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THE OLIVER C. SCHROEDER, JR. SCHOLAR-IN-RESIDENCE LECTURE

IMPROVING THE QUALITY OF HEALTH CARE: WHERE LAW, ACCREDITATION, AND PROFESSIONALISM COLLIDE*

Mark R. Chassin†

I want to talk to you about the intersection of law, regulation, accreditation, and professionalism relating to the quality of health care. Maybe at the risk of telling you too much about the quality of health care—more than you wanted to know—I'm going to put it all on the table.

Let me start by telling you a little about what the Joint Commission is, because it's probably not a household name. We are a private, not-for-profit, IRS-classified 501(c)(3). Our roots actually go back to 1917, when the American College of Surgeons created the first program designed to assess quality in hospitals. The Joint Commission was created by five organizations to take over that program in 1951: the American Medical Association, the American Hospital Association, the American College of Surgeons, the American College of Physicians, and the Canadian Medical Association. Later, the Canadian Medical Association withdrew and the American Dental Association joined to create the present-day Joint Commission. Hospitals are not the only organizations that we accredit or certify. Healthcare organizations pay us to come in to see whether they are complying with the standards we create on how to provide quality care. We have competition in all the fields in which we operate.

The program started by the American College of Surgeons created certain “minimum standards” for hospitals in 1917. There were five requirements: that (1) hospitals should have medical records for all patients; (2) hospitals should have laboratories and x-ray facilities; (3) hospitals must have a medical staff; (4) medical staffs should be licensed, competent, and “worthy in character”; and (5) medical staffs should review and analyze their clinical experience. On October 24, 1919, College officials announced the first results of the trials applying these standards at a conference in New York City, at the Waldorf Astoria

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hotel. The night before the conference—before they released the results—they were a little nervous: only 13 percent of the nearly 700 hospitals they surveyed passed the minimum standards. So the officials took the documents that listed the names of the hospitals, went down to the basement of the hotel, put those documents in the furnace, and burned them so they could not be released to the media. That is a true story. Fast forward to 2012, the middle of this year, when we now accredit about 20,000 health care organizations in the United States and almost 600 in fifty-two countries around the world.

What we do we actually do, though? We create and continuously update requirements for health care organizations that tell them how to provide safe and high-quality care. Then, in a parallel way that is equally important, we deploy individuals in the field—we call them surveyors or reviewers—to visit these different organizations for a very short period of time. How long depends on the size of the organization and the mix of services they provide; usually a medium-size community hospital would have three folks there for four or five days. During that visit, we are charged with assessing whether the hospital is complying with all of the standards that are in our mandates. That is a very challenging part of the business that we're in and part of the activity that is not as well-understood as some of the other things we do. We're constantly working on improving it. We also create and maintain the single most effective system for measuring quality in hospitals. That has been in existence for a little more than a decade. Finally, we are also an improvement organization. We develop and disseminate interventions to directly improve quality of care; for example, to get rid of hospital-associated infections, or reduce communication failures when patients move from one healthcare setting to another. So, that is a very brief overview of the critical functions that we perform.

When we say a hospital has passed this accreditation test, what does that mean? Let me first say what it's *not*. Accreditation is not a guarantee that no errors will occur. It's not a guarantee that preventable complications will never harm patients. It's not a guarantee that high-quality care will always be delivered to every patient. It's no more or less than an attestation that we've gone through our process, we've looked at the practices in an organization, and it passed the test. In other words, the organization complied with our standards at the time we went out there. Typically, we will find places where the organization is not in compliance and we point them out. To keep its accreditation, the organization will change what it is doing and then send us evidence that they complied. It's an ongoing process.

Accreditation can't solve all of our quality problems. You can see evidence of them almost every day in the newspapers or on the Internet. For example, a hospital in Louisiana had to notify 360 patients because it failed to properly decontaminate, clean, and sterilize its gastrointestinal endoscopes, exposing patients to Hepatitis B and C and even HIV infection. A hospital near Pittsburgh had to notify 141 patients that

they had had coronary artery stents put in unnecessarily. A few years ago, a patient went into a hospital in Minnesota with cancer in one kidney. The hospital removed the healthy kidney instead. An almost identical event happened in the UK, but a medical student in the operating theater told the surgeon he was operating on the wrong kidney. The surgeon continued the operation and the diseased kidney was left in. The patient died about five weeks later. And we set fire to patients in our operating rooms: surgical fires occur perhaps as often as 500 times a year in the United States, often producing severe patient injuries. Maybe that *is* more than you wanted to know about the quality of health care.

The healthcare industry has been intensely focused on improving quality of care in a way that is unprecedented in the past ten or twelve years. It is not for lack of effort that we still have these quality problems. It's fair to say that we are faced with a situation today in which routine safety processes fail rather frequently. So, whether it is our inability to get caregivers to wash their hands every time they should, to get rid of serious medication errors that harm patients, or to prevent other uncommon but completely preventable adverse events, we have a long way to go before we can assure that quality is what we all want it to be in health care.

As that headline from the UK reminds me to point out, all of these quality problems are indeed global. There is great diversity among developed countries in how health care is organized, financed, delivered, and structured. But when it comes to quality and safety, there is no such diversity—all developed health care systems struggle with exactly the same quality problems. I've given you a little bit of a flavor of what we struggle with in the United States. No system has figured out how to solve these critical problems. In fact, quality failures in all of them are very common. So, if this is a condition of health care in the twenty-first century, but we aspire to higher quality, we have to look outside of health care for models. I'll talk about that more in a moment.

If we put this set of quality problems into the context of all of the oversight that exists, there is obviously a lot of public law and regulation. First, there's the federal alphabet soup: the Food and Drug Administration, Centers for Disease Control and Prevention, Centers for Medicare and Medicaid Services, the Nuclear Regulatory Commission, and the Health Resources and Services Administration. There are many others. States have a critical role: they license healthcare organizations and individuals who practice medicine and other health professions. They are responsible for virtually all of the public health protections required to achieve good quality care from a population perspective. Private organizations like the Joint Commission, accrediting bodies in many fields, and other organizations in the private sector devoted to improving and maintaining quality are all over the place. Then there are the delivery system efforts—whether it is inside organizations like the Cleveland Clinic, the Mayo Clinic, or others like Kaiser—that have

pioneered quality improvement activities. The system of medical malpractice is also supposed to have an influence on the quality of care.

It is not for a lack of trying that we still have quality problems. How do all of these systems come together and what are their proper roles? I indicated some of the quality failures we see. Oversight failures also happen with extraordinary frequency. Every single one of the oversight functions I mentioned has flaws. None of them is perfect.

I think we need to look outside of health care. There are other models, like occupational safety. For example, if you look within that domain at mine safety, there is a federal Mine Safety and Health Administration that has had notable failures in the United States. Remember the coal mining disasters? But let me tell you the story of Alcoa.

Alcoa is a global company with mines in the United States and all over the world. It had one of the worst safety records some years ago. When a new CEO came into office, Paul O'Neill, who later became Secretary of Treasury, he pioneered a complete turnaround at Alcoa. The laws didn't change. The technology didn't change. What changed? Well, he brought to a board meeting a story of a man who was killed in an accident in one of Alcoa's mines. After he told the story, he looked around at the board members, all of whom were men, and he said, "Gentlemen, we killed this man." That is what started the turnaround at Alcoa—the governing body of the organization taking responsibility for worker safety. From that moment, a whole series of initiatives carried through from the board to the management that communicated to everyone across the globe in Alcoa that worker safety was not just priority number twenty-five out of fifty. It was the number one priority. Alcoa put a whole raft of innovations in place, including instant communication of the smallest workplace accident to everybody in the organization. They look back after an accident to find out why it happened, look for those flaws, fix them, and then communicate that information across the company around the world, so that every part of the organization can benefit from the learning that occurred at one place. I could go on, but I won't. That is an example, in a field where worker safety is hugely variable to this day, of an organization that created the best mine safety record in the world.

There is food safety, water quality, airline safety, and there is nuclear power. So if we are a little more systematic than that one story about looking outside of health care for the right interplay of law, regulations, and internal organizational activities, let's pick some industries that have really gotten it right. There is research literature on these organizations. They are called "high reliability" organizations because they deal with hazards that are every bit as dangerous and difficult as those we face in health care, but they do it a lot better. They have adverse event rates that are a thousand, even ten thousand fold, lower than in health care. Some of the usual suspects are air travel and nuclear power. But there are a number of other organizations that have been studied by scholars and practical improvers, and they are pretty far afield. Places

like amusement parks have a lot of characteristics that are very similar to the way airlines and nuclear power stay safe. Wildland firefighting crews and aircraft carrier flight decks are other examples. If you ever want a little bit of a scary experience, Google the TV series called “Carrier.” It was on PBS about ten years ago. Look for the pitching deck episode. This is where they practice landing on an aircraft carrier in high seas at night. The deck is pitching up and down, so that the instant before the jet fighter lands, it looks to the pilot like he is going to crash into the underside of the deck. Then it flattens out and he lands. They have a vanishingly small adverse event rate.

Why is that? What do all of these organizations have in common? To simplify it a little bit, in addition to a passionate devotion to safety like I described Paul O’Neill had, they have incredibly effective tools to improve the processes that they have to complete in order to be safe. They also have a safety culture that wraps around those nearly perfect processes and keeps them working at very high levels of performance for long periods of time. That safety culture is critically driven mostly by the expectations of the workers on the front line. I’ll talk more about that. That really distinguishes these organizations the most from health care. In health care, we are most often in the situation of experiencing—whether we’re a hospital, ambulatory surgery center, or a nursing home—an event in which a patient was harmed, and then we do something. Fifteen or twenty years ago, the Joint Commission introduced root cause analysis: figure out why that harmful event happened so we can start teaching folks how to correct the problem so that it doesn’t happen again.

But that is not how high reliability organizations stay safe. The way they stay safe is by everybody on that aircraft carrier deck, for example, always looking for the smallest thing that might go wrong. On an aircraft carrier, one of those things is a foreign object on the deck. If something as simple as a screwdriver gets left on the deck as one of these jets is landing, it can get sucked into the jet engine and blow it up. Everyone on the deck looks for the smallest thing that is wrong so that it can be identified before it poses a risk, way upstream from harm, when it’s actually much easier to fix than after it’s been allowed to mushroom into a very risky problem. They fix those things right away, using those highly effective tools. That leads to more reports of small things that are even further upstream from harm.

We’re nowhere near that capacity or that situation in health care. To describe this theme called “safety culture,” which I’ve said is so important to making a really safe organization, I will borrow from the work of James Reason. He pointed out that if you look inside these organizations, there are three imperatives that link all of them together: trust, report, and improve. Each of them is tied to the others. So in order to find the small things that are wrong, every worker needs to trust his or her peers, because finding something that is wrong usually means uncovering mistakes that were made. Say a safety procedure isn’t

constructed quite right, so people have to take a shortcut and violate protocol in order to get the work done. That is an unsafe condition. Revealing it means that somebody is going to have the opportunity to blame the people that took the shortcuts. High reliability organizations greatly value that reporting, so they don't "shoot the messengers." Once a worker identifies and reports the unsafe conditions, he or she also has to trust that management will take that report seriously, fix the problem, and communicate that improvement back so that the worker's initial trust is justified. That reinforces trust. You get more reports further upstream from harm. It turns into a very positively reinforcing culture that keeps these organizations safe.

In a room filled with healthcare professionals, typically in hospitals, I'll ask them to think about the place in the hospital where medical instruments for surgery are cleaned, decontaminated, and sterilized in preparation for the next group of surgical procedures. Think about the busiest time, usually mid-morning, after the first round of surgical cases has been completed and the instruments are being reprocessed. Think about a sterile processing technician who was just hired about three or four months ago. He sees a problem with one part of the cleaning and decontamination process. Then I ask the audience: How many of you are certain in your hospital that that technician would do the right thing and tell his supervisor right away that there is a problem with that part of the decontamination process? And how many of you are certain that the supervisor would do the right thing and stop the sterilization process, retrieve all those instruments that were improperly cleaned and decontaminated until the problem was corrected? I have asked this question all around the world, whether it's in the United States, Europe, the Middle East, or Asia Pacific. What would you guess is the percentage of hands that go up in answer to the question, "Are you certain?" Five percent; one in twenty. Then I say, that's the gap—between the 5 percent and 100 percent that you would get at a meeting of aircraft carrier flight deck engineers or amusement park engineers, or anybody in the high reliability industries like nuclear power and commercial aviation—that is the gap that health care has to traverse in order to get to be highly reliable.

Let me also show you a positive side of this. I had mentioned that airlines are really safe. From 1990 to 2001, on US air carriers, there were 129 deaths per year on average and 9.3 million flights per year. That is a rate of 13.9 deaths per million flights. At that time, the US airline industry was the safest in the world. But in just the next decade, from 2002 to 2010, the number of deaths fell to 18 per year for 10.6 million flights per year. That is a rate of 1.74 deaths per million flights. Moving from 13.9 to 1.74 is a drop of 87 percent in the death rate in US airlines. That's unbelievable in an industry that was already the safest on the planet. That is another characteristic of high reliability industries: they keep pushing the envelope further on safety.

How did air travel get that safe? First of all: progressively safer equipment. That was true from the 1940s through the 1970s. But when NASA looked at a series of air crashes in the 1970s, they found that the landscape had completely changed. Eighty percent of those crashes had nothing to do with equipment failure. They all had to do with failures of communication in the cockpit between two or three people about problems. Those failures involved things like the junior co-pilot saying, “I think there is a funny thing going on with this gauge.” The captain would often reply, “Shut up and do your job!” So, long story short, that finding led immediately to a radical change in the industry. They developed and deployed something called “crew resource management” training throughout the 1980s. It is now standard in the industry. Every cockpit crew goes through it every year, to eliminate the hierarchy in the cockpit, to set the expectation for clear communication about concerns, and to facilitate the immediate identification, communication, and resolution of anybody’s concern about an unsafe condition. That is what led to the dramatic improvement in the last twenty years in the safety of air travel.

Let’s compare this track record to that of health care. A famous Institute of Medicine report in 1999 estimated that between 44,000 and 98,000 people died each year in US hospitals due to errors. There are about 34 million hospitalizations a year. That is a rate of between 1,300 and 2,800 deaths due to error per million hospitalizations. The airline industry has a rate of 1.74. By this measure, hospital care is between 750 and 1,600 times less safe than air travel. If you don’t like that measure, here is another one. I will get back to this study at the end because it has a bearing on malpractice. The best study of errors and harm in hospital care showed that about 1 percent of hospital patients were injured or died due to negligent errors. That is a rate of 10,000 per million hospitalizations. Compare that to US airlines: out of 95 million flights from 2002 through 2010, a total of 341 people died or were seriously injured—a rate of 3.6 per million flights. That’s 10,000 compared to 3.6. On this metric, hospital care is almost 3,000 times less safe than air travel.

There is law and regulation in air travel, just as there is in health care. But law and regulation have important limitations. These limitations are especially important in health care and other fields where science and technology evolve. Regulation just can’t keep up with the state-of-the-art improvements in science and in healthcare practice. Also, the adversarial nature of enforcing law works against improvement. You hide stuff when the cops are around. In the “bad old days,” the Joint Commission had the atmosphere around it of being inspectors and cops. For instance, in a busy hospital, one of the things we look for is whether the hallways are crowded so that a fire response would be impeded. Hospitals used to know when we were coming and move all of the equipment that wasn’t being used, cluttering up the hallways, into giant moving vans. The vans would circle the city until we were gone, then

return and put the clutter right back in the hallway. We have gotten better in recent years as all of our surveys are now unannounced, for example. We've gotten much better at driving home improvement messages, as opposed to the steel-ruler-across-the-knuckles approach of punishing people.

The point is that law enforcement works against improvement. It also has other unintended consequences when it comes to quality. I'll give you a couple of examples. Fundamentally, when we are talking about the critical importance of culture, law can't change culture. It's not possible. There was a really interesting article by George Annas a couple of months ago, when the *New England Journal of Medicine* ran a series of two hundredth anniversary articles. George is a very well-known health lawyer, particularly in the field of ethics. He opened this article by saying medical care in 2012 is unrecognizable as compared to what it was in 1812. He wrote: "No nineteenth-century physician would be at home in a modern hospital. A nineteenth-century lawyer, however, would be completely at home in a contemporary courtroom. As would a present-day lawyer, transported back to the early nineteenth century."

I don't know if you agree with George on this point, but I bring it up because I think it is evidence that law changes more slowly than health care. Let me further illustrate this point with a specific health care example. The Medicare program, which is one of the federal structures of law and regulation that health care deals with, has things called Conditions of Participation, which are rules that providers have to meet in order to qualify for Medicare payment. They are enacted in federal regulation, which means they are hard to change. Many are aimed directly at improving quality—guaranteeing providers must deliver a certain level of quality in order to qualify for Medicare payment.

In 1965, when the Medicare program was created, the first version of these conditions were adopted. They were the Joint Commission accreditation standards of 1965. We changed and improved. We modernize our standards every year to keep up with changing science and practice. In fact, our customers think we change things too often and make compliance more difficult. That is a balance we have to strike.

The only time since 1965 when the Medicare conditions of participation regulations for hospitals were modernized as a whole was in 1986, when the program adopted the Joint Commission standards of 1986. As a result of the failure to continuously update the conditions, many of them are hopelessly out of date today. Here's one example. It is commonplace today for hospital medical staffs to authorize nurses to give medication under certain circumstances defined by a specific protocol. These protocols are typically referred to as standing orders. Picture a newborn arriving in a nursery at three o'clock in the morning. Most hospitals have established standing orders for all the routine procedures newborns need, such as the administration of antibiotic ointment to prevent eye infections and blindness. A few years ago, Medicare said because the doctor didn't sign that order specifically for that patient

then that is a violation of the conditions of participation, which is absurd. Because of the rigidity of the regulations, they felt it was mandatory to call that a violation. Through a huge amount of effort, we got Medicare to change that view.

Telehealth, the ability of a remote hospital to send an image of a CT scan of a patient with head trauma to a tertiary care facility and have a neuroradiologist read that result and give important information back to that remote hospital, didn't exist in 1965 or 1986. Again, Medicare's interpretation of those outdated conditions of participation severely restricted the growth of telehealth services until we brought this problem to closer attention. They changed that regulation, too.

The rigidity of law and regulation in trying to deal with quality and safety problems is an insurmountable obstacle. There are also unintended consequences when you create regulations badly. The Affordable Care Act has penalties for hospitals with rates of readmission that are too high, or rates of complications that are high. That resulted from some research that showed a lot of Medicare patients are readmitted to the hospital within thirty days of release. There was a whole brouhaha about waste, inefficiency, and hospitals providing poor care. It turns out that that measure is a very bad measure of quality. Hospitals are now penalized if their readmission rate within thirty days is high. Let me ask you, does a readmission at thirty-one days indicate better quality than at twenty-nine days? If you have a financial incentive to avoid the twenty-nine-day readmission and make it a thirty-one day readmission, maybe you'll keep patients at home or in an observation unit or ambulatory area while they are getting worse. You have an incentive to do that. Does that happen? We don't know, but it is a really bad measure of quality that encourages this kind of manipulation.

Measures of complications that form the basis of metrics that can also generate financial penalties for Medicare providers are based on calculations coming from data in hospital bills—not from looking at the clinical course of the patient and making a clinical judgment, but whether something is listed as a diagnosis on a bill. It turns out that it's a lot easier to manipulate the way you code some of those diagnoses than to do the hard work of improving care. These are a few examples of the overarching point that law and regulation are very poor vehicles for guaranteeing or improving quality in healthcare.

So, we can't rely on law and regulation in health care to do anything good for us in quality and safety. Certainly not to get us to the level of quality I've been talking about here in high reliability organizations.

I saved the best for last. What is the role of the way we handle medical malpractice? What is it supposed to do? It's supposed to deter negligent behavior, right? If you know you are going to get sued, you won't engage in negligent behavior. Malpractice law is supposed to encourage quality improvement, reduce the likelihood of negligent behavior, and compensate victims. I believe it doesn't do any of these things very well and that it can't be fixed. Primarily because the theory

on which we approach medical malpractice is completely discredited. Let me tell you what I mean by that.

Medical malpractice, the way we deal with it in the United States, is based on identifying when patients are harmed by errors. It's very simple. You make a mistake, the patient gets hurt. If it falls below the standard of care, it's negligent, and you are at fault. Well, the problem is that while this does exist as a pathway for leading to the kinds of adverse events we've been talking about, it turns out to be very rare.

Do we have people that do egregious things? Yes, we do. Charles Cullen was a nurse who is suspected to have killed as many as 400 patients over a sixteen-year career in nine hospitals in Pennsylvania and New Jersey. He was sentenced to 397 years: eleven consecutive life terms. But this is criminal behavior. Malpractice law does not deal with criminal behavior, yet it is based on the same thinking about what causes patient harm in medical settings. If you look behind an adverse event that would be the subject of a malpractice case, what you find is not *one* mistake. Not *one* individual who makes mistakes, but lots of people making lots of mistakes—fifteen, twenty, thirty, or forty depending on how closely you look. Most of the mistakes are really tiny, which I will discuss in a second. It's impossible if you look carefully at these events to identify the one that caused the adverse event—the one that caused the harm. They all had to happen in order for the harm to result. There were lots of opportunities for individuals as the events unfolded, if they had more of a safety culture outlook, to realize something was going wrong and to stop the sequence before harm resulted. All of these adverse events start with the same first step. Somebody makes the first mistake. That mistake challenges the defenses we create in our organizations, in our hospitals, to prevent the error from doing harm. But all those defenses have weaknesses. If the first mistake gets past the defense, it challenges the next one. Harm occurs only after a series of errors has penetrated all the defenses in front of that patient. James Reason, who is an intellectual giant in this field, has described this phenomenon in his “Swiss cheese” model. He has described this situation in complex organizations, whether it is the nuclear power plant at Chernobyl, the chemical plant at Bhopal, or the space shuttle accidents—they all have this characteristic pattern.

What do I mean by “defenses?” In health care, some of the defenses we have are leadership that puts a high priority on quality, programs to hire the right people and train them well, standardized safety protocols, computer systems that support high levels of quality, the most modern equipment that is well-maintained, and programs that assure excellent communication and teamwork. All of these defenses have weaknesses. So if you think about these defenses as slices of Swiss cheese, there are holes in them called “latent conditions” that don't do any harm until somebody makes the first mistake. Think about throwing a dart at that first slice of Swiss cheese from behind. If it's permitted to go through a hole, a weakness, because that weakness wasn't identified and corrected, it

challenges the next defense, or the next slice of Swiss cheese. Harm results only with a series of errors that get through every single defense.

Let me give you an example from outside of health care. There was a ferry called the Herald of Free Enterprise in 1987 that left the dock at Zeebrugge in Belgium, heading for Dover, England, crossing the English Channel. About twenty minutes after leaving port, it began to take on water over the bow. It sank in about two minutes, killing 193 people. What happened? This ferry was of a design called roll-on/roll-off. In order to get cars on, they needed to open the doors in the front of the boat. Somebody forgot to close those doors. That is how nearly 200 people died. One hole in the defenses of this boat was that the company rules said that the captain decided to leave port based on negative reporting. He assumed that all safety procedures were followed unless one of the crew called him and said otherwise. That is a classic latent condition; it won't do harm until someone makes a mistake and fails to report a problem. Another hole in a different defense was that there was no electronic indicator on the bridge that the captain could look at to confirm that the doors were closed. That is just two of them. What was the error? The boatswain's mate who was assigned to close the doors had come off a night maintenance shift and was asleep. He didn't get up to close the doors. It took that error to expose all the latent conditions. There were more, but you get the idea.

Here is a real health care case that I'll shorten for you that makes the point, I think, even more pertinently. This is one case I'm very familiar with from a previous life. This happened to an eighty-year-old woman who had a lot of problems and was admitted to the hospital from the emergency department with one of her medication orders being for Phenytoin, 300 milligrams three times a day. That is a huge dose for a younger person; it is an enormous dose for an older person. But this hospital had several pertinent defenses. It had an electronic data repository, or EDR, that had information about all the patient's drugs. The resident trainee on duty that night consulted the EDR and that was the order: 300 milligrams three times a day. A weakness in the EDR defense was that not all the data were right. A weakness in the resident's knowledge base was that he didn't recognize the potentially huge dose. Another defense this hospital had was a computer order entry system for all medications, but that system didn't flag that order as worrisome. The hospital also provided for pharmacists to review every new order for every patient. The pharmacist caught that error. He dispensed only one 300 milligram dose and communicated the potential error to the nurse and the doctor covering for that patient. Now it's about midnight on the night she was admitted. But there was a failure in the communication defense: there was no communication of the problem from the night shift to the day shift. So the nurse who came on in the morning saw the order for three times a day medication but there was no dispensed medication. This hospital had another defense called "unit dosing." Pills were wrapped, named and labeled for individual

patients. There were none labeled for that patient. Why? Because the pharmacy said this is likely a mistake. Let's resolve it in the morning and make sure we know what we are doing. The nurse confronted this situation, went to see her patient, who was a little confused because that is what happens to old people in unfamiliar surroundings. The nurse thought that the patient might not be able to swallow the very large pills that the medication comes in. So what do you think she did? She borrowed another patient's Phenytoin, which was dispensed as a liquid, a suspension. A hole in the unit dose defense for the hospital was that suspension wasn't dispensed in unit doses, it was dispensed in small bottles, so she was able to do that. This went on for several days. The patient became severely toxic until the problem was discovered, the medication was stopped and, fortunately, she recovered fully. There were lots more events here, but I relate this story to show you the reality of how patients are harmed by a cascade of small errors—the resident didn't know that was a big dose, there was a miscommunication between night shift and day shift, and so on. Cascades like this happen all the time. Where is the negligence here? Where is the smoking gun? Where is the single error that caused this? This is typical when we look at these adverse events. So the malpractice approach of blaming a single individual for making a single critical mistake is almost never consistent with reality. The study I mentioned that looked at negligent adverse events was a very large study first done in New York and repeated in Colorado and Utah that found a high rate of patients injured by negligence. It looked at the kinds of injuries that occurred in this situation and questioned the relationship between malpractice and actual patients injured by errors severe enough to be legally negligent. The study started by identifying a whole bunch of patients injured by negligence. How many of them filed malpractice lawsuits? Two percent. Thus, very few patients who are actually injured by negligent errors bring suit. But what about the other side, the people who did file malpractice claims? What was the ratio of negligent adverse events to malpractice lawsuits? More lawsuits or more patients injured by negligence? More patients injured—7.6 patients injured by negligent error for every lawsuit. So, malpractice doesn't work. It doesn't improve quality. It doesn't compensate victims. It doesn't deter negligent behavior, and is it's based on a theory that does not explain how patients are injured in health care.

Law and regulation are as necessary in health care as they are in any other sector of our society. They establish a general framework within which providers and others can do their work. When they work really well, they can provide some assurance that basic elements of quality are in place. But even the best law and regulation cannot generate improvement. And in health care, they often get in the way of improvement because science, technology, and medical practice change rapidly and legal processes cannot keep pace. Accreditation and professionalism and other private efforts are necessary but by themselves are not sufficient. The culture of a regulated industry is the most critical

determinant of the quality and safety in that industry. The second most important is the capacity for implementing improvement. Both of those are sorely lacking in health care. So, we need law and regulation as a general framework. But they are not remotely capable of accomplishing the task of quality improvement. One more example. The licensing of physicians has not changed in almost 200 years. If I am licensed as a physician, from the standpoint of the state, I can perform neurosurgery and deliver babies even though I'm not trained to do either. That hasn't changed much. To achieve high reliability, we need public pressure for better results, because they are achievable. As long as we continue to tolerate mediocrity, that is what we will get.

We need more aggressive efforts from the private sector, including from organizations like mine. We need to get rid of the behaviors and practices that undermine a culture of safety—the kind of intimidating behavior that suppresses reports from pharmacists and nurses about potentially lethal drug orders. Professionalism has to expand in health care to incorporate the goal of high reliability. One of the biggest obstacles in getting this ball rolling is the belief in health care that zero harm—which is what we almost have in airline safety—is not possible. But we do have examples of where it has been achieved. Getting to high reliability in healthcare will be a long and difficult road. But it is a journey we must begin—and begin now. Thank you very much.