Guest Speech 2

MEDICAL ERROR, DECEPTION, SELF-CRITICAL ANALYSIS, AND LAW'S IMPACT: A TRANSPACIFIC COMPARISON

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Thanks to Profs. Matsuura, Fujimoto, Kawashima. (Note Arkansas-Fulbright connection; Fulbright statue at University of Arkansas) It's great to be back here. (I am a poor replacement for Prof. Morishima; but it's an honor to take his place. My first stay in Japan as a Fulbrighter was in Nagoya; I became a Dragons fan.)

My collaborator on these issues is Prof. Futoshi Iwata of Jochi Daigaku. We're publishing some of this in a symposium issue on "Regulating for Patient Safety" in Widener Law Review next year.

As you all know, horrible examples of medical error have been all over the front pages of all the Japanese papers the last few years. The typical story has been that some disaster happens in the hospital, a patient dies due to some medical error, there's a coverup and the dead patient's family is told the death was due to the progress of the disease, not the process of care. Then a whistleblower within the hospital, maybe a nurse that the surgeon has treated badly, or another doctor at the hospital, calls up a journalist or the police. And often, the first time the family learns about the error is when the reporter calls up for comments.

As you can imagine, we have the same kind of social problem in the US. Medical error is very widespread in America – I'll show you the statistics – it's a topic of major national debate. But there are some

significant differences between the American approaches to this problem and the Japanese approaches, and those differences are the main topic of this talk.

Here's how I'd like to approach these issues this evening. (Go over slide)

I'm going to suggest that pressure for medical quality comes from different directions in the US and Japan. In the US hospital accreditation, the peer review process, and civil litigation all play an important role. In Japan, criminal law plays a considerably greater part in the regulation of medical mistakes than it does in the U.S. To give you one conclusion in advance: In America, doctors and hospitals that have committed negligence fear the malpractice lawyers. In Japan, they have greater concern for the whistleblower, the media, and the police.

Finally, I'm going to try to explore some of the implications of these differences for public accountability and patient safety, and mention an interesting pilot program that has just begun in Japan.

The liability system, the American civil justice system, has several fundamental goals. (READ THEM OFF)They're all worthy goals, but sometimes they're somewhat inconsistent with each other: We have to trade off fully achieving one goal in order to make progress on another. The main point I want to make here, one that's not always understood even by people trained in law, is this: The civil justice system isn't only about resolving disputes between this individual plaintiff and this individual defendant. The civil justice system has a responsibility in a lot of ways to society as a whole. In addition to compensating the tortiously injured, the system needs to advance the overall goals of patient safety, fairness, and efficiency, and public accountability, making the best tradeoffs we can when those goals are in tension with one another.

Next: How much of a problem is medical error in the US and Japan? Are cases like the ones in the newspapers isolated, or are they the tip of the iceberg?

The Institute of Medicine, probably the most prestigious research institution in American health care, concluded the situation's pretty bad. (Go over slide)

In Japan, numerical estimates are difficult to find. The Ministry of Health tells me that's mainly because problems with the quality of the medical records. But one thing's for sure: in the last few years, the steady drumbeat of media attention to these startling cases of error has dramatically undercut the general public's trust in medicine.

Now, what are the corresponding figures in the legal system?

US Medical Malpractice: Claims Closed, 1993-1999

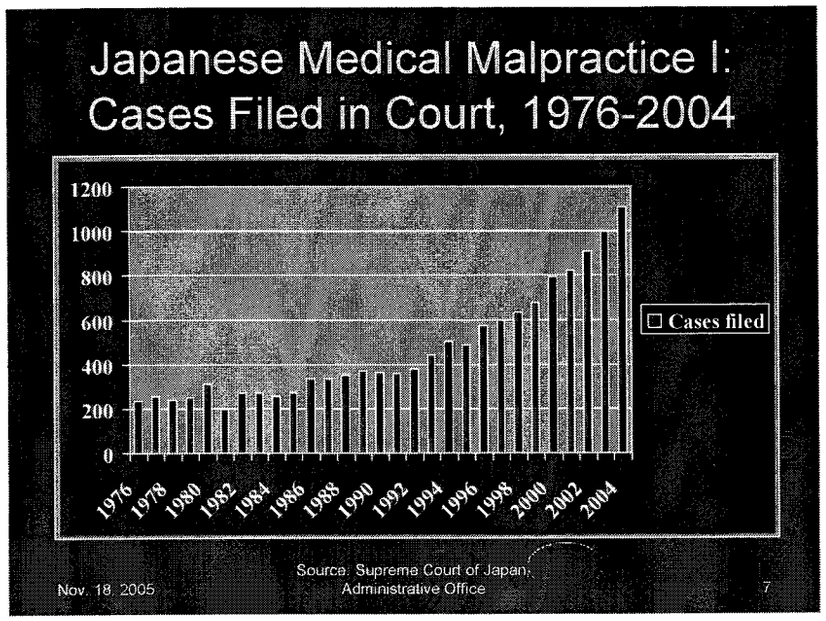
Year	Occurrence Policies		Claims Made Policies		Total
	With payment	Without payment	With payment	Without payment	
1993	7,303	22,657	22,701	56,494	109,155
1994	8,215	24,061	20,003	59,508	111,787
1995	8,569	22,525	20,944	64,345	116,383
1996	8,392	20,451	20,494	65,249	114,586
1997	7,927	20,337	21,433	61,057	110,754
1998	6,783	18,544	19,581	61,720	106,628
1999	5,495	16,565	15,924	60,855	98,839

Best's Aggregates & Averages 2003 ed., p. 78

Nov. 18, 2005 6

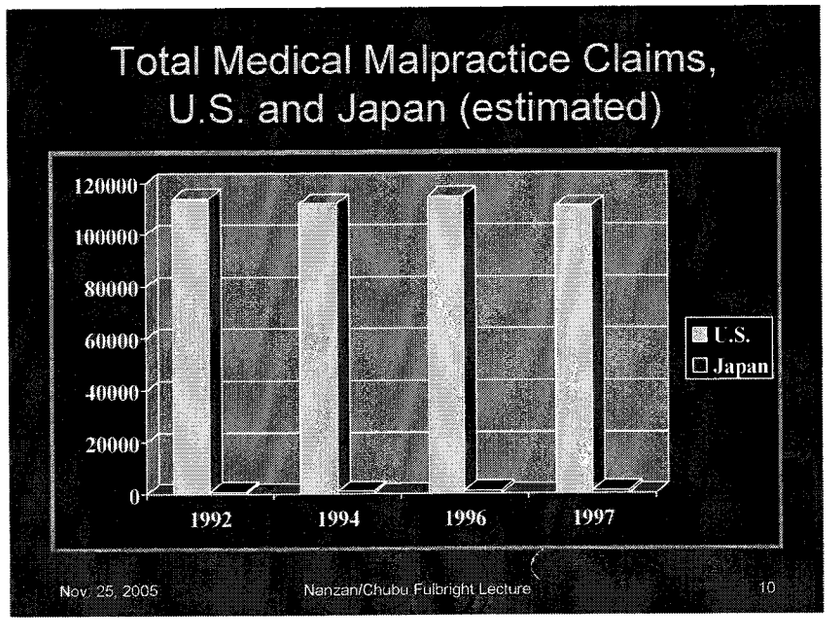
These are the best stats we have on the number of med mal claims closed in the US, and the number paid, in the most recent years for which relatively complete statistics are available. (Explain; note that the proportion of paid claims is roughly 1/4 the number of total claims)

By way of comparison, here are the figures on Japanese med mal court filings:



Add in claims from JMA & Osaka Med Assn non-judicial claims resolution systems:

Now let's put those numbers on a single chart and compare the two countries – total number of claims in the 1990s, in court and out.



Q: Is the system working properly to provide "just" compensation? Here's some impressive evidence on that question, from Dr. Troyan Brennan of Harvard, an MD-JD who was one of the lead authors of the Harvard Medical Practice Study of hospital discharges in New York State. In that study, physician reviewers looked at tens of thousands of medical charts to determine whether there was first of all any iatrogenic injury; second whether it was preventable; third, whether it resulted from any breach of the standard of care, that is malpractice; and fourth, whether it resulted in the patient filing a claim. Then they did a more recent follow-up study in Colorado and Utah. The NY study was the basis for the Institute of Medicine's estimate that as many as 98,000 Americans die from preventable hospital mistakes every year, and the Colorado-Utah study was the basis for the 44,000 deaths estimate.

Putting these figures into a pie chart: Those studies came to the conclusion that only about ¼ of the cases of preventable death resulted from a breach of the accepted standard of care, that is, from medical malpractice. The conclusion to draw from that is that only a relatively small minority of patients who suffer preventable error have a <u>right</u> to compensation under the way our law defines "just compensation." And as a practical matter, as you know, even fewer

people actually file claims. The vast majority of people injured by preventable error never receive a penny, and under the principles currently governing our medical malpractice system, they shouldn't.

Some might say that shows the law takes a narrow, pinched view of what's "just." Other countries, such as Sweden, have a broader compensation system where patients suffering <u>preventable</u> injury, rather than just <u>negligent</u> injury, are entitled to compensation, but typically in smaller amounts than the American system gives.

Well, even if the people who suffer <u>preventable</u> medical injury that's <u>not</u> due to negligence don't get compensated, what about the people who suffer medical injury that <u>is</u> due to negligence? Do they file claims and receive compensation? If they do, that would be one hallmark of a "just" compensation system.

As you see, both the New York study and the Colorado/Utah study show that most of them don't even file claims. Of those who do, some are compensated, some aren't.

So we have to conclude that there's a vast reservoir of potential claims, potentially valid claims of medical malpractice, that are never filed. According to plaintiffs' lawyers looking at these figures, it's wrong to say there's too much malpractice litigation. According to them, these figures show the opposite: there's not nearly enough.

But that's a bit too simplistic. Instead of looking at the valid claims that <u>aren't</u> filed, let's look at the actual claims that <u>are</u> filed. The majority of claims were filed in cases where there wasn't even an adverse event, according to the experts' appraisals of these medical records! (Hyman & Silver disagree) Even where there was an adverse event, in a substantial proportion of the cases, it wasn't due to negligence. The authors point out that when compensation's actually awarded, the decision to award it seems more closely tied to the seriousness of the patient's injury than to the presence of a breach of the standard of care.

Central to any program of quality improvement within an organization is self-critical analysis: the gathering and analysis of reliable data on mistakes, both those leading to harm and the near-misses, and based on that self-critical analysis, the institution of corrective measures. That process is an essential part of the project of creating a "culture of safety" within the hospital. But it's not an easy

thing to do, particularly when the threat of a malpractice action is looming over your shoulder.

In the US, almost all hospitals have to undergo an accreditation process every three years to be eligible to participate in Medicare and Medicaid. This process is typically carried out by the Joint Commission for Accreditation of Healthcare Organizations, or JCAHO. Since 2001, the accreditation process has required hospitals to undertake thorough "root cause analyses" of each serious preventable event adversely affecting patient safety, as part of a general quality assessment and performance improvement program.

You will not be surprised to learn that medical providers are afraid that if these analyses fall into the hands of plaintiffs' lawyers, that's trouble. So maybe the analyses don't get done, or don't get done properly. As Troyen Brennan, an MD-JD who's lead author of the Harvard Medical Practice Study, put it, "Any effort to prevent injury due to medical care is complicated by the dead weight of a litigation system that induces secrecy and silence. No matter how much we might insist that physicians have an ethical duty to report injuries resulting from medical care or to work on their prevention, fear of malpractice litigation drags us back to the status quo."

I think Dr. Brennan's concerns may be somewhat overblown, or at least mitigated by the past 4-5 years of developments in patient safety. In every state, hospital self-critical analyses are protected by state-law peer review privileges. (Explain "privilege") This privilege protects pretty much everything of an evaluative nature that the hospital generates, except for what's in the patient's chart and the incident reports. With that kind of legal protection, and with the JCAHO and CMS emphasis and voluntary hospital initiatives on patient safety, self-critical analyses seem much more likely to get done today than they were 8 or 10 years ago, medical malpractice crisis or no. They're virtually a professional standard in the hospital industry.

So, how should we evaluate the performance of the American civil justice system so far, when it comes to malpractice litigation? When it comes to providing "just" compensation for the injured – my conclusion is: Probably not so good. There's a big gap between the way the system's supposed to function in theory, and the way it does function in practice. Most people who deserve compensation don't get it, and too many of the people who don't deserve compensation, do get it.

Effective deterrence, fairness, efficiency – all questionable. What about "sunshine"?

Whether or not hospitals' self-critical analyses are ever made available to plaintiffs' attorneys as a matter of civil law, a consensus has formed that the fact that an error was made harming the patient has to be disclosed to the patient or the patient's family, as a matter of medical ethics. This ethical principle has been reinforced by a requirement from JCAHO, the hospital accrediting organization, that every hospital create a plan for informing patients and families about adverse medical outcomes. In addition to that, studies tentatively show there's not only an ethical value to disclosure of errors, but also a practical value to hospitals: Since one of the major reasons injured patients sue is because they want to find out the truth about what happened to them, an honest disclosure policy, according to this theory, cuts down on the amount of liability hospitals incur. A report from the University of Michigan Health System indicated that since encouraging its doctors to apologize for errors, the system's annual attorney's fees have dropped by two-thirds, and malpractice suits and notices of intents to sue have fallen by half. But there's a lot of resistance to that idea, particularly from hospital defense lawyers.

What about information about medical results for the general public? Statistical compilations about adverse outcomes at individual hospitals have started to become available, first in New York, now across the country. (Demonstrate if time, from NY CABG PDF file) There's public and professional demand for it, and without going into detail, I think the trend toward transparency in matters of American hospital performance seems unstoppable.

Now let's turn to Japan. I'm told that unlike the U.S. situation, not many Japanese hospitals conduct regular "peer reviews" where doctors frankly critique each others' performance. Unlike US hospitals, Japanese hospitals aren't required, either by hospital accreditors or by government reimbursement policy, to perform self-critical analyses. In fact, accreditation's totally voluntary for Japanese hospitals, they don't have to be accredited to be eligible for government payments, and the vast majority of them aren't accredited. Nevertheless, quite a few Japanese hospitals are beginning to do self-critical analyses, based in part on recommendations from a committee of university hospital presidents and guidance from MHLW.

Do Japanese doctors have the same fear as American doctors have, of plaintiffs' lawyers finding out about the content of hospital self-critical analyses? As we've seen, the level of civil malpractice lawsuits is fairly low in Japan, although it's increasing.

Three separate legal grounds are of concern to Japanese physicians on this point: national and local Freedom of Information rules applicable to public hospitals and the liberalized discovery rules under Article 220 of the civil procedure law, and the reporting requirements under Article 21 of the Physicians' Law, which I'll talk about in a few minutes in connection with the role of criminal law. Ministry of Health reporting requirements have also recently gone into effect.

Let's turn to the criminal side. In Japan, far more than in the U.S., a significant locus for the accountability function is the criminal justice system, amplified by the media's power.

Medical Error and the Criminal Justice System

Criminal prosecutions of medical personnel are rare in the US, but they do sometimes happen. By one estimate, in the past twenty years we've seen maybe 25-30 cases of criminal prosecutions for medical negligence in the U.S. These cases were typically brought on the basis of the defendants' reckless disregard for patients' safety – a standard considerably stricter than the negligence standard applied in civil cases.

Why are prosecutions so rare? Here are the standard reasons given: the factual complexity typical of medical cases, the need for expertise on issues such as causation and professional standards of care, the discretion allowed doctors in matters of medical judgment,

the high burden of proof beyond a reasonable doubt, and the fact that responsibility for prosecution decisions typically falls on busy local prosecutors' offices lacking ready access to medical expertise.

Another reason for the rarity of criminal prosecutions here is that there are other more-or-less effective disciplinary mechanisms available. Civil malpractice actions, peer review, hospital accreditation inspections – they've all got problems, but they function.

In contrast to the U.S., the prospect of police investigations and criminal prosecutions is a major source of concern to Japanese hospitals and physicians. All the front-page publicity given to prosecutions for medical disasters has helped create a public expectation that police and prosecutors have a routine role to play in sorting out medical mishaps. This expectation is evident in the actions of medical malpractice victims. Experienced plaintiffs' attorneys tell me that patients and families sufficiently indignant about medical injuries to consult a lawyer often also seek police investigations, and want to see medical wrongdoers prosecuted. A Japanese friend of mine who lost his teenage daughter is very much of that frame of mind. This sense of indignity is often due in part to anger over the practice of deceit about harm suffered in the hospital, and falsification of patients' medical records.

Legal Grounds for Criminal Prosecutions: Japanese prosecutors have several legal weapons in medical cases that are not part of American prosecutors' standard arsenal. Most importantly, the standard charge brought against medical personnel under the Japanese Criminal Code is "professional negligence causing death or injury" – a crime not found in American statute books. Other sanctions are available in the Criminal Code for attempts to cover up medical wrongdoing by altering patients' charts, and under Article 21 of the Physicians' Law for failing to report "unusual deaths" to police.

Although there aren't many prosecutions under Article 21, that law's causing considerable controversy within Japanese medical circles. What's an "unusual death"? There's disagreement about whether this ambiguous provision requires only the reporting of deaths in which ordinary non-medical criminal activities might be suspected – the traditional interpretation – or whether the provision extends to cover deaths in which professional negligence might be involved.

The Article 21 issue exemplifies the tension between the principles of public accountability and patient safety in Japan. Accountability considerations demand that circumstances raising suspicions of medical error be communicated to some competent, neutral entity outside the hospital, rather than being kept under wraps in the traditional fashion. But who should it be communicated to? Where are the pressure points for quality control?

Peer review in Japanese medicine is almost non-existent. There's no mechanism by which doctors routinely criticize each other's work. There's no hospital accreditation requirement. There simply haven't been any external entities capable of effective response, except the media and the police. So in spite of the limitations of police in terms of medical expertise, you can understand how some people might favor a structure encouraging reporting to police as a public accountability mechanism. But that doesn't lead very far in terms of promoting serious self-critical analysis and correction of errors.

The Health Ministry's going to try to move the system in a different direction. Starting this October, the Ministry is funding a pilot project ("moderu jigyou") in cooperation with four medical specialty societies in Tokyo, Nagoya, Osaka, and Kobe in an attempt to address these problems. I think the project's creative, well worth monitoring and evaluating. Here's how it's going to work.

When a patient dies in a hospital under circumstances indicating the possibility of medical error, an independent, third-party investigation by medical specialists can be requested on the initiative either of the patient's family, or (with the family's consent) of the hospital. An autopsy takes place – autopsies have traditionally seldom been performed in Japan, but the pathologists and forensic medicine people are eager to raise their professional profile – and specialists from the relevant medical disciplines review the patient's chart and interview the attending physician. An evaluation board reviews the evidence, submits a report on the cause of death and on needed preventive measures both to the hospital and to the family, and then with personal identifiers redacted, the report is made public.

This third-party mechanism wouldn't have anything to do, as a formal matter, with the question of compensation for the family. But as a practical matter, no doubt its conclusions will carry a lot of weight in negotiations between the family and the hospital. Where negligence is found by the investigators, given their prestige and standing, it will

likely lead quickly to: apology, formal expression of remorse by the hospital and doctors, attention to fixing the problems so they wouldn't happen again, and agreement for compensation to the family within standard amounts. The process could therefore serve as a substitute for the civil malpractice action, although it wouldn't preclude the possibility of an action. The effect of the process would probably also be to buffer providers from the draconian criminal law.

If this experiment works well and takes root in Japan – and there are plenty of cultural reasons why it might not – one of the aspects of this proposal that's promising is that it would bring, for the first time in Japan, external peer review into medicine. It wouldn't be secret peer review; the mechanism would have accountability built into it, in terms of getting the facts both to the family, to the profession, and perhaps to the general public. The aim of the pilot project is to get the answers in much more timely, less expensive, and perhaps more accurate, objective fashion than the civil law malpractice system does.

Conclusion: Police and prosecutors aren't ideally suited for the medical quality control role that has been thrust upon them. But democratic societies demand public accountability, and the relative weakness of other social structures regulating medicine has made the criminal justice system (together with the media) into an accountability mechanism of last resort. Unfortunately, the threat of criminal prosecution and accompanying adverse publicity no doubt undercuts initiatives within hospitals to perform self-critical analyses.

With regard to one important point, though, the involvement of the criminal justice system in the medical error arena in Japan offers an unqualified benefit. The traditional practice of deceiving patients about medical harm can't last much longer. Whistleblowers in hospitals uncover these deceptions, prosecutors are not inclined to tolerate them, and the media are unforgiving. This will have a beneficial corrective effect on the practice of deceiving patients, the people to whom physicians owe a fiduciary and ethical duty.