Testimony to the Senate Subcommittee on Primary Health and Aging

17 July 2014 **John T. James, PhD**

I thank Chairman Sanders for inviting me to testify about patient safety. I speak today on behalf of hundreds of thousands of Americans whose voices have been silenced forever by *preventable* adverse medical events.

Background: The seminal event that turned me into a patient safety activist occurred in the late summer of 2002. My son Alex was 19 years old and had returned for his junior year at Baylor University. While running in the evening of August 20th he collapsed on the university campus, self-recovered, but was taken to a local hospital. He was evaluated there for 4 days by cardiologists and underwent an electrophysiology test at another hospital in Waco. Five days after discharge he had a follow-up visit with a physician-in-training who gave him a clean bill of health. In a week he returned to running. On September 15th, approximately 2 weeks after he resumed running, I received a call late in the evening that he had collapsed again while running, but this time his heart had stopped and he was in a deep, unresponsive coma. He died 3 days later in the hospital where he was first taken for evaluation.

Once I was able to get his medical records, I discovered that my suspicions about the cause of his death were borne out. During his first hospitalization, I had noted to his lead cardiologist that his potassium was low and this might have been the cause of his initial collapse. He discounted this possibility, and so potassium replacement was never administered. In fact, as I deduced much later, at least three catastrophic errors were made by his doctors: (1) they failed to apply a guideline from the National Council on Potassium in Clinical Practice, calling for potassium replacement if heart arrhythmias are present, (2) they failed to diagnose acquired

long QT syndrome, and (3) they knew he should not return to running, wrote this in his medical record, but never warned him not to run; Alex's only discharge instructions were not to drive for 24 hours.

I have written about the details of his poor-quality care in a book that I published in 2007. Many physicians have read my book and none have disputed my analysis. In fact an electrophysiologist, after reading my book affirmed to me in an email that she too has been frustrated in attempts to get her cardiologist colleagues to pay more attention to potassium. Apparently, I gained a measure of credibility in the cardiology community because in the past few years I have completed 25 invited reviews of cardiology manuscripts for a cardiology journal.

As I unraveled the errors made in my son's care, and then discovered that his cardiac MRI was never done properly, I began to realize that medical errors like those that ended his life were not uncommon. I saw that the Institute of Medicine, had estimated that up to 98,000 Americans die each year from medical errors. Other reputable estimates at that time were as high as 284,000. If the harmed patient survives, then, with few exceptions, the hospital will be paid to fix the error.

Estimating Harm: By 2011 I had noticed four new studies that had used the Global Trigger Tool to identify adverse events in medical records. Two were peer-reviewed studies published in medical journals, and two were from the Office of the Inspector General. This tool was much more efficient at identifying adverse events than unguided physician reviews. I noted that the individual studies gave a remarkably consistent picture of the prevalence of lethal adverse events. In addition, other studies had been published showing that medical records often do not contain discoverable evidence of serious patient harm even when the patients

know they were seriously harmed. In 2013 the *Journal of Patient Safety* published my study on the prevalence of preventable adverse events in hospitals. It has been supported by leading doctors in the patient safety community.

The math behind my calculation is rather simple. There were 34 million hospitalizations in 2007 of which approximately 0.9% involved lethal adverse events, and of those approximately 69 percent on average were judged to be preventable. This yields an estimate of 210,000; however, the trigger tool, while good at detecting errors of commission, misses many errors of omission, communication, context, and diagnosis. It would not have detected any of the catastrophic errors made by my son's doctors. Furthermore, it misses events for which no evidence appears in the medical record. Correcting for these limitations yields an estimate that more than 400,000 lives are shortened by preventable adverse events each year.

Proposed Solutions: The Senate should establish a stand-alone committee on improving patient safety. It should establish a National Patient Safety Board (like the National Transportation Safety Board) to investigate patient harm.

Congress should also pass a national patients' bill of rights containing rights like those enjoyed by workers and minorities. The law must include the following rights for patients:

- Legally defined and enforced right to give *genuinely-informed* consent
- To know the safety record of their physician, outpatient clinic, nursing home, and hospital
- To know costs for tests and elective procedures before hand
- To transparent accountability in the case of an adverse event
- To evidence-based care

- To know when drugs are prescribed off-label
- To be warned about bad lifestyle choices
- To have an advocate present while hospitalized
- To care by teams of professionals that build individual and team excellence through 360-degree performance reviews. These are anonymous reviews by patients, subordinates, colleagues, and leaders.

Patient safety is not going to improve substantially until the ‘playing field’ between the ill patient and the healthcare industry is leveled by an enforced bill of rights. Despite our high per capita expenditures on healthcare, our industry ranks last overall when compared to systems in other developed countries.