

Date: September 22, 2003-09-23

Dear Ms. Albert,

Welcome back from your vacation. I hope you had a good time. I thought you would be interested to learn that the President of JCAHO, Dennis O'Leary, MD, stated on November 24, 2002 at the CMA Leadership Meeting that he believes that: "THERE ARE SOME WHO BELIEVE THAT THIS WHOLE SYSTEM HAS TO BE BLOWN UP AND START OVER AGAIN, I HAPPEN TO BE ONE OF THOSE ADVOCATES".

Following please find the transcript that my office staff prepared based on the audio tape of Dennis O'Leary's lecture. He analyzed the so-called Business Case for CEOs of hospitals and concluded that there is no such economic relationship between higher quality of care and higher revenues for the hospitals.

In fact, I demonstrated that the Business Case for CEOs of Hospitals is the exact opposite. The lower the quality of care, the higher the complications rate, the higher the revenues for the Hospital. Following please find my analysis in "The Rape of the Medical Peer Review Process by Tenet Health System". This is a public record as it is part of the administrative record presently with the Court of Appeal of California.

Please do not hesitate to call me anytime: 310-858-1300.

Respectfully yours,

Gil Mileikowsky, MD.

A handwritten signature in black ink, appearing to read "Gil Mileikowsky" with a stylized flourish at the end.

CMA's 6th Annual Leadership Academy
Sunday 24 November 2002 at La Quinta, California

Let me now introduce **K.M. Tan, MD**, Chair of the Board of our subsidiary the Institute for Medical Quality (IMQ).

Thank you very much. Thank you Richard. Good morning to all of you, I thank you for being present on this lovely Sunday morning in all these lovely surroundings and not taking the temptation to stay in bed. In the last three years, the Institute of Medicine has released reports on Medical Errors and the need to cross the Quality divide. We have heard over the last two days about a number of changes affecting Healthcare delivery including a shift from acute to chronic care, evidence those medical technological innovations working as a team and changing patients' clinical, patient-doctor relationships. It is essential that we help professionals develop new skills and new roles. To that end, it is my pleasure to introduce our speakers this morning who will examine some of the origins in medical errors and the challenges and opportunities in assuring patients' safety. Our three speakers will each make a presentation and then sit down as a panel so please hold your questions for them until the end. Our first speaker follows a distinguished career that included service as a Dean & Medical Director at George Washington University Medical Center, has served for the past fifteen years as President of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO). Under his leadership, JCAHO has issued new patients' safety standards this year, which will be implemented starting in January and about which he will inform us this morning. IMQ and the Joint Commission have had a long-standing relationship in California as the survey Medical Staff issues and worked with the Joint Commission to understand the unique needs of California Hospitals and physicians. We serve essentially as the frontline in reviewing Quality Care. Please join me in welcoming Dr. Dennis O'Leary.

Dennis O'Leary, M.D., President JCAHO
Joint Commission on Accreditation of Healthcare Organizations
(JCAHO)

Thank you very much; it is really a distinct pleasure to be back here at this Leadership Conference, I was here a couple years ago and even though I was only coming for a two days Board Meetings, I felt that this is really critical and important to be here. I enjoyed the video and I thought it was quite a good lead into my remarks of this morning and the Institute of Medicine came out with this Report to ERR in the late 1999. There were some people who suggested that it would really be a good idea to develop a Business Case for patients' safety but that was immediately responded to as a thought: that's a really dumb idea, the Business Case obviously exists. Why do we want to bother with that exercise?

A couple years later that idea was brought up again and people said: "Well, maybe we ought to think about doing that" and then, still later, people said: "Maybe there isn't a Business Case". So we decided to convene a National Invitational Conference on Business Case of Patient Safety that was in September of this year. It was co-sponsored with the Agency for Healthcare Research & Quality, the CMS, the Department of Defense, and the American Hospitals Association.

We particularly decided to target the CEOs of Hospitals because they are the people who would be making a lot of the financial decisions and it was to them that the message needed to be targeted.

Just before Gail Gillespie spoke at the conference, she was the second speaker; I've known Gail for years. I went up and just asked her to flat out as an economist if she thinks the Business Case exists, and she said no. And I guess I kind of expected that based on my own experience but this is much I guess what a lot of the Hospitals CEOs who were not there already knew that. We attracted a grand total of 13 Hospital CEOs; another 35 sent somebody on their staff. The other 5,800 had better things to do.

Now by the end of the conference, all the CEOs that were there and one of them from a small Hospital in Texas noticed the fact that even though the Business Case had not been made and it wasn't. He felt that all his colleagues, all 5,800, should have been there because it was that important of a discussion. We should be clear that Business Case as used in this context is defined in strict financial terms: "A return on investment to the investor that matches or exceeds the original investment". That has to be distinguished from a moral imperative for Patient Safety. As we find it was echoed by a number of CEOs and other people at the Conference. There were also Quality or Patient driven Market Strategy issues, we heard a lot about.

And Brent James at the conference really provided some dramatic examples with wonderful data showing the dollars and cents impacts of patient safety and quality interventions in Healthcare.

However, and I guess there are lots of "Howevers" and "Buts". The Sobering News is that they feel those who pay for patients' safety intervention are not the same people who realize the benefits of those interventions.

That's a fundamental misalignment of incentives, that's what the second area in the report fundamentally pointed out and in a way the CEOs among others were asking: "Whose investment is this anyway?"

Further, the fee for service payment system introduces additional perverse incentives, we all know those here, the care patients with iatrogenic injuries leads to increased reimbursements by private sector payers into the Federal DRG System.

Conversely, a successful patient safety intervention such as introduced drug events or postoperative wound infections can actually place Healthcare Organizations in financial jeopardy by reducing revenues as consequence of shift in patients DRG mix.

This problem was also amply dramatically illustrated by Healthcare data.

No Good Deed will go unpunished. So PMX is a big deal in this arena and it has a lot of influence on the thought processes of people who are leaders in organizations. There is even a more fundamental problem with the Federal Medicare program and a lot of our Federal programs and indeed in the private sector, that is: "We'll pay you, the Federal Government, exactly the same dollars whether you provide wonderful high quality care or truly lousy unsafe care". They don't care from a payment standpoint and that is a very powerful public policy message.

Now let's say that CEOs support the concept of patient safety and at the end of the day I think almost all of them and maybe all of them, actually do. But there are still significant barriers to get where we need to get. First of all, finding money, new money inside financially stripped organizations is a problem.

There are hospitals in this country; there are hospitals in California who are worried about making payroll on Friday. It is a little hard to plan ahead through Monday concerning planning ahead for patient safety investments.

Certainly the quality problem, as Brent James suggested, is actually a problem between Healthcare Organizations Management and the Medical Staff. Here again I think we have fundamental misalignments of incentives. And we also have a problem that because of our orientation in treating as physicians, we have a centrist view of accountability that is that when we get good outcome, we feel good about it personally and when bad outcomes occur we take that also very personally and it makes it difficult to engage physicians as part of the problem solving process under these circumstances because of the instinctive belief that the hospital, the CEO, the trustees etc are out to get you. Yet, we are going nowhere in addressing patient safety problems and quality improvement problems without physician engagement.

Further, there is a fundamental lack of information technology infrastructure in our organizations so we don't have much good data to work with if we are trying to use data to drive our decision-making processes. Brent James, indeed has suggested that one of the approaches to aligning incentives is to develop shared-risk contracts between providers and purchasers so that, let's say the hospital invests in patients 'safety and they realize savings then, there is an agreement with the purchasers that they will split the benefits from those investments.

There are big problems. We started talking about major investments: computerized position order entry CPOE is an expensive process. I've been told by a Hospital CEO of a small hospital in Pennsylvania in a rural community that it would cost him 6 million dollars to put the CPOE in place.

In a larger Community Hospital in Washington DC, the price tag is 15 million dollars and in the Detroit Medical System which has several large hospitals the price tag is one billion dollars.

And if you're going to go buy CPOE, there is no standardization and the next question is "Which system should I buy", when no one knows the answer to that question. And now you take the fact that there is hardly any organization in this country that has not been burned by making a bad IT investment and these are not small changes, there are big dollars and you have virtual paralysis.

The next big problem we have is the problem of culture in organizations that is also a derivative of a culture in this society, which is blame and punishment society. We all have grown up in that society. The answer to our problems is to sue somebody or punish somebody. That is the underpinning of our liability system and liability problems. We have the same cultural problem inside our organizations as well and I am not going to go into those because Kathleen is going to, but it is a huge barrier to getting to where we want to get.

There are two other significant issues. One is the staffing problem that we have in our organizations. We have lots of organizations around this country that have insufficient numbers of staff in order to carry out very basic patient care tasks. That's for nurses, but it's other people as well and what we have left are often nurses that are not properly trained or competent to do what they are doing.

There are agency nurses not familiar with this hospital and everybody is overstressed and overworked and if we are looking for a prescription for patients' safety problems, we just found it.

And then you have this whole communication problem, that may be as simple as the nurse afraid to challenge a physician who has an abusive behavior track record to the operating room which is a fundamental hierarchical structure where people are reluctant at least to challenge the surgeon and there have been ample case studies in the airline industry that illustrates this basic problem is one that has to be overcome as well.

While having this array of very difficult problems on the table, I would not want you to think that the people at this conference were ready to throw the towel, in fact many people were ready to make a step forward with some meaningful solutions and the kind of things they talked about were the following and I am not going to go down to some of the detailed level things we talked about but at a little bit higher level.

Basically for standardization, that is worth investing in and Jim in his new time presentation. Jim, as some of you know, beyond his medical VA background, was an astronaut and there are a lot of problems in the airline industry right after World War II, there was no standardization and they did not have any checklists. And planes fell out the sky on a fairly regular basis. If you wanted to fly, there was a risk that you might not make it from Point A to Point B. So they introduced checklists in the cockpit and they tried to normalize operations and behaviors.

There were a lot of pilots who did not think it was too hot of an idea and they left but the planes stopped falling out of the sky, thankfully for those of us who travel a lot on airplanes.

We don't use checklists inside our hospitals and if we did not have any problems, we would say: "So what?" but guess what, we have some very major problems and I am not going to tell you if the number of wrong side surgeries is going up or down because I don't really know that but I can tell you that we're having a very steady flow of reporting, mostly voluntary to us, of events that absolutely should not happen, they just should not happen.

There are needs for procedural simplification, there are needs for the use of protocols and a lot of us don't think the best of protocols but if you have protocols that are standards orders, you are under the obligation to the physician to be the exception to cross out an order that should not be there rather than try to recall from memory and maybe leave out something that turns out to be fatally important.

And finally in our organizations we need to build in, I am sure Kathleen will talk about this. The question always needs to be raised: "What happened that we made this error?" Now the Conference provided an excellent State of the Art Review of Patients' Safety challenges but I will confess that I left no less frustrated than I do for a lot of these discussions.

This is a problem that many purchasers and consumers simply believe should not exist and it is hard to explain to them why it exists.

For those of us who are inside Healthcare, we think this a set of problems we should be able to cure but we don't seem to be able to do that. But that should probably tell us that we are dealing with some deep seeded barriers to the successful resolution of this problem.

So, in my remaining time, I'd like to spend a little bit of time looking at some of these deeper problems. We first need to be reminded that Healthcare shares some important characteristics with other error problem industries. The performance of complex procedures, almost everything we do is complex, there is a requirement for multiple steps in order to complete any activities and a lot of these are very tightly coupled. There is not time to sit back and say: "Let's just take a look at what we did" and there are additional time pressures in addition to the intrinsic problem and all of this is enormously dependent upon human beings who, by definition, will make errors and our challenge lies in making sure that the errors that are made do not reach the patient.

Now there are some very specific challenges in Healthcare, I probably will not tell you things that you do not know, but I want to underscore them. First of all, the systems and procedures that we have in organizations were no way designed with quality or safety in mind. This is not necessarily a criticism, but we just kind of, did them. I ran an hospital for a number of years so I did this too, but we weren't thinking: "What could go wrong and what are we going to do to prevent this from going wrong?" So whether we are talking about administration of drugs, administration of bloods, administration of equipment, credentialing, informed consent ...list can go on and on. All of those have procedural aspects to them and those have designed elements which if achieved could prevent bad things from happening to patients. But the list of things that we need to be paying attention to is very long.

This is not a new piece of news to us. In the late 1980's, Bob Burdock introduced concepts of continuous quality improvement into Healthcare and suddenly we'd have to be paying attention to systems if we'd really want to improve care.

And 14 years later we're still struggling with this issue, it does not seem to have gotten on our screen and it is an organization cultural problem but there are also some major technical challenges and to make it worse, we are in an environment where we are continuously introducing powerful new drugs, complex new procedures and various new technologies. Often times you read about that in your early morning newspapers, which will marvel about the great improvement in patients 'care that are associated with this. But nobody talks about the risks associated with these.

Every one of these new things has risks associated with them and in order to introduce them we have to design procedures in our individual organizations and we are still not designing safety and quality into those systems so we are perpetuating a very very serious problem.

Next, it is a fundamental truth and I do speak as a physician, that physicians, nurses and other healthcare professionals have very little knowledge about systems thinking, systems analysis and systems improvement. We just don't understand that. We still have a very centrist view of ourselves, and it really is a problem. You know if something really bad happens and you have your fingerprints on that case, I've been there. We don't have one victim we have two victims.

We have the patient and we have the practitioner and we need that practitioner back on the playing field to help look at what happened and help redesign the system so that this does not happen again.

We still worry about whether that incident even gets to the surface because for the physician who was on the sharp end of this event, there is no incentive in most of our organizations to report. You're going to get reported to the State Licensure Board, you're going to get sanctions, you're going to have your privileges curtailed, you're going to be publicly humiliated. You're already humiliated yourself because this happened.

So we have created a dysfunctional problem and we are not providing the support system inside our organizations in order to promise for efforts to prevent this from occurrence in the future unless we are dealing with the cultural issues in our organizations. But we also have some educational and training issues, which I'll come back to in a minute.

Thirdly, we have not been able to convince the organizations that if there is a problem, the solution must become not a top priority but the top priority within Healthcare organizations. We are talking about CEOs; but we are also talking about Chief Medical Officers, Chief Nursing Officers and Trustees. In the newspaper, there is little talk about the need for these issues to be reported. When you pick up the newspaper, you read the patient's safety is the top priority in this organization. It is not enough to be spiritually behind this, we have to be tangibly behind this. If you are a CEO of an organization, you can't pass this down or if you pass it down, it can go to the COO but that's about it because the leaders in the organizations: medical, nursing, administrative and trustees need to be out walking the talk, really, physically walking the floors in organizations.

The Joint Commission together with the National Quality Forum this year started a series of patients' safety awards called the John Eisenberg awards and we gave the first sets of awards during our Annual Meeting in October and the people who won the award made presentations and there were several involving CEOs who told really compelling stories about how very personally they would walk the floors, talking to nurses and physicians, asking: "What's the problem?," "Where do you see the vulnerabilities and what needs to be done in the organization?". And they took that information and they did something with it.

That's more common than it was five years ago but far less common than it needs to be inside our organizations. And quite frankly within organizations, there also needs to be some real investment of resources into this activity. We have a requirement on our standards that when something bad happens, that you need to do a root cause analysis. It takes people's time, it takes other resources, and a lot of organizations have rebelled against doing that but most of them have said that once they've done it, it is the most important thing they have ever done. That's one side of the coin. In an ideal world, there would never be another root cause analysis because we will have fixed all of our systems and we will never have any more adverse events.

I won't be around by the time we have achieved that, but we'll have introduced new standards requirements that require proactive risk analysis, you can pick your poison if you like. Probably the most demanding methodology is the Failure Model Critical Effects analysis that will identify vulnerable systems, there is no problem finding vulnerable systems.

The question, the priority is: "Where do you think the money is going to be in good systems. Do you want to pick a part and build back together and make it better and stronger, like the 6 million dollar man?"

There also needs to be investments in just in time training, if we know where the problems are, we need to be training physicians, nurses and other Healthcare practitioners how to recognize and avoid problems. At some point, we need to invest in new technologies; it will come a day when we need to invest in computerized physician order entry. Some people have also suggested that one of the ways you engage trustees is you make patients' safety a standard agenda item together with the Financial report from the Treasurer. You know, if this is not visible to the Boards, then it is not on their screen.

Finally, we have not capitalized on the opportunity to engage patients as part of the solution. It's interesting when you talk to the media or other public people about Quality, the time from starting to eyes glazing over is always under 30 seconds but if you talk patients' safety and errors to people, they understand it. They've been studies clearly showing this, almost everybody has either had a bad experience themselves or they know somebody who's had a bad experience. There are opportunities to capitalize upon this and make the patient part of this solution.

Let me finally talk about some of the potential solutions.

First of all, we need a safe Heaven for reporting, that at a national level, the Joint Commission and others, and there are a lot of major players that have been working with the Congress to create safe Heavens for reporting, we've been working on that since 1996. This year, in the Congress we are going to have four bills, two in The House, two in The Senate. We almost got over the finish line but we got the lame duck session, I am sure most of you would agree that it was especially long this year. So this will be revisited next year, and I think we've got a good shot at it but it is an important public policy message and the people that lead us in the Congress really got it, they do understand this problem.

You can either publicly report these adverse events, hang people out to dry, that's the accountability model, you can do that but if you do that, you will drive everything that is hidable, and a lot of this stuff is hidable underground, and you will never see it again.

This is a fork on the road issue and you cannot do what Yogi Bear suggested which is when you come to a fork on the road, take it.

If you want to improve patient's safety, then you're going to have to protect the reporting and all four of these bills provide for protected reporting for patients' safety organizations. So I think, there is a lot of hope through that here.

Secondly, there are a set of standards issues that I have eluded to most of the things we require. We require organizations to define reportable events which are internal, those by definition have to be at least as rigorous as our own definition which is unanticipated deaths or permanent loss of function, it can certainly be more than that and include things like..?

You have to create reporting channels, you have to apply root cause analysis to these events, you have to take actions, based upon the analysis, believe me, and you always find something that needs to be fixed. Usually multiple things and then you have to demonstrate that there have been some impact classic CQI steps.

We also require the creation of internal safety programs but that's like requiring internal culture changes. Believe me, as an outside crediting body, we know our limitations, we can't make this happen, this has to happen inside organizations.

We have an obligation to provide effective timely training, Failure Model Effects Analysis, Risk Analysis; those things need to happen. And then we finally have a requirement, Daniel will talk about it, that if something bad happens, there is a requirement that the physician talks to the patient or the patient's family and explain what happened. Now, those patients' safety standards were fully put in place a little over a year ago. This year, our Board adopted a series of National patients' safety goals and that's with the recognition that the patients' safety standards, I mean, over half of our standards now deal with the patients' safety issues. This is a pig and beacon relationship for us. But most of the problems that we deal with are below the radar and everybody can be in compliance with all of the standards and I think we are still going to continue to see problems and that's why the Board did this and we have six goals associated with eleven recommendations that get into things like infusion pumps, alarm systems, wrong side surgery patient identification and so on and so forth.

There are kind of Dick & Jane sort of admonitions, sign on sight, make sure this is the right patient, make sure the alarm system works, no free flow infusion pumps, when you get an order, read it back, this cannot be much more explicit. I would hope that every hospital in this country meets these basic requirements and they are central. Now, these were developed, we had an experts panel put a lot of these things together for us, we got another 44 of these in our bank but we wanted to start with something that people could focus upon. By the end of this year, the National Quality Forum will have adopted maybe an even a more extensive group and we will grow up from that pool, going forward to meet our National Patient Safety goals which will be adjusted each year going forward. We are working hand in hand with the other players in this arena, but we believe very strongly that there needs to be parsimony in order to commit focus.

If organizations see that we introduce eleven simple recommendations we are going to be looking for, then they'll be looking for other things they can do. These are all cheap, they are not going to cost you anything to meet these requirements, in fact you might save something and that you save might commit you to make further investments in patients' safety. What a novel idea.

Finally, we need a whole new way of training Healthcare professionals. A lot of the problems we had to deal with are being perpetuated by the fact that we keep training our doctors, nurses, pharmacists and respiratory therapists the same way we've been doing all these years so why are we surprised that we still have a problem.

Some people have suggested that we need to add things like systems thinking, team training, human factors, a whole bunch of things to the Medical School Curriculum. I was in an Academic Health Center for a long time, and I want to tell you what many of you who would do that.

Know there is not this empty bucket called curriculums that needs to be filled up, it is overflowing right now. And the question is, whether we are doing teaching and training both in those schools and in our post graduate programs that is still relevant to taking care of patients in the year 2002.

THERE ARE SOME WHO BELIEVE THAT THIS WHOLE SYSTEM HAS TO BE BLOWN UP AND START OVER AGAIN, I HAPPEN TO BE ONE OF THOSE ADVOCATES. I am not persuaded that what we are doing and what we are trying out is the product that we need for tomorrow. This issue is not going to go away, it is going to have to be dealt with.

FINALLY, LASTLY, WE NEED A NEW BUSINESS CASE. I THINK THAT THE BUSINESS CASE FRAMEWORK IS HOPELESS, QUITE FRANKLY. What we are going to need to do is and let's start with the Medicare Program, WE NEED TO START PAYING DIFFERENTIALLY FOR OBJECTIVELY DEMONSTRATED GOOD PERFORMANCE. We have the measures to do this now; we have a National Quality Forum that can address these measures. If you start rewarding people for the behavior you want, you will get their attention. Even those CEOs who are former MBAs and CFOs, you will have their attention. Again we are not the only ones championing this, this is becoming very popular.

Let me close then by saying what you know, and that is that not everyone, even after this morning, is persuaded that there is a problem, nor even a need for a call for action. IT IS TRUE THAT THERE ARE MILLIONS OF TRANSACTIONS BETWEEN PATIENTS AND PHYSICIANS EVERY SINGLE DAY. IN THAT CONTEXT, THE NUMBERS OF ERRORS AND EVEN 98,000 DEATHS MAY SEEM RELATIVELY MODEST BUT YOU ALSO KNOW THAT THESE ARE NOT SIMPLY NUMBERS. THEY ARE VERY REAL HUMAN BEINGS AND PEOPLE. INDEED TOMORROW THEY CAN BE YOU, OR ME OR SOMEONE THAT WE LOVE. THAT'S THE PROBLEM, AND WE HAVE A LOT OF WORK TO DO. Thank you.