reduce blood stream infections -- should be expanded, and those that do not work should end. Paraphrasing our president, those of us who provide healthcare, and those who manage the public's dollars need to spend wisely, reform bad habits, and do business in the light of day.

Substantial improvements in healthcare quality and costs are possible. For too long we have lacked clarity of purpose and the commitment to invest the necessary resources to make this vision a reality. Courageous leadership must hold all stakeholders accountable for results. My hope and expectation is that together we find this courage.