naga kept on with the injection. He confirmed the patient's heart stoppage on the monitor, checking for lack of a heartbeat and pulse. He said to the son "It's over." At about 8:46 pm, the patient died of heart stoppage caused by an acute high level of potassium in the blood.

Judgment of the Court

Part I. Introduction

[The court makes general observations about medical progress, euthanasia, and how this case forces us to define the legal limits; what's important about the case; the consequences of the decision.]

Part II. Requirements for Cessation of Treatment

Death must be unavoidable; the patient must be in the last stages of an incurable disease with no prospect of recovery. The cessation of treatment originates in the patient's right of self-determination and the limit of a physician's duty in cases of medical futility. This is not to recognize the patient's right to die as such, or right to choose death. It simply recognizes a right to choose the method or process of facing death. This is to prevent us from viewing death too lightly. It is desirable that more than one physician make the judgment that recovery is impossible. Also, if the treatment in question is one that has only a small influence on the patient's continued life, it should be easier to terminate the treatment than if it ties in directly with the patient's death—in which latter case the patient should be actually facing death before the treatment is terminated.

It is necessary for the patient to have made an expression of intent that treatment cease, and that that intent [not be revoked] at the time of the cessation of treatment. It goes without saying that it is most desirable for the patient himself to have clearly expressed that intention. The expression of intention should be based on the patient's own accurate knowledge of his disease, nature of treatment, and prognosis. For this reason the importance of informing the patient of his diagnosis and of informed consent is indicated.

However, in the great majority of cases, patients will be unable to express their intention about cessation of treatment at the time the decision must be made. Most Japanese today, we expect, would want meaningless treatment stopped, and we can expect that in future, living wills will become more prevalent. But we must consider whether substituted consent [lit. "inferred intent"— *suiteiteki ishi*] should be recognized.

If there is a prior expression of will by the patient, whether written or oral, it is powerful proof—if near in time. But if remote in time, or vague, then the case should be treated like situations where no expression of will by the patient exists. Where no reliable expression of the patient's intent exists, it is best to rely on the family to state the patient's "inferred intent." Better this, than digging into fragmentary evidence of what the patient might have said in passing. The family is likely to know the patient's character, values, and view of human existence. The family, like the patient, should be given accurate information about the patient's condition, nature of treatment, prognosis, etc. To judge the family's ability to speak for the patient, it is necessary for the physician to know about the patient's relationship to his family, how close they are, and so forth.

The treatments that may be terminated include drugs, chemical treatment, artificial respiration, blood transfusion, nutrition and hydration—both measures for treatment of disease and life support measures. However, what treatments should be stopped, and when, are medical judgments about when the treatments are meaningless.

Part III. Requirements for Euthanasia

Conditions for active euthanasia by a physician:

a. Physical pain difficult to bear.
b. The time of unavoidable death is drawing near.
c. Methods of eliminating or easing physical pain are exhausted, and no substitute means remain.
d. There is a clear expression of intent to accept the shortening of life.

Conditions for cessation of treatment: An expression of intent by family members who can infer the patient's will, will suffice. [Moreover, cessation must be medically appropriate.]

Defendant's acts here did not meet the conditions allowing either "cessation of treatment" or "active euthanasia."

The patient had bone marrow cancer. A doctor at Tōkai University Hospital received a request from the patient's son to "put him to rest," saying "I want to take him home quickly" [i.e., as a corpse].

A distinction must be made between physical suffering (whether existing or probable in the future), which can serve as a justification for active euthanasia, and mental suffering, which cannot. Judging mental suffering is too subjective; we could start to view death too lightly.

Active euthanasia is permitted as long as death is imminent. But if it is not, "indirect euthanasia" [*kansetsu-teki anrakushi*], in the sense of pain relief treatment with the possibility of hastening death, can be used.

The idea of allowing euthanasia is based in part on the concept of patient autonomy: the patient must choose whether to undergo suffering or shorten life. So an indication of the patient's will is essential. Whether a clear indication of the patient's will is required, or whether merely an inference of the patient's intent will suffice, depends on the method of euthanasia.

[The court sets out three types of euthanasia:

Passive (*shōkyokuteki*): the cessation of life-prolonging treatment, a non-deliberate (*fusakui*) act

Indirect (*kansetsuteki*): giving pain relief treatment with the possibility of hastening death

Active (*sekkyokuteki*): treatment deliberately inviting death in order to free the patient from suffering]

The permissibility of euthanasia differs according to which of the three types is in question.

The permissibility of passive euthanasia is to be judged merely as a matter of whether it is medically appropriate to cease treatment. Indirect euthanasia is permitted in accordance with the principle of patient autonomy. An inference of the patient's intent will

suffice; and this can be inferred from the family's expression of intent. Active euthanasia is permissible only when all means of removing or easing pain have been exhausted, and no other alternate methods exist. Then as the Nagoya High Court said in its December 22, 1962 judgment (Hanrei Jihō 324:1): "It must be performed by a physician."

Active euthanasia is based on the principles of emergency refuge [*kinky ū hinan*] and patients' self-determination; so it is permissible only with a clear expression of intent by the patient. Passive euthanasia is permissible only if the patient is in an incurable state, nearing death, with no prospect of recovery. Some evidence of the patient's intent is required for passive euthanasia. Clear evidence of the patient's will at the time of the decision to cease treatment is desirable. It should be based on continuing consideration and accurate information concerning prognosis, accurately understood.

However, clear evidence of the patient's will is not necessary for cessation of treatment. Passive euthanasia is also allowed based on inferences from the patient's own previous expression of will, or from the family's statement of intent. Still, to recognize that the family is properly inferring the patient's will, the family must know the patient's character and values, and must have full and accurate information on the nature of the disease, treatment, and prognosis. Moreover, the physician assessing the family's expression of will must be in a position to know both the patient's own thoughts and position concerning his disease and treatment, and the level of the patient's relationship with his family.

The conditions justifying active [or indirect] euthanasia were not met here. The fatal injection was not for the purpose of relieving physical pain, since at that time the patient was not suffering; and since the patient had never been told he was suffering from cancer, there was no clear statement available as to the patient's own intent.

Part IV. Evaluation of Defendant's Specific Acts

Removal of I.V., Foley Catheter & Breathing Tube: Both Dr. Tokunaga and Dr. Nozaki judged that the patient, as of April 13, 1991, had only a day or two to live. Other physicians said the same; even with aggressive treatment, the patient could at most have survived 4–5 days. So objectively, the patient's condition was at the stage appropriate for consideration of termination of treatment.

As for the expression of the patient's will, this patient had not been informed of his diagnosis, and had not received an accurate explanation of his condition and prognosis. At the time of decision, he was incapable of expressing his will. So we must determine whether the family could properly speak for the patient. Both the wife and son had lived with the patient for many years, and knew his character, values, and outlook on life. They kept insisting on cessation of treatment over several days. We can conclude that they were capable of expressing the patient's inferred intent. However, the family were not properly informed of the patient's inability to feel pain. On April 13, when they asked that the I.V. and Foley catheter be discontinued, they were not told that he had no response to painful stimuli. So their request cannot be considered to be properly grounded, inferred expressions of the patient's intent.

This defendant had only known the family for a short time—less than two weeks—at the time he became attending physician for this patient. There is doubt whether he really understood their position. He was not in a position to judge whether their decisions were a proper expression of the patient's intent. The patient's intent was neither expressed nor could be inferred from the family. Therefore the withdrawal of the I.V. etc. was not permitted by law.

2. The Injections of Horizon and Sereneisu

Not being premised either on the patient's own expression of intention nor on the patient's inferred intent stated by a properly informed family, these injections do not fall within the permitted indirect euthanasia.

3. The Injections of Wasoran and Potassium Chloride

Since the patient was feeling no pain at the time, the prerequisite for legal active euthanasia—intractible physical pain—was not met. Nor was there a finding that alternative measures were not available. Neither did the patient give express consent. The conditions for legally permissible active euthanasia were not fulfilled. Defendant pleaded that the son was an "instigator." But the court considered the doctor's higher status and position, and rejected the argument.

Reasons for Punishment

[The court concluded these illegal acts undercut trust in medicine, and speculated that doctors might start shortening the lives of patients who are not facing immediate death.]

Even though the hospital at which defendant was employed has high standards, its system for end-of-life care was deficient. The "team concept" did not function well, because of the shuffling around of staff.

The family's influence on end-of-life decisions is great. This doctor's training and experience in dealing with such situations was poor. [The court gave reasons for leniency with the punishment: e.g. the family does not hold bad feelings toward the defendant.]

Sentence: Two years, suspended. [The sentence was not appealed.]

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REGULATING FOR PATIENT SAFETY: THE LAW'S RESPONSE TO MEDICAL ERRORS: ARTICLE: MEDICAL ERROR AS REPORTABLE EVENT, AS TORT, AS CRIME: A TRANSPACIFIC COMPARISON*

* Some of the sources cited in this article were unavailable for review by the Widner Law Review but have been verified by the authors.

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Both Western and Japanese names are given family name last, to avoid inconsistency. Yen amounts are given in dollars at $ 1 = 110, an exchange rate typical of recent years.

LEXISNEXIS SUMMARY:
... Pervasive safety problems in medicine, scarcely noted a decade ago except among specialists, in the past few years have found a place on the health policy agenda of developed nations worldwide. ... Perhaps the supervising physician, who authorized the operation without requiring a more experienced surgeon to proctor it, might also have suffered some discipline. ... In the United States, what brought the problem of medical error to the forefront of public attention was epidemiological studies of hospital injury, drawn together in compelling fashion with insights from behavioral science in the Institute of Medicine report, To Err Is Human. ... A major difference between Japan and the United States in this respect is that medical malpractice liability premiums in Japan do not vary depending on the physician's specialty or geographical area of practice. ... Now, at least with regard to this aspect of medical malpractice litigation, if the principle of the Saitama Medical University decision is broadly applied, the tables may well have turned: Japanese law may tilt more than U.S. law toward error information disclosure in the judicial process. ... It is possible that the threat of criminal prosecution and accompanying adverse publicity may undercut sorely needed initiatives within Japanese hospitals to perform self-critical analyses, although statistics demonstrating a recent substantial increase in reporting of medical accidents to police cast some doubt on the extent of this potential patient safety problem. ...

TEXT:
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I. Introduction

Pervasive safety problems in medicine, scarcely noted a decade ago except among specialists, in the past few years have found a place on the health policy agenda of developed nations worldwide. [1] Japan is no exception. However, **[*190]** significant aspects of Japan's law-related responses to individual cases of medical error, and to patient safety problems in the aggregate, differ considerably from what most American readers of this Law Review might expect. This article describes some of the most noteworthy of those differences, suggests some explanations for their existence, and offers some preliminary assessments regarding the likely effectiveness of various elements of Japanese policies regarding patient safety.

The structure of the article is as follows: In Part II, we take a "first cut" at comparing American and Japanese structures and practices regarding medical error. We highlight the striking weight given in Japan to criminal prosecutions (enhanced by wide media coverage) in carrying out the critical social function of public accountability for medical mistakes-a social function performed in large part by the civil justice system in the United States We illustrate this point with the story of a surgery gone wrong at Tokyo's Aoto Hospital in 2002. We then reflect on the differing trajectories that brought the problem of medical error to the attention of the two nations.

In Part III, we explore the civil liability systems of the United States and Japan regarding medical injury. We note significant differences between the two systems in the quantity of claims filed and in liability insurance practices. We compare the prevalence of and legal protection for self-critical analysis by hospitals, focusing on the tension inherent in disclosure practices between measures to ensure public accountability and those to promote patient safety. We also note the increasing focus on the issue, unresolved in both countries, of the proper degree of candor by medical providers towards patients, families, and the public.

In Part IV, we take up criminal liability for medical error, offering an explanation for the relative prominence of the criminal forum as an accountability mechanism in Japan, and suggesting that, in some respects, medical practitioners' fear of criminal liability in Japan bears a functional similarity to American providers' fear of tort. The extent to which that fear in fact deters self-critical analysis and reporting of accidents, however, seems as unclear in Japan as it is in the United States. Finally, in Part V, we describe an innovative project currently under way in Japan on error investigation and dispute resolution.

We conclude that although the institutional structures of Japanese medical and legal systems present severe obstacles to satisfactory progress toward the patient safety goals that all nations share, nevertheless, Japanese initiatives and practices in some respects may usefully inform health policies and practices in the United States and elsewhere. Nationwide risk pooling of medical liability insurance, without regard to medical specialty or geographic location, may stabilize the harmful volatility of liability premiums experienced in the United **[*191]** States. A recently recognized civil-law duty of error disclosure to patients may suggest analogues in American medical jurisprudence. An experiment in impartial expert investigation of suspected medical error cases may offer a useful method for speedier, more objective resolution of quality-of-care disputes. Finally, although the engagement of the criminal justice system as a quality control mechanism has serious drawbacks, in Japan, at least its looming presence has served the beneficial purposes of helping motivate medical leaders to undertake systemic reforms, and to deter medical providers' widespread practice of deceiving patients and families.

II. First Cut: Public Accountability and Public Awareness - Aoto Hospital and the Roles of the Media, Civil, and Criminal Law

In American jurisprudence, it is tort law-specifically, medical malpractice law- that casts the longest shadow over controversies relating to medical injuries. Whether the topic is avoiding defensive medicine, encouraging self-critical analysis for the purpose of quality improvement, ensuring the availability of high (legal) risk medical services, or protecting the rights of the injured, all eyes turn first to torts. Malpractice law and proposed reforms thereto are at center stage in the state and federal legislatures. In Japan, by contrast, although medical malpractice litigation is increasing, [2] in the eyes of physicians and hospital administrators, civil damage actions are not of primary concern.

In American medicine, extra-judicial oversight activities carried out by entities such as internal hospital peer review committees, state licensure and discipline boards, Medicare Quality Improvement Organizations, and quasi-public accrediting organizations such as the Joint Commission for Accreditation of Healthcare Organizations (JCAHO) and the National Committee for Quality Assurance (NCQA) constitute key quality control mechanisms.

In Japan, by contrast, the analogous entities have traditionally been weak or dysfunctional. [3] Peer review has been uncommon. [4] Until recently, the nation's disciplinary board for physicians and dentists, the Medical Ethics Council (Id shingikai), has sanctioned practitioners only after a criminal conviction (typically for reimbursement fraud, morals violations, or drug abuse). [5] Quality-of-care **[*192]** concerns have almost never formed the basis for administrative sanctions. The hospital accreditation entity analogous to JCAHO, the Japan Council for Quality Health Care (JCQHC, Nihon iry kin hy ka kik), operates on a far smaller scale and with a lower profile than JCAHO. This is due in large part to the fact that, unlike in the United States, Japanese hospitals need not be accredited to obtain payment for services rendered; the great majority have not undergone the JCQHC accreditation process [6] -which, in any case, focuses chiefly on structure and process criteria, not on patient safety-related outcomes. [7] Quality control has simply not been a significant aspect of the formal structure of Japanese health care.

However, there is a public accountability function that must be performed, at least in any society attentive to the rights and interests of individual citizens. Who offers assurance that the competence and the integrity of the professional class meet at least minimally acceptable standards? Who disciplines the profession's wayward members? In Japan, that public accountability function has been carried out in considerable part by the criminal justice system-police and prosecutors-amplified by the power of the media.

Consider the following events that took place at Aoto Hospital, a facility affiliated with Jikei Medical University in Tokyo. The story occupied column-meters of newspaper space and newscast top billing for a while in 2003. [8]

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In November 2002, three neophyte urology surgeons at Aoto Hospital, eager to gain experience with a high-tech procedure, obtained their supervisor's permission to perform a "keyhole" laparoscopy on a prostate cancer patient using sophisticated imaging equipment with which they were only slightly familiar. In obtaining the patient's consent, the lead surgeon, Dr. Jun Madarame, pitched the "keyhole" technique as promoting quick healing. He neglected mentioning his lack of experience at the procedure, the possibility of serious intra-abdominal bleeding experienced by patients of the university's other surgeons, or the existence of well-established standard alternative treatments. Neither Dr. Madarame nor his supervisor was required to clear either the consent materials or the proposed surgery itself with the medical school's ethics committee.

Reading from the equipment manual in the operating room, the surgeons consulted with the manufacturer's representative by phone as the operation proceeded. They persisted with the imaging equipment (giving them an indirect view of the operative field by TV monitor) despite nicking a vein, rather than falling back on standard surgical technique of opening the abdomen to afford a clearer direct view. Nine and a half hours into the surgery, the patient was bleeding heavily, but unfortunately the surgeons had also failed to procure an adequate supply of the patient's unusual AB blood type for transfusion purposes. An emergency transfusion could have been performed with Type O blood, likely available at the hospital, but neither the surgeons nor the anesthesiologist acted on this elementary fact. The patient went into shock, suffered serious brain damage from lack of oxygen, and died a month later. Following the patient's death, the hospital director met with the patient's family and gave them a sanitized and misleading account of the circumstances of the operation.

Were this tragedy to have taken place in the United States, the young surgeons would have been subjected to a peer review process within the hospital, as would the anesthesiologist who failed to intercept the course of events while the patient's blood pressure was dropping to dangerous levels. [9] Suspensions of hospital privileges might have been in order, particularly if any of the physicians had exhibited a pattern of repeated sloppiness or lack of candor. Perhaps the **[*194]** supervising physician, who authorized the operation without requiring a more experienced surgeon to proctor it, might also have suffered some discipline. The incident would certainly have qualified as a "sentinel event" reportable to JCAHO, although whether in fact the hospital would have reported it is open to serious question. [10] There is some chance that the patient's family might have filed a civil malpractice action-at most a one-in-three chance and probably much less, if the Harvard Medical Practice Study figures are to be believed. [11] If a malpractice action were brought, the trial might merit mention in the local news.

In fact, events in Japan proceeded in a rather different fashion. The family has not, as of this writing, brought a malpractice action or even engaged an attorney. [12] But police, who learned of the case from an anonymous whistle-blower, arrested the three surgeons for criminal negligence resulting in death, and filed papers with the prosecutor charging the supervising physician with the same crime. A dozen investigators spread out over the hospital confiscating evidence, including the video of the thirteen-hour operation. Ultimately two of the three surgeons pleaded guilty. Criminal charges were dropped against the supervising physician for lack of sufficient evidence, but his medical license was suspended (along with those of the two who pleaded guilty) [13] by the Ministry of Health, Labor and Welfare's Medical Ethics Council-apparently the first license suspension for a failure of supervision in the Council's history. The story was national front page news when the surgeons were arrested, and since then the **[*195]** case has received steady continuing coverage by Japan's major newspapers. [14] A leading urologist has already published a book calling attention to how the various errors committed and system flaws demonstrated in the case are manifestations of deep-seated infirmities in the structure of Japanese medicine. [15]

Nor is the case unique. It is one of a series of recent high-profile medical mishaps to which the media have given intensive coverage: cases stunning in their quotidian banality, many of them followed by a cover-up and deception of patients and families suffering harm. [16] Often the events come to light only because a whistle-blower within the hospital-perhaps a nurse chafing under an arrogant surgeon's abuse-contacts a journalist or the police. Among the many recent cases, three besides the Aoto Hospital case have attained representative significance: the heart and lung patients' mixup at Yokohama City University Hospital in 1999, [17] the Tokyo Hiroo General Hospital fatal injection in 2000, [18] and the Tokyo Women's Medical University heart-lung machine blunder in 2001. [19]

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In the United States, errant physicians and hospitals fear the malpractice lawyers. In Japan, their greater concerns are the whistleblowers, the media, and the police. [20]

In the United States, what brought the problem of medical error to the forefront of public attention was epidemiological studies of hospital injury, [21] drawn together in compelling fashion with insights from behavioral science in the Institute of Medicine report, To Err Is Human. [22] Those epidemiological studies were sparked by the medical malpractice liability crises of the 1970s and 1980s, which impelled the funding of the studies. [23] Certainly, the media have also played an important role in publicizing the patient safety issue, as well as in illustrating a few particular cases of malpractice. [24] But in essence, the interaction of **[*197]** malpractice law with liability insurance drove epidemiological science, and science has driven policy.

In Japan, by contrast, no epidemiological studies have delineated the overall extent of medical error. [25] As will be seen in the next section, neither civil malpractice liability nor liability insurance has been a factor powerful enough to launch research programs or to move health bureaucracies to act. The salience of the topic of patient safety as a problem for national health policy must be attributed instead chiefly to the extensive media treatment given to cases such as those noted above. [26] The widely remarked appearance of To Err Is Human not long after the first of the cases, the Yokohama City University Hospital heart and lung patients' mixup, [27] magnified the newsworthiness of the medical error problem, enabling the media to portray it as a matter of international rather than merely local significance.

The upsurge of public concern in Japan about patient safety must be viewed against the background of a society moving away from traditional hierarchy and secrecy, especially prevalent within the medical world, towards greater openness, transparency, and citizen participation. The Diet recently passed a national freedom of information law, [28] following the lead of prefectures around the **[*198]** country. Informed consent in medicine, a concept virtually unheard of until the late 1980s, has become widespread in clinical practice [29] (albeit with a Japanese coloration and ample opportunity for abuse, as in the Aoto Hospital case). Public demand for information about hospital quality is high, as witnessed by brisk sales of popular publications purporting to rank hospitals in various fields of medicine by reputation, by volume of procedures performed, etc. [30]

In this environment of increased public expectations for openness, traditional practices of deception and secrecy are increasingly met with stony disapproval. And malpractice actions, once rare, are on the rise.

III. Malpractice Law, Self-critical Analysis, and Policies of Candor

A. Litigation Volume, Damages, and Liability Insurance

Without question, Americans file far more medical malpractice claims, in court and out, than Japanese do. Claims incidence figures are not directly comparable, since the best available U.S. statistics count claims closed annually, while the only available Japanese statistics count claims filed annually, and do not include all claims made outside the judicial system. Nevertheless, in the face of the vast disparity between the claims figures, differences in counting methods are trivial. For example, in 1997 there were 110,754 medical malpractice claims closed in the United States, [31] compared with a total of 1,089 claims filed in the **[*199]** Japanese courts [32] and with the Japan and Osaka Medical Associations. [33] Given that the population of the United States is about 2.2 times that of Japan, [34] an American in 1997 was as much as forty to fifty times more likely (as an upper-bound estimate) to have filed a medical malpractice claim than was a Japanese. [35]

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Damage awards to successful medical malpractice plaintiffs in Japan are more standardized and predictable than awards in the United States. Awards in Japanese malpractice cases are usually based chiefly on guidelines used by courts for injuries in traffic accident cases. [36] Under these guidelines, for example, in death cases, pain-and-suffering awards range from 20-28 million (US$ 180,000- $ 250,000), [37] to which would be added funeral expenses and lost earnings to the presumptive retirement age of sixty-seven discounted to present value, from which latter amount thirty to fifty percent is subtracted for presumptive living expenses not incurred. [38] Punitive damages are never awarded in Japanese civil cases, [39] eliminating a source of some variation in United States awards. Comparison of the magnitude of awards in Japan and the United States is difficult, because of the diversity of U.S. judicial forums and the lack of nationwide statistics; but mean and median awards in U.S. wrongful death cases, at least, seem not to diverge radically from the Japanese scale of damages. [40]

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Medical malpractice premiums in Japan, which could be considered a very rough- hewn proxy for liability payouts in the long term, [41] are but a small fraction of those charged in the United States. The premium paid by a physician member of the Japan Medical Association liability insurance program in 2000 was 55,000 (US $ 500). [42] General hospitals insured by Yasuda Fire & Marine Company paid 16,130 (US $ 150) annually per bed in 2000. [43] By contrast, American

internists pay more than ten times as much; physicians in high-risk specialties in high-verdict locales may pay 300 times as much; and hospital premiums are far higher as well. [44]

Overall levels of claims and premiums tell only part of the story, however. Trends, and perceptions of trends, are also significant. The quantity of civil malpractice cases filed in Japanese courts is accelerating, as Figure 1 illustrates, and at a rate that outstrips increases in most other categories of litigation. [45]

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The plaintiff's malpractice bar is increasing in number and sophistication. [46] Of greatest significance is the media attention devoted to medical cases. Though the number of litigated cases is small in comparison with the United States, media coverage-even of cases that would be deemed so common by major American papers as to be without news value-magnifies their impact on the public and the medical profession. With adverse publicity comes damage to reputation. [47] Civil malpractice litigation has a sentinel effect out of proportion to its quantity. [48]

[SEE FIGURE 1 IN ORIGINAL]

[*203]

In the United States, a standard component of the rhetoric of medical tort reform is that liability premiums for physicians in high-risk specialties, such as obstetricians, neurosurgeons, and orthopedists, have risen to unsustainable levels, particularly in geographic areas where large liability awards are common. However, as Mark Geistfeld and William Sage have recently observed, [49] this phenomenon is in large part an artifact of American medical liability insurers' conventional practice of basing premiums on a physician's specialty and geographic location-a practice that "is not preordained, and in fact is socially counterproductive." [50] This risk class segregation practice results in volatile risk pools composed of small numbers of physicians, justifying spikes in premiums due to a few large liability payouts in a particular specialty or locality.

A major difference between Japan and the United States in this respect is that medical malpractice liability premiums in Japan do not vary depending on the physician's specialty or geographical area of practice. [51] Essentially, the risk pool is the nation's doctors. Overall payouts should therefore be far more predictable than in the United States, and in fact premiums were stable throughout the 1990s. It is true that the Japan Medical Association indemnity insurance system has suffered substantial red ink in recent years and found it necessary to increase annual premiums from 55,000 (US $ 500) to 70,000 (US $ 640) in 2003. [52] Nevertheless, these amounts are still inconsiderable by American standards. From the standpoints of efficiency, cost spreading, and stability, there is much to be said for the Japanese medical liability insurance approach.

B. Self-Critical Analysis and the Law

As pioneers in the field of medical system safety have long pointed out, [53] and as To Err Is Human stressed, [54] essential to a hospital's project of creating a "culture of safety" is self-critical analysis: the gathering and study of reliable information on preventable mistakes and the implementation of corrective measures. Since 2001, JCAHO has made the conduct of "thorough and credible root cause analyses" of all sentinel events a subject for hospitals' triennial **[*204]** inspections. [55] Since 2003, the Department of Health and Human Services (DHHS) has required all hospitals participating in the Medicare and Medicaid programs to develop and maintain a quality assessment and performance improvement program, incorporating self-critical analyses as part of the process. [56] So thoroughly has this concept penetrated the hospital administration world, in fact, that the institution of in-hospital systems for producing self-critical analyses of accidents and near misses may be considered to have become an established standard for American health care institutions.

Many physicians and hospital administrators, cautioned by defense counsel, fear that these self-critical analyses, in the hands of plaintiffs' attorneys, will serve as weapons for infliction of legal liability and professional embarrassment. It is often claimed that this fear deters honest, thorough reviews of adverse events, hindering quality improvement efforts. [57] Whether the fear of disclosure of self-critical analyses in fact stifles efforts at error reduction is empirically unproven, [58] and in any case the fear may be considerably overblown in the light of state-law peer review privileges rendering hospital deliberations about incidents relating to the quality of care nondiscoverable and inadmissible as evidence in civil trials. [59] Still, uncertainties persist about the scope of the peer review privilege, [60] **[*205]** which varies a bit from state to state [61] and which is not recognized in some federal courts. [62] So caution on the part of some medical providers about the legal consequences of conducting self-critical analyses is not without reason.

This concern, against the background of the heated debate over medical tort reform, [63] impelled Congress to enact the Patient Safety and Quality Improvement Act of 2005. [64] The new law, discussed more fully elsewhere in this issue, [65] creates a voluntary system for providers to report medical errors to DHHS-certified Patient Safety Organizations; it makes the reports confidential, shielding them from use in civil and criminal proceedings. Original medical information such as patient charts and incident reports will still be available to litigants as under existing state law, but evaluative information transmitted to a Patient Safety Organization will be protected. [66]

Unlike U.S. hospitals, Japanese hospitals are not required to perform self- critical analyses by hospital accreditation authority [67] or by government reimbursement policy. Nevertheless, many Japanese hospitals are beginning to do self-critical analyses, spurred in part by recommendations from the National University Hospital Presidents' Conference [68] and by guidance from the Ministry **[*206]** of Health, Labor, and Welfare (MHLW) [69] following the well-publicized medical misadventures noted above. [70] These recommendations have met resistance, not only due to institutional inertia and lack of comfort with the disruption of traditional practices. Part of the resistance is attributable to concerns by Japanese medical leaders, similar to those voiced in the United States, about the possibility that such analyses could be used to medical defendants' detriment in civil malpractice actions or in criminal proceedings. [71]

Four separate sources of legal obligation are of concern to Japanese hospitals and physicians in this respect: (1) national and local Freedom of Information rules applicable to public hospitals; (2) the liberalized discovery rules under Article 220 of the civil procedure law; (3) an asserted contractual obligation, recognized in recent cases, to investigate hospital accidents and report the results to patients; and (4) the requirement for reporting to police of "unusual deaths" in Article 21 of the Physicians' Law. The first three sets of rules, relating to civil cases, are discussed in this section of the article; the fourth, violation of which is grounds for criminal prosecution, is discussed in Part IV on criminal law.

Under the national information disclosure law, enacted in 1999, records kept by public hospitals are potentially subject to disclosure unless an exception to disclosure applies, for example to protect individual patients' privacy. [72] However, the privacy exception does not necessarily protect the names of individual physicians. For example, in response to an Asahi Shimbun journalist's request for information on an accident at a public hospital, the Cabinet's Information Disclosure Review Board, which handles administrative appeals under the law, called for the disclosure of the names of attending physicians, the minutes of internal hospital committees investigating the accident, and the contents of apology letters to patients and families. [73] Although such disclosures are apparently uncommon, [74] they contain the potential for considerable embarrassment to medical personnel. [75]

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The recent liberalization of the previously restrictive discovery rules of the Japanese civil procedure code [76] has opened up the possibility that hospital incident reports and internal analyses of adverse events might become generally available to plaintiffs' attorneys. (Unlike the information disclosure law, the civil procedure law applies not only to public entities, but to any potential party in a civil case.) Article 220 of the civil procedure law now recognizes a new general principle of discoverability of specifically identified documents, but contains several exceptions. The Supreme Court in its 1999 Fuji Bank decision recognized that "documents produced solely for internal use" (naibu bunsho) are exempt from discovery, under one of these exceptions. [77] Hospitals' internal reports arguably fall within this "internal use" exception.

Applying the principles of the Fuji Bank case to the hospital setting, the Tokyo High Court in 2003 ruled that a hospital's internal report concerning a patient's death was disclosable, in part, to attorneys for the patient's family. [78] In its Saitama Medical University decision, that court drew a distinction between the portion of the report containing fact-gathering interviews with hospital personnel, on the one hand, and the portion containing "objective" conclusions about the patient's course, the causes of her death, proposed corrective measures and accident prevention strategies, on the other. The court held the fact-gathering section of the report non-disclosable on the grounds that disclosure would interfere with a protectable interest that the court characterized as "free formation of ideas" (jiy na ishi keisei) on the part of the medical personnel, and that the fact-gathering was solely for internal use. However, the court ruled that the portion of the report containing factual conclusions and quality improvement strategies was disclosable. Although this portion of the report was, in part, for internal use, it was also the basis for the hospital's report on the case to prefectural health authorities, and it contained an apology to the family and a prayer for the eternal repose of the departed patient-factors that took this portion of the report out of the "internal use" exception. [79]

The Tokyo High Court's decision applied a disclosure principle somewhat broader than that generally employed under American state-law peer review statutes, which typically call for disclosure of incident reports but protect from **[*208]** discovery all documents with evaluative content. [80] This broader disclosure principle may have wide-ranging impact, due to a mandatory accident reporting requirement recently adopted by the MHLW and applied to a class of larger hospitals. [81] This reporting requirement, under the rationale of the court's decision, may vitiate the force of the "internal use" exception to the new general discovery principle, as explained below.

Similar to the controversy over accident reporting in the United States, [82] a major issue facing MHLW in structuring its patient safety programs has been the choice of a system to implement for the reporting and analysis of medical errors. [83] The ministry has wobbled somewhat on the issue. MHLW initially required tokutei kin by in (an administrative category comprising about eighty-one advanced-level hospitals) to establish safety management systems incorporating systems for internal reporting to hospital patient safety committees of accidents involving injury. [84] Fearing provider resistance, MHLW originally required neither tokutei kin by in nor general hospitals to submit any external reports, either of accidents involving injury or of "near misses" in which an error did not result in harm. The ministry encouraged all hospitals, however, to send in reports of "near misses" on a voluntary basis.

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MHLW's original reporting program was not a success. The "near miss" reports, which ministry officials had hoped would contain virtually as much information useful in identifying specific problems as reports of actual accidents might contain, were entered into a rigid, unhelpful coding system that made root cause analysis difficult. [85] Few staffers were available to read and analyze the reports and give feedback; the lack of feedback in turn discouraged conscientious reporting. Vast variations appeared in the thoroughness with which tokutei kin by in conducted their internal reporting systems for accidents involving injury. [86] The upshot was that the ministry had no reliable information on the actual extent of medically caused injury in Japan. [87]

In 2003, acting on an advisory committee report, [88] MHLW changed course and determined that accidents causing harm to patients, in addition to "near miss" events, would be the focus of the redesigned reporting system. Since 2004, reporting of accidents causing harm has become mandatory, rather than voluntary, for a class of 275 larger and specialized facilities, including national and university hospitals. [89] Reports are made not to any governmental entity with enforcement powers, such as MHLW, but rather to an independent quasi-public entity whose purpose is the collection and analysis of medical accident data and the formulation and dissemination of corrective measures [90] -a structure somewhat analogous to the air safety reporting system in the United States. Although reporting is required, no penalty is assessed for failure to report-a compromise policy aimed at simultaneously mollifying media and patients' groups' criticisms of the previous voluntary reporting system, and appeasing **[*210]** Japan Medical Association opposition to strictly enforced mandatory accident reporting. [91]

The newly mandatory nature of medical accident reporting to a quasi-public outside entity, analogous to the prefectural authority that received the hospital report in the Saitama Medical University case, may well disqualify those reports from protection under the "internal use" exemption of Article 220 of the revised civil procedure code, discussed above. [92] It may be that the rationale of the Tokyo High Court's decision in that case (if accepted by other courts) would require hospitals subject to the mandatory reporting requirement to disclose to plaintiffs' attorneys, as a routine matter, the "objective" parts of the internal accident investigations upon which their accident reports are based. [93]

Not long ago, Japanese civil procedure law was criticized as too restrictive in its evidence-gathering rules, to the prejudice of the quality of justice, and U.S. discovery procedures were heralded by critics of the old code as providing a freer flow of relevant information to the judicial process. [94] Now, at least with regard to this aspect of medical malpractice litigation, if the principle of the Saitama Medical University decision is broadly applied, the tables may well have turned: Japanese law may tilt more than U.S. law toward error information disclosure in the judicial process. The possible effects on self-critical analysis in Japanese hospitals remain to be seen.

C. Policies of Candor

Legal compulsion, of course, is not the only means by which information about hospital accidents may be disclosed to affected patients, families, and the public. Some hospitals have

adopted policies of rather thoroughgoing voluntary **[*211]** disclosure. For example, after its nationally publicized heart and lung surgery patient mix-up [95] and other misadventures, Yokohama City University Hospital implemented a policy of public disclosure of all cases of malpractice resulting in death, serious injury, or lesser injury, where hospital safety practices are called into question. [96] The national university hospitals' organization has also announced a similar policy calling for prompt public disclosure of individual cases of malpractice involving death or serious injury, and periodic public compilations of cases involving lesser fault and lesser harm. [97]

Regardless of whether a hospital discloses its mistakes to the general public, or its self-critical analyses are made available to plaintiffs' attorneys, in the United States a consensus has formed that errors resulting in harm to patients must be disclosed to the patient and family as a matter of medical ethics. Medical mistakes must not be covered up. This ethical duty of truthtelling about error may not be universally observed-in fact, in actual practice it may be disregarded as often as not [98] -but the duty is made clear in the American Medical Association's Code of Medical Ethics, [99] and the JCAHO hospital accreditation process now reinforces that ethical principle as an accreditation requirement. [100]

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Neither the Japan Medical Association's code of ethics [101] nor the hospital accreditation criteria of the Japan Council for Quality Health Care [102] contain any provisions concerning error disclosure to patients corresponding to the stances of the American Medical Association and the JCAHO. We are unaware of any studies on the extent of error disclosure to Japanese patients and families. On the one hand, the importance of sincere apology as an essential element in dispute resolution in Japan [103] suggests that candor should be at a premium. On the other hand, there are gradations of candor, and frequent is the case in which a "sincere apology" is extracted only after the harm-causer is driven into a corner by exposure of the facts. It is apparent that a great deal of the distrust in physicians that the Japanese public has come to harbor is a consequence of the medical world's blanket of secrecy.

However, recent judicial decisions have recognized that hospitals have a legal duty to investigate the causes of medical accidents and to report the conclusions faithfully to the patient. Both the Kyoto District Court [104] and the Tokyo District Court [105] have held that this duty to investigate and report on accidents arises out of the hospital-patient contract, in which the medical provider undertakes an implied obligation to explain the nature and course of treatment and its results. Reinforcing the autonomy principle recognized in recent Japanese medical jurisprudence, [106] these decisions should help lay the groundwork for greater **[*213]** candor toward injured patients. The decisions also suggest avenues worth exploring in American litigation over medical accidents in which medical providers have been duplicitous or evasive about adverse outcomes.

Access by medical error victims and the general public to reports of patient safety hazards through the civil justice system, administrative mechanisms, and voluntary private initiatives is not the only means by which the principle of public accountability for medical error can be vindicated. In Japan, far more than in the United States, a significant locus for the accountability function is the criminal justice system, amplified by the power of the media.

IV. Patient Safety and the Criminal Justice System

Criminal prosecutions of medical personnel for medical acts [107] resulting in harm to patients are rare in both Japan and the United States. Barriers to successful criminal prosecution are high, and properly so. Nevertheless, the criminal law is available in both nations (as it is in European legal systems) [108] as a restraint on patient-endangering acts of uncommon turpitude.

In this section of the article we compare the frequency of criminal prosecutions for medical acts in the two nations and the relative significance of the prospect of prosecution to medical personnel, finding that the criminal law casts a longer shadow in Japan. We set out the chief legal grounds for **[*214]** prosecuting medical acts, grounds generally unavailable to American prosecutors. We note that in the years since the spotlight has begun to shine on prosecutions of medical personnel, hospitals' reports to police of medical accidents have increased. We describe the considerations prosecutors say they take into account in bringing medical cases in Japan, and speculate that a reason Japanese medical error victims appear more likely than their American counterparts to seek prosecutions of erring medical providers may be a greater convergence of objectives between prosecutors and victims in Japan than in the United States.

A. Prosecutions for Medical Acts in the United States

In the United States, it has been estimated that two recent decades have seen perhaps twenty-five to thirty-five cases of criminal prosecutions for medical negligence. [109] These cases were typically brought, and convictions sometimes obtained, on the basis of the defendants' reckless disregard for patients' safety-a standard considerably stricter than the negligence standard applied in civil cases. [110] The rarity of these prosecutions is at least partly explained by the **[*215]** factual complexity typical of medical cases and the need for expertise regarding matters such as causation and professional standards of care, the discretion afforded physicians 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. These factors together make the prosecution of medical personnel a costly and difficult endeavor.

Accordingly, in comparison with the relative frequency of civil medical malpractice actions, the threat of criminal prosecution does not loom large as a concern of American physicians and hospitals. Injured patients and their families seldom seek to have a harm-causing physician indicted; the private law remedy is vastly preferred.

B. Medical Prosecutions in Japan

1. Significance to Medical Personnel

A major source of concern to Japanese hospitals and physicians is the prospect of a police investigation and criminal prosecution. [111] (This concern is not shared in the United States, though it is to an extent in some European nations.) [112] Even before the recent surge of public attention to the problem of medical error, an average of two to three prosecutions per year were brought in medical cases in Japan [113] -a per capita frequency considerably higher than that reported in the American literature. [114]

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More important than the absolute number of prosecutions is the level of media coverage. The front-page publicity accorded to prosecutions for recent medical disasters has set the medical profession on edge and has helped create a public expectation of sorts 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. Attorneys experienced in representing Japanese medical malpractice plaintiffs report that patients and families sufficiently indignant about medical injuries to consult an attorney frequently also seek police investigations, and want to see medical wrongdoers prosecuted. This sense of indignity is due in part, but only in part, to anger over providers' not uncommon practice of deceit about harm suffered in the hospital, and falsification of patients' medical records.

2. Legal Grounds for Criminal Prosecutions; Reporting of Medical Accidents to Police

Japanese prosecutors employ several legal weapons in medical cases that are not part of American prosecutors' usual arsenal. Most importantly, the standard charge brought against medical personnel under the Japanese Criminal Code is "professional negligence causing death or injury" [115] -a crime not found in U.S. statute books. (As noted above, [116] the few convictions in recent years in American medical cases almost always involve charges of recklessness or intent-a higher level of mens rea than negligence.) Additional sanctions are available in the Criminal Code for attempts to cover up medical wrongdoing by altering patients' charts, [117] which plaintiffs' attorneys charge is a common **[*217]** practice, [118] and under the Physicians' Law for failing to report "unusual deaths" (ij shi) to police. [119] Japanese prosecutors may be reluctant to bring medical crime cases for various reasons including the factual difficulties, but as these provisions demonstrate, their statutory obligation to protect the public certainly extends into medical facilities.

The crime under Article 21 of the Physicians' Law of failing to report an "unusual death," though infrequently prosecuted, [120] is causing considerable controversy within Japanese medical circles. Disagreement exists about whether this ambiguous provision of the Physicians' Law 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. [121]

The issue exemplifies the tension between the goals of patient safety and public accountability. Like the prospect of being named a defendant in a civil malpractice action in the United States, the possibility of criminal sanctions and adverse reputational consequences could create, in the minds of medical personnel, the incentive to cover up medical mishaps. Thus, the opportunity for analysis and correction of errors would be lost-a point that has escaped the notice of neither scholars nor medical practitioners. [122] Accountability considerations, however, demand that circumstances raising suspicions of **[*218]** medical error be communicated to some competent, neutral entity outside the hospital, rather than being kept under wraps in the usual fashion. At present, there are few external entities capable of effective response to such communications, except the media (to whom whistleblowers within the hospitals have increasingly turned) and the police. So, despite the limitations of police in terms of medical expertise, it is understandable that some might favor a structure encouraging reporting to the police as a public accountability mechanism. Indeed, leaders of the medical world, attentive to shifts in public attitudes, recognize the social importance of a functioning accountability mechanism as a way of regaining the public's shaken trust in their profession. [123]

Since the well-publicized arrest and conviction of the director of Hiroo General Hospital in Tokyo for failure to report a malpractice-related death, and the affirmance of the conviction by the Supreme Court of Japan, [124] many physicians and hospitals have chosen to err on the side of caution and have filed "unusual death" reports whenever a patient dies in circumstances raising the possibility of professional negligence. The number of reports to police has increased six-fold since the Hiroo Hospital case became public (Figure 2). [125]

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[SEE FIGURE 2 IN ORIGINAL]

This jump in Japanese medical providers' reports to police may have implications for the debate in the United States over the proper extent of legal protection for self-critical analyses. The statistics on increased reporting indicate that the threat of legal sanction does not invariably lead medical providers to conceal evidence about adverse events. Economic incentives derived from reputational loss constitute a significant counterweight. When a hospital's coverup is revealed, public distrust of the hospital is magnified, and the hospital's patient census may drop precipitously. The prospect of avoiding that disquieting possibility has apparently reinforced hospitals' inclination to make a clean breast of hospital deaths that may be medically related. [126]

As noted above, [127] MHLW recently adopted a mandatory reporting system for adverse events, with reports to be submitted by a subset of hospitals to an independent entity without enforcement powers. As this new system gains traction, the accountability-based pressure for reporting to police is likely to diminish. Whether the lodging of a part of the public accountability function in **[*220]** the new reporting system will affect the interpretation of the ambiguity in the Physicians' Law remains to be seen.

3. Prosecutorial Considerations

According to Tokyo prosecutors experienced in medical cases, several factors are most important in decisions about whether to prosecute. Factors supporting prosecution are (1) the bringing of a complaint by the patient or family, (2) the seriousness of the harm, (3) the egregiousness of the medical personnel's acts or omissions, (4) the clarity of proof of negligence, and (5) failure by the medical personnel involved to have provided compensation and apologies to the injured. [128] Other relevant considerations include the extent of media coverage, the current weakness of professional disciplinary sanctions within medicine, and perhaps, the deterrent effect of prosecution on other harm-causing behavior. [129] Few cases meet these criteria, but those that do, when they become public, have enormous impact.

4. Why a Greater Role for Criminal Law in Japan? A Conjecture

Criminal law plays a far greater role in the public regulation of medical error in Japan than in the United States. Japanese aggrieved by perceived medical error have a greater tendency to call for police and prosecutorial involvement than Americans. The lack of other accountability mechanisms in medicine-for example, the weakness of peer review and professional discipline structures, [130] the lack of mandatory hospital accreditation, [131] the absence of objective hospital-by-hospital statistics on outcomes of medical treatment, and the relative infrequency of civil malpractice litigation [132] -enhances the social importance of the criminal law as a way of increasing transparency in the medical world.

Various theories have been offered for the tendency of Japanese to rely on police and prosecutors in cases of medical harm. One explanation draws on a traditional predilection among Japanese to look to public authorities to resolve **[*221]** private disputes that Americans would resolve privately. [133] Another explanation emphasizes the practical difficulties and delays [134] in obtaining civil law remedies through malpractice actions, impelling victims to turn instead to public officials who are more accessible and may be more likely to act.

One other conjectural explanation, drawing on the work of David Johnson, [135] focuses on a comparison between the goals of victims of medical error and the goals of prosecutors. Recent scholarship on medical error victims' experiences and goals, [136] and victims' own accounts, [137] indicate that their objectives include compensation, a sincere apology, knowledge of the truth about what happened, sometimes revenge, and the institution of measures to avoid similar injuries in the future.

Prosecutorial objectives in Japan are rather well aligned with those of medical error victims. As Johnson demonstrates, Japanese prosecutorial culture emphasizes establishing the exact facts of each case, taking victims' wishes into **[*222]** account when deciding to dispose of cases, and pursuing defendants' rehabilitation by encouraging remorse. [138] Prosecutors' considerations in the charging decision include whether the victim has received compensation and apology. [139] It is reasonable to assume these prosecutorial priorities are known to the public, at least in a general way. [140] It is not surprising, then, that Japanese medical error victims should turn to prosecutors for assistance.

By contrast, American prosecutors are typically far busier than their Japanese counterparts and generally less exacting about determining the precise facts of each case, particularly with regard to non-violent crimes. [141] They lack the high regard for the importance of remorse and apology that forms part of Japanese prosecutorial culture. [142] They are more remote a source of potential assistance to those suffering from medical error than are private attorneys specializing in personal injury. [143] In short, the prosecutor is less appealing as an ally to injured patients and families in the United States than in Japan.

V. The Health Ministry "Model Project" on Investigation of Medical Accidents

Keenly aware of the criticisms of the extent of the criminal justice system's involvement in the patient safety arena but attempting to work within existing legal and institutional structures, the Ministry of Health, Labor and Welfare launched a "model project" in the autumn of 2005 [144] to try to move the system **[*223]** in a different direction. [145] Four medical specialty societies [146] helped launch the "model project,"viewing it in part as a possible alternative accountability mechanism that could ultimately displace some of the emphasis heretofore placed on criminal prosecutions. The project, initiated in Tokyo, Osaka, Nagoya, and Kobe, will work as follows. [147]

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 undertaken with the agreement of both the patient's family and the hospital. An autopsy would be conducted. (Autopsies have seldom been performed in Japan, largely for cultural reasons, but pathologists and forensic medicine specialists are eager to raise their professional profile, and both the pathology and the forensic medicine specialty societies are participating in the experiment.) Specialists from the relevant medical disciplines will review the patient's chart and interview the attending physician and other hospital personnel. An evaluation board will review the evidence and submit a report on the cause of death and on needed preventive measures both to the hospital and to the family. Then the report, with identifiers redacted, will be made public.

This third-party mechanism will have nothing 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 considerable weight in negotiations between the family and the hospital. Where negligence is inferrable by the facts found by the investigators, given their prestige and standing, it would most likely lead quickly to apologies and formal expressions of remorse by the hospital and physicians, attention to needed preventive measures, and agreement for compensation to the family within standard amounts. The process could therefore serve as a speedy substitute for the civil malpractice action, although it would not 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 the process it envisions takes root in Japan, one of its promising aspects is that it would help bring external peer review into Japanese medicine. It would not be secret peer review; rather, the mechanism **[*224]** would have accountability built into it, by providing the facts and the experts' conclusions to the family, the profession, and the general public.

The aim of the "model project" is to obtain the medical facts and conclusions in much more timely, less expensive, and perhaps more accurate, objective fashion than the civil law malpractice system currently allows. It is an experiment well worth monitoring. If it succeeds, reformers seeking to link patient safety and improvement of the American medicolegal dispute resolution system may find its conclusions instructive.

VI. Conclusion

Both Japan and the United States are coming to realize that reduction of the human toll from medical error is a social objective of the first importance. Leaders in both nations recognize that accurate information on the nature, frequency, and causes of medical errors is essential to any successful quality improvement program. Both nations are grappling with the problem that obtaining accurate information through programs of self-critical analysis in medical facilities may create serious tension between the goals of patient safety and public accountability.

Differences in the two societies' legal structures, however, have forced efforts to resolve this tension into somewhat different trajectories. In the United States, battles over the rules of civil malpractice litigation are fierce, and tort law occupies center stage in the debate. The hospital accreditation process plays a critical role in medical quality control, and peer review is relatively well developed, so a major issue (resolved to some extent by the Patient Safety and Quality Improvement Act of 2005) has been protecting from plaintiffs' attorneys internal hospital information developed for purposes of quality improvement and accreditation requirements. In Japan, although the volume of medical malpractice cases is increasing, malpractice premiums (stabilized by nationwide risk pooling without regard to medical specialty) do not pinch the medical profession to a comparable degree. Pressures on hospitals from civil litigation and from hospital accreditors are much less stringent, and peer review and professional discipline are weak. The debate in Japan focuses to a larger extent on the proper role of the criminal justice

system as a regulator of medical quality.

It is possible that the threat of criminal prosecution and accompanying adverse publicity may undercut sorely needed initiatives within Japanese hospitals to perform self-critical analyses, although statistics demonstrating a recent substantial increase in reporting of medical accidents to police cast some doubt on the extent of this potential patient safety problem. In any case, few would contend that police and prosecutors are ideally suited for the medical quality control role that has been thrust upon them. Nonetheless, democratic societies demand public accountability, and the relative weakness of other social structures **[*225]** regulating medicine in Japan has made the criminal justice system (together with the media) into an accountability mechanism of last resort.

With regard to two important points, however, the involvement of the criminal justice system in the medical error arena offers Japan unqualified benefits. First, it has helped motivate the medical profession to undertake internal system improvements [148] and to cooperate in the health ministry's innovative "model project" for neutral expert investigation of medical accidents. Second, under the criminal law's looming presence, the entrenched practice of systematic deception of patients about medical harm cannot long endure. Whistleblowers within hospitals have uncovered these deceptions, prosecutors are not inclined to tolerate them, criminal sanctions as well as civil damage judgments have ensued, and the media are unforgiving. Thanks in part to the criminal justice system, the practice of medical dishonesty by doctors and hospitals seeking to cover up their mistakes is likely on the wane.

Legal Topics:

For related research and practice materials, see the following legal topics:
Healthcare Law > Business Administration & Organization > Accreditation

Torts > Malpractice & Professional Liability > Attorneys

Torts > Malpractice & Professional Liability > Healthcare Providers

FOOTNOTES:

n1 See, e.g., World Health Organization Executive Board, Quality of Care: Patient Safety, EB 109/9 (2001); Alice L. Bhasale et al., Analyzing Potential Harm in Australian General Practice: An Incident-Monitoring Study, 169 Med. J. Austl. 73 (1998) (the "Quality in Australian Health Care Study"); R. Q. Lewis & M. Fletcher, Implementing a National Strategy for Patient Safety: Lessons from the National Health Service in England, 14 Quality & Safety in Health Care 135 (2005); Charles Vincent et al., Adverse Events in British Hospitals: Preliminary Retrospective Record Review, 322 BMJ 517 (2001); Dept. of Health (U.K.), An Organisation with a Memory (2000); Gesundheitsministerkonferenz, Ziele f r eine einheitlichen Qualit tsstrategie im Gesundheitswesen [Health Minister's Conference, Goal for a Unified Quality Strategy in the Health C a r e S y s t e m] , (1 9 9 9) , www.gesetzeskunde.de/Rechtsalmanach/Gesundheitswesen/ gesundheitsministerkonferenz.htm (last visited March 23, 2005) (Germany); Emmy M. Sluijs & Cordula Wagner, Kwaliteitssystemen in zorginstellingen: De stand van zaken in 2000 [Quality systems in health care institutions: The state of affairs in 2000] (2000) (Netherlands); Synn ve deg rd, S kerheten i v rden b r fokusera p prevention. L r av flyget, k rkraftsverken och offshoreindustrin [Prevention Should Be the Focus of Measures in Health Care: Lessons To Be Learned from the Aviation, Nuclear Energy, and Offshore Oil Industries], L kartidningen 3068 (1999) (Sweden).

n2 See infra notes 45-48 and accompanying text, and Figure 1.

n3 See John Creighton Campbell & Naoki Ikegami, The Art of Balance in Health Policy: Maintaining Japan's Low-Cost, Egalitarian System 187-190 (1998); Robert B Leflar, Informed Consent and Patients' Rights in Japan, 33 Hous. L. Rev. 1, 9-10 (1996).

n4 Campbell & Ikegami, supra note 3, at 188 (noting that "few hospitals have quality assurance programs" and that "[c]onducting peer reviews is usually technically not possible because the state of medical records is so poor that they may be incomprehensible even to the writer.").

n5 Interview with officials in the Ministry of Health, Labor, and Welfare's patient safety office, Tokyo (Aug. 6, 2004) [hereinafter MHLW Aug. 2004 Interview]. These officials noted that the Medical Ethics Council, which operates under health ministry auspices, embarked on a new policy in late 2002 whereby serious malpractice could be the basis of an administrative sanction. However, information about incidents of malpractice is hard to come by. The ministry's patient safety office is staffed with only eight people, who have a multiplicity of other tasks besides investigating malpractice incidents. Moreover, unlike the police, health ministry officials lack subpoena power, and some hospital administrators have refused their requests for documents. Id.

n6 See, e.g., Masahiro Hirose et al., How Can We Improve the Quality of Health Care in Japan? Learning from JCQHC Hospital Accreditation, 66 Health Pol'y. 29, 39-40 (2003) (577 of 9,286 hospitals accredited as of late 2001; authors suggest linking accreditation to reimbursement). The number of accredited hospitals has increased to 1,794 as of Oct. 17, 2005. Nihon iry hy ka kik [JCQHC], Nintei by in ichiran [List of Accredited Hospitals], available at http://jcqhc.or.jp/html/ listindex.htm (last visited Dec. 1, 2005).

n7 JCQHC surveyors, unlike their JCAHO counterparts, do not check whether hospitals carry out self-critical analyses of adverse events. Interview with Hisashi michi, director, JCQHC, Tokyo (July 31, 2003) [hereinafter michi Interview].

n8 The account given here was compiled from interviews with government sources, attorneys, and physicians, and from the following news stories: "By in ni ki na kekkan": 3 ishi taiho de inch ra ga kaiken ["Major Problems at This Hospital," Director Says of Arrest of 3 Doctors], Yomiuri Shimbun, Sept. 25, 2003; Three Urologists Held over Patient's Death; Inexperienced Doctors Read from Manual While Performing Surgery, Japan Times, Sept. 26, 2003; Taiho no Jikei idai by in 3-ishi, Rinri-i no sh nin torazu shujutsu [3 Jikei Medical U. Docs Arrested; Operated Without Ethics Committee OK], Yomiuri Shimbun, Sept. 26, 2003; 3-nin dake no shitt de oshikiru- Jikei-kai by in no jiken [Jikei Hospital Case: Surgeons Insisted on Team of Only 3], Yomiuri Shimbun, Sept. 27, 2003; Jikei idai by in no shujutsu bideo nin'i teishutsu, ishi no b s kaimei e [Jikei Hospital Turns Over Surgery Video; Will It Explain Docs' Surgical Joyride?] Yomiuri Shimbun, Sept. 28, 2003; Jikei idai by in no shujutsu misu, 2 hikoku to moto shinry buch o ch kai kaiko [Jikei Medical U. Hospital Surgical Error: 2 Defendants and Ex-Supervisor Sacked], Yomiuri Shimbun, Dec. 26, 2003; Jikei Medical School Fires Three Doctors Standing Trial for Malpractice Death, Japan Times, Dec. 27, 2003; Moto Jikei idai Aoto by in 2-ishi ni gy mu teishi 2- nen: Id - shin [Medical Ethics Board Gives 2 Former Aoto Hospital Docs 2-year License Suspensions], Yomiuri Shimbun, Mar. 17, 2004; Panel Floats Suspension for Surgeons, Japan Times, Mar. 18, 2004; Jikei idai Aoto by in jiken [Jikei Medical U. Aoto Hospital Case], Yomiuri Shimbun, June 18, 2005.

n9 For excellent portrayals of the morbidity and mortality conference, a focal point of the hospital peer review process, and its relation to the enterprise of medical quality control, see Atul Gawande, Complications: A Surgeon's Notes on an Imperfect Science 57-64 (2002); Charles L. Bosk, Forgive and Remember: Managing Medical Failure 114-16, 127-46, 242-43 (2d ed. 2003) (describing conferences of an earlier era, aspects of which persist today). See also Robert M. Wachter & Kaveh G. Shojania, Internal Bleeding: The Truth Behind America's Terrifying Epidemic of Medical Mistakes 276-81 (2004) (quoting and commenting on Gawande's and Bosk's portrayals).

n10 The JCAHO Sentinel Events Database receives only about 500 reports annually, a tiny proportion of the likely actual number of serious adverse events in hospitals. JCAHO Sentinel Event Trends: Total Sentinel Events Reported by Year, http://www.jcaho.org/accredited+organizations/ambulatory+care/sentinel+events/set+all+reviewed+events.htm (last visited Nov. 11, 2005). See also JCAHO, Health care at the Crossroads: Strategies for Improving the Medical Liability System and Preventing Patient Injury 12 (2005), available at http://www.jcaho.org/news+room/press+kits/tort+reform/medical liability.pdf.

n11 See Paul C. Weiler, Medical Malpractice on Trial 13 (1991) (summarizing HMPS finding of only one tort payment for every three potential tort claims involving the most serious or costly injuries); Paul C. Weiler et al., A Measure of Malpractice: Medical Injury, Malpractice Litigation, and Patient Compensation 70 (1993) (describing HMPS finding of one tort claim for every 7.6 negligently caused injuries). Factors suppressing the filing of malpractice actions when negligence is present include the lack of information available to injured patients and their families concerning the facts regarding patient care; potential plaintiffs' disinclination to undergo the rigors of obtaining and cooperating with legal counsel in the preparation and trial of a lawsuit; and the practical difficulties to plaintiff's attorneys of obtaining and marshaling proof of negligence and causation of injury in a cost-effective manner.

n12 The hospital may have offered compensation to the family on a private, informal basis; we are unaware whether that is the case.

n13 The youngest of the three urologists, who acted only as a surgical assistant, pleaded innocent. The hospital suspended him from work for ten days. As of this writing his criminal trial continues.

n14 See supra note 8.

n15 Hideki Komatsu, Jikei Idai Aoto By in jiken: Iry no k z to jissenteki rinri [Practical Ethics and the Structure of Health Care: The Jikei Medical U. Aoto Hospital Case] (2004).

n16 This phenomenon has received sporadic international attention. See, e.g., Yumiko Ono, In Japan, a Doctor Shakes Up Medicine in Malpractice Case, Wall St. J., June 10, 2002, at A1 (physician's negligence action against hospital in which her daughter died).

n17 A heart patient had part of his lung removed, and a lung patient with a similar name had part of his heart valve excised. The mistake was not discovered until the evening after the operations. Three doctors and two nurses were found criminally liable for professional negligence. 1087 Hanrei Taimuzu 296 (Yokohama Dist. Ct., Sept. 20, 2001). See Court Fines Medical Staff for Heart, Lung Mixup, Japan Times, Sept. 21, 2001.

n18 A patient died after a nurse injected her with what the nurse believed to be a heparin solution. In fact the syringe contained a disinfectant, and had been left on the cart by another nurse. The two nurses were convicted of the crime of professional negligence causing death or injury. The hospital director was convicted of forging a death certificate containing a false cause of death, and of failing to report the case to police. 1771 Hanrei Jih 156 (Tokyo Dist. Ct., Aug. 30, 2001); see also Coverup of Patient's Death Gets Director Suspended Term, Japan Times, Aug. 31, 2001; Nurses Get Suspended Sentences in Hiroo Malpractice Case, Japan Times, Dec. 28, 2000. The Supreme Court affirmed the hospital director's conviction. 58(4) Keish 247 (Sup. Ct. April 13, 2004) (Hiroo Hospital case).

n19 Improper operation of a heart-lung machine by one doctor during heart surgery led to a decreased blood flow to the brain of the twelve-year-old patient, who later died. Another doctor, who was in charge of the surgery, falsified data on the patient's chart in a coverup attempt. Two Doctors Arrested in Malpractice Death, Int'l Herald Tribune/Asahi Shimbun, June 29, 2002, at 1. The first doctor was arrested and indicted for professional negligence causing death, the second for destruction of evidence. 2 Doctors Indicted for Girl's Death, Int'l Herald Tribune/Asahi Shimbun, July 20-21, 2002, at 22. The hospital was stripped of its prestigious and remunerative status as a tokutei kin by in (an administrative category of advanced-level hospitals). An external investigative committee later found that one of the doctors had not "acquired the basic knowledge required for heart surgery," and that three other patients had died after he had operated on them. Masahiro Umemura & Atsuko Kinoshita, Hospital's System Slammed; Surgeon's Lack of Training, Supervision Possible Causes of Deaths, Daily Yomiuri, Apr. 8, 2005, at 3. However, he was recently acquitted on the professional negligence charge. Doctor Acquitted in Girl's Death, Int'l Herald Tribune/Asahi Shimbun, Dec. 1, 2005, at 28.

n20 We base this assertion on extensive conversations with physicians (among them former hospital administrators), health ministry officials, and attorneys representing both plaintiffs and medical providers. Among the recurrent reasons offered in these conversations is the fact that reputational damage to the medical provider can often be largely or completely avoided in the case of civil law compensation claims, by means of confidential private settlements. By contrast, in the case of media reports and official acts by police and prosecutors (which become matters of public record and typically are pounced upon by the media), reputational damage is inevitable. We do not mean to minimize reputational concerns among hospitals in the United States. As patient safety specialists Robert Wachter and Kaveh Shojania have noted with reference to North American medical providers, "fear of media exposure runs neck-and-neck with fear of lawsuits in reasons for 'failure to disclose' by caregivers and hospitals." Wachter & Shojania, supra note 9, at 266. See generally William M. Sage, Reputation, Malpractice Liability, and Medical Error, in Accountability: Patient Safety and Policy Reform 159-83 (Virginia A. Sharpe ed., 2004). Our claims are rather that civil liability occupies a relatively less prominent position in Japan than in the United States, and that criminal liability plays a more important role in the Japanese system than in the North American systems.

n21 Cal. Med. Ass'n & Cal. Hosp. Ass'n, Report on the Medical Insurance Feasibility Study (Don H. Mills ed., 1977); Troyen A. Brennan et al., Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I, 324 New Eng. J. Med. 370 (1991); Eric J. Thomas et al., Incidence and Types of Adverse Events and Negligent Care in Utah and Colorado, 38 Med. Care 261 (2000).

n22 Institute of Medicine, To Err Is Human: Building a Safer Health System (2000) [hereinafter To Err Is Human].

n23 Tom Baker reminds us of this instructive point in an excellent treatment of the relationship between liability insurance cycles and political pressure for tort reform. Tom Baker, Medical Malpractice and the Insurance Underwriting Cycle, 54 DePaul L. Rev. 393, 433-34 (2005).

n24 Media exposes, in particular the Boston Globe's 1995 account of the death of one of its columnists at the Dana Farber Cancer Institute due to medication mistakes, drew attention to the scientific evidence of the widespread incidence of medical error and helped spark the national debate over the issue. See Michael L. Millenson, Moral Hazard vs. Real Hazard: Quality of Care Post-Arrow, 26 J. Health Pol. Pol'y & L. 1069, 1074 (2001).

n25 There have been a few studies of error within particular medical disciplines. See, e.g., Ken Nagaya et al., Causes of Maternal Mortality in Japan, 283 JAMA 2661 (2000) (finding an association between maternal mortality and "[i]nadequate obstetric and anesthetic services and laboratory facilities"); Y. Kawashima et al., Annual Study of Perioperative Mortality and Morbidity for the Year of 1999 in Japan: The Outlines-Report of the Japan Society of Anesthesiologists Committee on Operating Room Safety, 50 Jap. J. Anesthes. 1260 (2001) (in Japanese with English abstract). A health ministry official explained, perhaps somewhat disingenuously, why no quantitative studies of the overall incidence of medical error have been undertaken in Japan: "It's impossible. Our medical records are too bad." Interview with Tetsuya Fujimori, M.D., Deputy Director, MHLW General Affairs Division, Health Policy Bureau, Tokyo (Apr. 12, 2001). Since that time, the health ministry has begun a pilot study, led by Dr. Hideto Sakai, to estimate the extent of medical accidents at a group of larger hospitals. Preliminary results as of early 2005 estimated that 6.4% of hospitalizations resulted in some kind of injury. MHLW, Iry jiko no zenkokuteki hassei hindo ni kansuru kenky [The Nationwide Frequency of Medical Accidents], summarized at http://web.kyoto- inet.or.jp/org/khoken-i/syukan/pages/2005/03/sf00003 3.html. This is a rate not incommensurate with North American findings, although methodological differences make direct comparisons problematic.

n26 On the role of the Japanese media in creating the climate of public opinion as well as reporting on it, see Ellis S. Krauss, Japan: News and Politics in a Media-Saturated Democracy, in Democracy and the Media: A Comparative Perspective 266, 274-77 (Richard Gunther & Anthony Mughan eds., 2000); John C. Campbell, The Media and Policy Change in Japan, in Media and Politics in Japan (Susan J. Pharr & Ellis S. Krauss eds., 1996); Ofer Feldman, Politics and the News Media in Japan 17, 22-25 (1993).

n27 See supra note 17.

n28 Gy sei kikan no hoy -suru j h no k kai ni kansuru h ritsu [Law Concerning Access to Information Held by Administrative Organs], Law No. 102 of 1999.

n29 See generally Leflar, supra note 3 (explaining development of informed consent doctrine and its expansion in medical practice); Robert B Leflar, Nihon no iry to h : Inf mudo konsento runessansu [Law and Health Care in Japan: The Renaissance of Informed Consent] 125-46 (2002) (Michiyuki Nagasawa, trans.) (setting out informed consent developments from 1996 to 2001).

n30 E.g., "Erabareru by in" no jidai [The Era of Hospital Choice], Aera, Nov. 4, 2002, at 34-39; Daich gan shuy 103 by in: "Shujutsu jisseki" wa konna ni chigau [Vast Differences in Colon Cancer Surgery Results at 103 Leading Hospitals], Sunday Mainichi, July 28, 2002, at 44-49; Kanja ya chiiki ni hirakareta by in: J h k kai de shinrai kankei j sei e [Accountable Hospitals: Building Trust with Patients and Community Through Information Disclosure], Nikkei Business, Aug. 20, 2001, at 118-19.

n31 Best's Aggregates and Averages, Property-Casualty 78 (2003). The figure includes all insurance claims files opened, whether the claims were filed in the judicial system or not.

n32 Annual statistics on claims filed in court are published by the Supreme Court of Japan's Administrative Office. They are available at http://courtdomino2.courts.go.jp/shanyou.nsf/0258b7a1680aa82849256467004875a6/c8cb38bc9660a65049257013000a1ed2 (2005) OpenDocument, and in hard copy in Yutaka Tejima, Ijih Ny mon [A Primer on Medical Law] 137 (2005). In 1997, 597 medical injury claims were filed in court.

n33 See Kazue Nakajima et al., Medical Malpractice and Legal Resolution Systems in Japan, 285 JAMA 1632, 1633, 1638 (2001). These statistics represent claims filed with the nationwide nonjudicial dispute resolution system under the auspices of the Japan Medical Association liability insurance program, which covers forty-three percent of Japanese physicians, and with its second largest local chapter. Claims filed with the JMA - 321 in 1997 - encompassed the larger claims (1 million or more). Those filed with the local chapter - 171 in 1997 - represented the smaller claims. Id. at 1634, 1637-38. It would be incorrect to take the number of lawsuits plus the number of JMA and local Osaka claims as anything more than a minimum estimate of the number of medical malpractice claims in Japan as a whole. About eight percent of the claims filed in the JMA system are also filed in court. See id. at 1635; the Osaka claims represent only a fraction, albeit a substantial one, of all the small claims filed with local medical associations; other nonjudicial dispute resolution systems exist outside the medical associations; some other medical injury claims are filed only with the special compensation system for drug-related adverse events; and an unknown number of other potential claims are settled by other informal means. See infra note 35. Ramseyer and Nakazato, relying on earlier data but using a method similar to that employed here, estimated ranges for malpractice claims of about 800 to 3,700 for Japan and 70,000 to 110,000 for the United States. J. Mark Ramseyer & Minoru Nakazato, Japanese Law: An Economic Approach 69 (1999).

n34 Census figures put the U.S. population in 2000 at about 281 million. U.S. Census Bureau, Profile of General Demographic Characteristics: 2000 (2000), available at http://factfinder.census.gov/home/en/datanotes/expsf1u.html. Japan's population in 2001 was about 127 million. Statistics Bureau, Ministry of Internal Affairs and Communications (Japan), Annual Report on Current Population Estimates as of Oct. 1, 2004, available at http://web-japan.org/stat/stats/01CEN21.html. (last visited Feb. 7, 2006).

n35 Given the census figures in supra note 34, the Best estimate of U.S. claims, Best, supra note 31 and accompanying text, yields a U.S. claims rate per 100,000 population of roughly forty. A simple summing of Japanese court filings, JMA and Osaka Medical Association claims yields a Japanese claims rate per 100,000 population of roughly 0.9 - a "minimum estimate" for the denominator of the United States/Japan ratio for the reasons given in supra note 33. So the forty-to-0.9 ratio should be considered an "upper bound" estimate. The "lower bound" estimate of this ratio remains obscure. One should revise the ratio's denominator upward to reflect the small claims filed with medical associations in the other 46 prefectures. One might simply extrapolate from Osaka figures to arrive at a national estimate for these claims. But Osaka, with its well-developed plaintiff-side medical malpractice bar, probably has a higher-than-average medical injury litigation rate. See Ramseyer & Nakazato, supra note 33, at 68-69 (indicating substantially higher claims rates for Osaka than for two other nearby urban prefectures, Hyogo and Kyoto). So, such an extrapolation would be problematic. The denominator should also be revised upward to reflect claims settled by informal mechanisms, paid by liability insurers or from medical providers' personal resources, and not captured by any database available to the authors. The number and amounts of such payments by liability insurers is held in strict confidence, and payments by individual providers are impossible to enumerate. Well-informed defense attorneys have suggested to one of the authors that the number of payments by liability insurers might well be characterized as "the sunken part of the iceberg" - perhaps eight or ten times the number of claims recorded in the judicial system. Interview with Tatsuo Kuroyanagi and Yasushi Kodama, Naha, Okinawa, Feb. 25, 2006.

n36 Shigemi Oshida, Yasushi Kodama & Toshihiro Suzuki, Jitsurei ni manabu iry jiko [A Real-World View of Medical Accident Cases] 20-21 (2002).

n37 Osaka bengoshikai k ts jiko iinkai [Osaka Bar Ass'n Traffic Accident Comm.], K ts jiko songai baish gaku santei no shiori [Guide to Calculating Traffic Accident Damages] 11 (2005) [hereinafter Traffic Accident Damages Guide]. Pain- and-suffering damages (ishary) in death cases include awards to surviving family members for their grief, and may be adjusted up or down for unusual circumstances. Id.

n38 Oshida, Kodama & Suzuki, supra note 36, at 21; Traffic Accident Damages Guide, supra note 37, at 10-11 (2005); Interview with Prof. Hisanaga Kuroki, Osaka University, (Nov. 27, 2005) (forty percent typically subtracted for living expenses). For a table computing typical net lost earnings awards by age and sex, ranging from 21-48 million (US $ 190,000-$ 440,000) for males and 11-27 million (US $ 100,000-$ 250,000) for females, see Ramseyer & Nakazato, supra note 33, at 90, Table 4.1.

n39 Ramseyer & Nakazato, supra note 33, at 89 n.53.

n40 Neil Vidmar and colleagues, in their study of Florida medical malpractice awards from 1990 to 2003, found that for 5,552 death claims paid, the median payment per claim was $ 194,835 and the mean payment per claim was $ 289,675. Neil Vidmar et al., Uncovering the "Invisible" Profile of Medical Malpractice Litigation: Insights from Florida, 54 DePaul L. Rev. 315, 340 Table 7 (2005). These amounts are not incommensurate with, and may well be lower than, the sum of pain-and-suffering, lost earnings, and funeral expenses available under the Japanese damages scale. See supra notes 37-38 and accompanying text.

n41 See Baker, supra note 23, at 402-06 & Figure 2. As Baker explains, however, the existence of the underwriting cycle, together with the long liability tail characteristic of medical malpractice insurance and various other behavioral and institutional factors, make the relationship between premiums and payouts quite imprecise.

n42 Nakajima, supra note 33, at 1633, Table 1. The amount of the annual premium increased to 70,000 (US $ 640) in 2003. See infra note 52.

n43 Nakajima, supra note 33, at 1633, Table 1.

n44 See U.S. Dept. of Health & Human Servs., Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs by Fixing Our Medical Liability System 1 6 , T a b l e 6 (2 0 0 2) , a v a i l a b l e a t http://aspe.hhs.gov/daltcp/reports/litrefm.pdf.

n45 See Tatsuo Kuroyanagi, Iry jiko to shih handan [Medical Accidents and Judicial Decisions] 3, Table 1 (2002) (showing a 129% increase in medical malpractice case filings from 1990-2001 vs. a forty-six percent increase over the same period for civil cases generally); Tatsuo Kuroyanagi, Iry jiko sosh no shori ni tsuite [The Management of Medical Accident Litigation], 130 H no shihai 5, 12, Figure 1 (2003) (same). For discussions of the increase in civil litigation in Japan as a general matter, see Tom Ginsburg & Glenn Hoetker, The Unreluctant Litigant? An Empirical Analysis of Japan's Turn to Litigation (2004), available at http://law.bepress.com/cgi/viewcontent.cgi? article=10138context=uiuclwps; John O. Haley, Litigation in Japan: A New Look at Old Problems, 10 Willamette J. Int'l L. & Disp. Resol. 121, 134-38 (2002).

n46 Informal plaintiff-side medical malpractice groups (iry bengodan) in most major metropolitan areas are backed by specialized resource centers such as Iry jiko ch sadan (Medical Accident Research Group) and Iry jiko j h sentaa (Medical Accident Information Center). They have collected and published expert opinion testimony in a wide variety of cases, together with lists of medical experts willing to testify for plaintiffs, and made these available to attorneys nationwide. E.g., Iry jiko j h sentaa, Iry kago sosh kanteishosh dai-13-sh [Collection of Expert Witness Reports in Medical Malpractice Litigation No. 13] (2002). A measure of the expansion of the plaintiffs' malpractice bar is the number of full members of Iry jiko j h sentaa, most of whom are attorneys devoting at least a significant part of their practice to medical cases. The number has increased from 111 in 1990 to 451 in 2000, Iry jiko j h sentaa, Iry higaisha no ky sai o mezashite [Striving for Compensation for Medical Victims] 7, Table 4 (2000), and to about 600 as of August 2005. Personal communication with attorney Yoshio Kat (Sept. 11, 2005). (This number is still orders of magnitude smaller than the number of plaintiff-side malpractice specialists in the United States.)

n47 See generally Sage, supra note 20, at 159-183.

n48 See Campbell & Ikegami, supra note 3, at 182.

n49 Mark Geistfeld, Malpractice Insurance and the (Il)legitimate Interests of the Medical Profession in Tort Reform, 54 DePaul L. Rev. 439, 446-52 (2005); William M. Sage, Medical Malpractice Insurance and the Emperor's Clothes, 54 DePaul L. Rev. 463, 472-75 (2005).

n50 Sage, supra note 49, at 473.

n51 Nakajima et al., supra note 33, at 1633.

n52 Ishi-muke baiseki hoken, 139-oku-en no akaji; Sosh z ka nado gen'in [Doctors' Liability Insurance Program 139 Billion (US $ 125 Million) in the Red; Rise in Lawsuits Seen as Cause], Asahi shimbun, May 26, 2004, at 1.

n53 See, e.g., David Blumenthal, Making Medical Errors into "Medical Treasures", 272 JAMA 1867 (1994); Lucian L. Leape, Error in Medicine, 272 JAMA 1851 (1994); Lucian L. Leape et al., Promoting Patient Safety by Preventing Medical Error, 280 JAMA 1444 (1998).

n54 To Err Is Human, supra note 22, at 86-108.

n55 JCAHO, Hospital Accreditation Standards, 200; JCAHO Sentinel Event Policies and Procedures (2005), http://www.jcaho.org/accredited+organizations/sentinel+event/se p p.htm.

n56 Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement, 68 Fed. Reg. 3435 (Jan. 24, 2003) (codified at 42 C.F.R. § 482.21).

n57 Troyan Brennan, co-author of the Harvard Medical Practice Study, has argued, "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." Troyen A. Brennan, The Institute of Medicine Report on Medical Errors - Could It Do Harm? 342 New Eng. J. Med. 1123, 1125 (2000). See also, e.g., To Err Is Human, supra note 22, at 22, 43; Bryan A. Liang, Risks of Reporting Sentinel Events, Health Aff., Sept.-Oct. 2000, at 112.

n58 See David A. Hyman & Charles Silver, The Poor State of Health Care Quality in the U.S.: Is Malpractice Liability Part of the Problem or Part of the Solution? 90 Cornell L. Rev. 893, 914-17 (2005) (arguing that "[n]o study has shown that exposure to liability has a statistically significant negative effect on the frequency of error reports"); Lucian L. Leape, Reporting of Adverse Events, 347 New Eng. J. Med. 1633, 1635 (2002) ("No link between [error] reporting and litigation has ever been demonstrated.").

n59 See generally Donald P. Vandegrift, Jr., The Privilege of Self-Critical Analysis: A Survey of the Law, 60 Alb. L. Rev. 171 (1996); Daniel Mulholland, Unanticipated Consequences of Unanticipated Outcomes Disclosures, 35 J. Health L. 211, 214- 19 (2002) (surveying statutes and case law as applied to hospital reports to JCAHO).

n60 For example, there is sometimes a grey area between original medical records and factual "incident reports," both of which are typically discoverable and admissible in evidence, and evaluative or deliberative documents protected by the peer review privilege. This leads hospital attorneys to counsel devising incident report forms so as to provide only minimal information, devoid of evaluative content, and thereby potentially less useful for patient safety-oriented analysis.

n61 See, e.g., To Err Is Human, supra note 22, at 120- 21; Susan O. Scheutzow, State Medical Peer Review: High Cost But No Benefit - Is It Time for a Change? 25 Am. J. L. & Med. 22, 28 (1999); Melissa Chiang, Promoting Patient Safety: Creating a Workable Reporting System, 18 Yale J. on Reg. 383, 400-01 (2001).

n62 E.g., Syposs v. United States, 63 F. Supp. 2d 301 (W.D.N.Y. 1999); LeMasters v. Christ Hosp., 791 F. Supp. 188 (S.D. Ohio 1991). Contra, Weekoty v. United States, 30 F. Supp. 2d 1343 (D.N.M. 1998). In Veterans Administration hospitals, a specific federal statute exempts peer review and quality assurance documents from discovery. To Err Is Human, supra note 22, at 123.

n63 The House of Representatives passed H.R. 5, the controversial bill according various protections to medical providers and medical product suppliers, the day before President Bush signed the Patient Safety and Quality Improvement Act. Health Care - Damages: House Approves Medical Malpractice Bill with $ 250,000 Noneconomic Damages Cap, 74 U.S.L.W. 2059 (2005).

n64 Patient Safety and Quality Improvement Act of 2005, Pub. L. No. 109-41, 119 Stat. 424.

n65 See, e.g., John D. Blum, Combating Those Ugly Medical Errors-It's Time for a Hospital Regulatory Makeover!, 12 Widener L. Rev. 53, 65 (2005); Bryan A. Liang, Collaborating on Patient Safety: Legal Concerns and Policy Requirements, 12 Widener L. Rev. 83, 90 (2005).

n66 Some commentators have disparaged the likely effectiveness of the Patient Safety and Quality Improvement Act in developing useful information, citing a lack of sufficient proposed appropriations to fund the Act's adverse events analysis efforts and a lack of incentives for medical personnel to report errors to Patient Safety Organizations. E.g., Hyman & Silver, supra note 58, at 988.

n67 See michi Interview, supra note 7.

n68 Kokuritsu daigaku igakubu fuzoku by inch kaigi j chi iinkai [Nat'l U. Hosp. Presidents' Conf.], Iry jiko b shi no tame no anzen kanri taisei no kakuritsu ni tsuite - ch kan h koku [Interim Report: Establishing Safety Management Systems for the Prevention of Medical Accidents] (2000).

n69 E.g., MHLW, Risuku maneijimento manyuaru sakusei shishin [Guidelines for the Creation of Risk Management Manuals] (2000).

n70 See supra notes 17-18 and accompanying text.

n71 See, e.g. Takashi Yokota et al., Will Accident Reports Filed in Hospitals in Japan Be Used in the Future as Evidence in Malpractice Lawsuits? 19 Am. J. Emergency Med. 597 (2001).

n72 Gy sei kikan no hoy -suru j h no k kai ni kansuru h ritsu [Law Concerning Access to Information Held by Administrative Organs], Law No. 102 of 1999, art. 5(1).

n73 J h k kai shingikai [Information Disclosure Review Board], Opinion of Jan. 9, 2002, at 13-14. See Kokuritsu by in no iry jiko, "Tant i nado kaiji o": J h k kai-shin ga hatsukijun ["Disclose Physicians' Names" in National Hospital Medical Accidents: Information Board Sets Standards], Asahi shimbun, Jan. 9, 2002, at 1.

n74 Interview with Prof. Katsuya Uga, University of Tokyo Faculty of Law (Aug. 7, 2003).

n75 The MHLW official in charge of patient safety efforts stated subsequently, however, that he believed the possibility of disclosure of hospital documents under freedom of information rules had not decreased the number of incident reports submitted to MHLW by public hospitals. Interview with Kazuhiro Araki, Tokyo (July 29, 2003) [hereinafter Araki Interview].

n76 The new discovery provisions came into effect in 1998. Analyses useful to English-language readers include Shozo Ota, Reform of Civil Procedure in Japan, 49 Am. J. Comp. L. 561 (2001), and Toshiro M. Mochizuki, Baby Step or Giant Leap? Parties' Expanded Access to Documentary Evidence under the New Japanese Code of Civil Procedure, 40 Harv. Int'l L.J. 285, 299- 309 (1999).

n77 53(8) Minsh 1787 (Sup. Ct., Nov. 12, 1999) (holding that certain bank documents are for internal use and not subject to discovery) (Fuji Bank case). For a discussion of the "internal use" exception, written before the Supreme Court's decision, see Mochizuki, supra note 76, at 301-07.

n78 1842 Hanrei jih 57, 1145 Hanrei taimuzu 298 (Tokyo High Ct., July 15, 2003) (Saitama Medical U. case).

n79 Id.

n80 The new Patient Safety and Quality Improvement Act should not significantly change the current operation of state- law discovery procedures in this respect. See supra notes 64-65 and accompanying text.

n81 See infra notes 88-90 and accompanying text.

n82 Among the major issues debated are whether reporting systems should be mandatory or voluntary; whether their target should be accidents involving (serious) harm, "near misses," or both; to what entity the reports should be made; whether information based on the reports should be released to the public; and if so, in how specific a form. The Institute of Medicine report favored a combination of separate mandatory and voluntary reporting systems. To Err Is Human, supra note 22, at 86-108. Twenty-one states (as of 2003) had mandatory reporting systems for hospitals, though details varied. Joel S. Weissman et al., Error Reporting and Disclosure Systems: Views from Hospital Leaders, 293 JAMA 1359, 1360 (2005). The reporting system to be set up under the new Patient Safety and Quality Improvement Act, Pub. L. No. 109-41, 119 Stat. 424, supra note 64, is structured on a voluntary basis.

n83 Reporting of medical mistakes can serve a variety of social purposes, including (1) detection of systemic problems with a view to formulating corrective policies, (2) informing the general public about the performance of health care facilities and personnel, (3) providing a basis for employers and health insurers to select for their patronage facilities with better records, and (4) creating incentives for better performance among medical personnel, to avoid the embarrassment and bother of having to submit reports. See Weissman et al., supra note 82, at 1359-60; To Err Is Human, supra note 22, at 86-108. Assessments of which purposes are most highly valued, and of the likelihood of compliance, inform the design of the reporting systems.

n84 The ministry later established similar internal reporting system requirements for general hospitals as well. MHLW Sh rei [Ministerial Ordinance] No. 111 (2002), available at http://www.mhlw.go.jp/topics/2001/0110/tp1030-1.html#2-1 (MHLW website on medical safety measures).

n85 An implicit admission of the inadequacy of the original coding system is found in a 2003 report by the official in charge of MHLW's patient safety office, setting out the ministry's activities and plans in the field. See Kazuhiro Araki, Iry anzen sulshin s g taisaku ni tsuite [General Measures for the Promotion of Medical Safety], 18 Iji h gaku [J. Med. L.] 60, 65 (2003) (noting revisions in coding system).

n86 For example, Kitasato University Hospital conscientiously reported about 3,000 incidents - a fifth of the total reported nationwide. By contrast, neither Asahikawa Medical College Hospital nor Hamamatsu University Hospital reported a single incident. Medical Accident Tally at 15,000, International Herald Tribune/Asahi Shimbun, Apr. 24, 2002. Kitasato University Hospital is said to have suffered a decrease in patient census when the story came out.

n87 Araki Interview, supra note 75.

n88 MHLW, Iry ni kakaru jiko jirei j h no toriatsukai ni kansuru kent -bukai h kokusho [Report of the Subcommittee for the Study of the Handling of Information on Medical Accident E v e n t s] (2 0 0 3) , a v a i l a b l e a t http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/index.html (MHLW website on medical safety measures) (last visited Nov. 22, 2005).

n89 MHLW, Iry jiko j h sh sh -t jigy [Medical Accident Information Collection Project], available at http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/jiko/index.html (last visited Feb. 22, 2006).

n90 This function is performed by the Japan Council for Quality Health Care (Nihon iry kin hy ka kik , see supra notes 6-7 and accompanying text).

n91 Interview with Yasushi Kodama, an attorney/physician who has served on MHLW advisory committees on patient safety (Aug. 1, 2003). In fact, initial compliance with the reporting requirement has been low. In the first nine months of the system's operation, only 889 reports of medically related harm, including 108 reports of deaths, were submitted. 125 of the 275 reporting facilities submitted scarcely credible reports stating "zero accidents." Moreover, forty percent of the reports of deaths contained no usable information, rendering the reports unhelpful for safety improvement purposes. Iry shib jiko 9- kagetsu de 108-ken [Fatal Medical Accidents: 108 in 9 Months], Nihon keizai shimbun, July 29, 2005. Of course, underreporting is expectable when any new reporting system is set up. Nor is Japan unique with respect to underreporting of medical accidents. See, e.g., Richard Perez-Pena, Audit Finds Hospitals Failed to Report Hundreds of Mistakes, N.Y. Times, Sept. 29, 2004, at A23; Hospital Infections 'Seriously Underreported,' JCAHO Says, Announcing New Advisory Panel, 11 BNA's Health Care Pol'y Rep. 132 (2003).

n92 See supra notes 76-80 and accompanying text.

n93 It is possible, however, that courts might develop and apply some other basis for an exception to the general disclosure principle, for example in the nature of a privilege to protect medical personnel's privacy or to encourage self-critical analysis.

n94 See Ota, supra note 76, at 569-70; Mochizuki, supra note 76, at 286-294.

n95 See supra note 17.

n96 Yokohama shiritsu daigaku by in kaikaku iinkai [Yokohama City U. Hospital Reform Comm.], Iry jiko no k hy kijun [Standards for Public Disclosure of Medical Accidents] (2001) (on file with the authors). The policy, adopted at the instigation of city government, requires patients' or

families' consent before public disclosure, to protect their privacy. Incidents not involving harm to patients, in principle, are not to be disclosed. Some private hospitals not subject to information disclosure ordinances have adopted similar policies, despite extensive media coverage about medical error. Interview with Dr. Isao Mori, President, Ishinkai Yao General Hospital, Osaka (July 8, 2001) (describing hospital policies).

n97 Kokuritsu daigaku by in f ramu [National University Hospitals Forum], Iry -j no jiko-t no k hy shishin sakutei: Anzensei k j to t meisei kakuho e [Policy on Disclosure of Medical Accidents: Improving Safety and Securing Transparency] (2005), available at http://nuh-forum.umin.jp/topnews/ index.htm.

n98 See Thomas H. Gallagher & Wendy Levinson, Disclosing Harmful Medical Errors to Patients: A Time for Professional Action, 165 Archives Internal Med. 1819 (2005); Kathleen M. Mazor et al., Communicating with Patients About Medical Errors: A Review of the Literature, 164 Archives Internal Med. 1690 (2004); Rae M. Lamb et al., Hospital Disclosure Practices: Results of a National Survey, Health Aff., March/April 2003, at 73.

n99 American Med. Ass'n, Current Opinions of the Council on Ethical and Judicial Affairs E-8.12, "Patient Information" (1994), available at http://www.ama-assn.org/ama /pub/category/8497.html. See also National Patient Safety Foundation, Talking to Patients About Health Care Injury: Statement of Principle (2000), www.npsf.org/html/statement.html; Stephen Jencks, Public Reporting of Serious Medical Errors, 3 Effective Clinical Prac. 299, 301 (2000) ("Almost all ethicists agree that the patient has an absolute right to know what has happened and whether what has happened is the result of an error.").

n100 JCAHO Hospital Accreditation Standards 73 (2002) (discussing Standard RI.1.2.2). See generally Nancy LeGros & Jason D. Pinkall, The New JCAHO Patient Safety Standards and the Disclosure of Unanticipated Outcomes, 35 J. Health L. 189 (2002); Mulholland, supra note 59 (discussing legal issues related to error disclosures).

n101 See Nihon ishikai [Japan Medical Ass'n], Ishi no shokugy rinri shishin [Physicians' professional ethics guide] §§ 2(1), 2(2), 2(7) (2004) (recognizing, subject to exceptions, physicians' duties to explain patient's medical condition to patient and to disclose medical records, but not addressing issue of explanation of errors).

n102 michi interview, supra note 7.

n103 The classic article on the subject is Hiroshi Wagatsuma & Arthur Rosett, The Implications of Apology: Law and Culture in Japan and the United States, 20 Law & Soc. Rev. 461 (1986). The insights of Wagatsuma and Rosett have informed a rapidly expanding literature on improving the dispute resolution process. See, e.g., Jennifer K. Robbennolt, Apologies and Legal Settlement: An Empirical Examination, 102 Mich. L. Rev. 460 (2003); Max Bolstad, Learning from Japan: The Case for Increased Use of Apology in Mediation, 48 Clev. St. L. Rev. 545 (2000); Jonathan R. Cohen, Apology and Organizations: Exploring an Example from Medical Practice, 27 Fordham Urban L.J. 1447 (2000).

n104 1907 Hanrei jih 112, 124-25 (Kyoto Dist. Ct., July 12, 2005) (K no v. Jinshinkai case). In a civil action against a hospital and its staff for brain damage suffered by a child from heart stoppage due to a medication error and subsequent inadequate resuscitation efforts, the court found that the hospital had engaged in a coverup of the facts. In addition to awarding damages and costs of 243 million (US $ 2.2 million) plus interest on the malpractice counts, the court awarded 1 million (US $ 9,000) for breach of the contract duty to investigate and report faithfully.

n105 1194 Hanrei taimuzu 243 (Tokyo Dist. Ct., Jan. 30, 2004), aff'd in relevant part, 2004 LEX/DB 28100472 (Tokyo High Ct. Sept. 30, 2004) (K no v. Tokyo-to case). This decision, in the civil action arising out of the Hiroo Hospital accident and coverup, supra note 18, adopted both contract and tort grounds to support the conclusion that the hospital had breached its duty to faithfully explain the patient's deathto the family.

n106 See, e.g., 54(2) Minsh 582, 1710 Hanrei jih 97, 1031 Hanrei taimuzu 158 (Sup. Ct. Feb. 29, 2000) (Takeda case) (recognizing Jehovah's Witness's right to truthful information about possibility of receiving blood transfusion, in connection with patient's right of self-determination). See also supra note 29 and accompanying text.

n107 We exclude from consideration criminal acts committed by medical personnel outside the course of usual medical care, such as billing fraud, assaults on patients, violations of controlled drug laws, euthanasia, and physician- assisted suicide, and acts constituting the unlicensed practice of medicine. However, prosecutions under some of these headings, selectively targeted, can have the effect of deterring patient- endangering practices, as Associate U.S. Attorney Jim Sheehan emphasizes. E.g., James G. Sheehan, Symposium on Regulating for Patient Safety: Current Patient Safety Enforcement, Widener University School of Law (Oct. 15, 2004).

n108 See, e.g., R. v. Adomako, [1995] 1 A.C. 171 (H.L. 1994) (leading U.K. case recognizing criminal liability of anesthetist for involuntary manslaughter under a gross negligence standard); Timothy Stoltzfus Jost, Schlichtungsstellen and Gutachterkommissionen: The German Approach to Extrajudicial Malpractice Claims Resolution, 11 Ohio St. J. Dispute Resolution 81, 85 n.28 (1996) (noting basis for criminal prosecution in Germany in §§ 222 & 230, Strafgesetzbuch [Penal Code]). Overviews of the basis for criminal liability for medical malpractice in various other nations, chiefly European, can be found in a series of twenty-one "national monographs," separately paginated and variously dated, collected by Kluwer Publishers under the title International Encyclop dia of Medical Law. See, e.g., Gerard M meteau, France, France 99-101 (1998) (explaining potential applicability of articles 221-6, 222-19 and 222-20 of the Criminal Code); Hans Akveld & Herbert Hermans, The Netherlands, Netherlands 56 (1995) (explaining culpability for medical death or injury under articles 307 and 308 of the Penal Code).

n109 James A. Filkins, "With No Evil Intent": The Criminal Prosecution of Physicians for Medical Negligence, 22 J. Legal Med. 467, 471-72 n.51 & 53 (2001) (describing nine appellate cases, and estimating from "fifteen or so" to "perhaps two dozen" more non-appellate cases over the twenty-year period 1981-2001, based on a Westlaw database search and a canvas of other studies). The actual number of prosecutions may be somewhat higher than Filkins' estimate, because the cases are not recorded in any systematic way and the Westlaw database Filkins searched is incomplete. See also George J. Annas, Medicine, Death, and the Criminal Law, 333 New Eng. J. Med. 527, 527 (1995) (criminal prosecution of physicians for patients' deaths "extraordinarily rare"). By comparison, one writer has enumerated twenty-three criminal cases brought against twenty-eight doctors in the United Kingdom from 1990 to 2003. Jon Holbrook, The Criminalisation of Fatal Medical Mistakes, 327 BMJ 1118, 1118-19 n.5-9 (2003) (editorial citing reports by R. E. Ferner and C. Dyer).

n110 See Filkins, supra note 109, at 475-90. Filkins's review of modern appellate cases reports convictions upheld for reckless or intentional acts in Com. v. Youngkin, 427 A.2d 1356 (Pa. Super. Ct. 1981) (involuntary manslaughter); People v. Einaugler, 618 N.Y.S.2d 414 (N.Y. App. Div. 1994) (reckless endangerment); Wisconsin v. Chem-Bio Corp., (reckless homicide discussed in Filkins, note 109, at 477-78); and People v. Kivana, 15 Cal. Rptr. 2d 512 (Cal. App. 1992) (second-degree murder). In all these cases, recklessness or conscious disregard for a known risk to life was proven. Physicians have occasionally been prosecuted for crimes with mens rea less than recklessness, for example negligent homicide (under a concept of negligence stricter than that applied in civil cases). E.g., State v. Warden, 813 P.2d 1146 (Utah 1991). But in the modern cases except for Warden, they were either found not guilty, or their convictions were overturned. See U.S. v. Billig, 26 M.J. 744 (1988) (military case); People v. Verbrugge, 998 P.2d 43 (Colo. Ct. App. 1999). In an earlier era, negligent homicide cases against physicians were sometimes successful. Donald C. Barrett, Annotation, Homicide Predicated on Improper Treatment of Disease or Injury, 45 A.L.R.3d 114, §3(a) (1972). However, the modern cases typically require intent or recklessness. See Kara M. McCarthy, Note, Doing Time for Clinical Crime: The Prosecution of Incompetent Physicians as an Additional Mechanism to Assure Quality Health Care, 28 Seton Hall L. Rev. 569, 607-13 (1997).

n111 See supra note 20.

n112 See, e.g., Jost, supra note 108, at 85-86 n.29 (observing that in Germany "[e]ven today there are probably as many criminal as civil complaints brought against doctors"); Holbrook,

supra note 109, at 1118 (noting increase in prosecutions for medical manslaughter in the United Kingdom).

n113 According to one recent report, seventy-three prosecutions were brought in medical cases over the period 1974- 1999 - a rate of two to three per year. "Shohoteki misu": Iry kago y hatsu keiji saiban 73-ken, Ky dai joshu bunseki ["Elementary Mistakes": 73 Criminal Cases Triggered by Medical Malpractice, Kyushu U. Researcher Finds], Nishi Nippon Shimbun, Aug. 25, 2003, http://www.nishinippon.co.jp/media/news/news- today/20030825/morning news001.html (reporting study by Dr. Sh ichi Maeda). This study found twenty-one prosecutions during the 1970s, twenty-two during the 1980s, and twenty-seven during the 1990s. This rate appears not to have varied much in the fifty years following the end of World War II. See Hideo Iida & Issei Yamaguchi, Keiji iry kago [Criminal Medical Malpractice] 1 (2001) (reporting 137 prosecutions brought in the fifty years following the end of World War II).

n114 Filkins's estimate, based on incomplete data, puts the U.S. prosecution rate at slightly more than one per year - less than half the pre-2000 Japanese rate, though the U.S. population is more than double Japan's. See Filkins, supra note 109. The low numbers involved and the imprecision of Filkins's estimate preclude anything approaching statistically accurate comparisons with Japan. Nevertheless, one may obtain a rough measure of the relative frequency of criminal versus civil medical malpractice litigation in the two nations by comparing the ratio in each country of criminal cases brought per 100,000 population to civil cases brought per 100,000 population. Cf. supra note 35 and accompanying text (comparing civil malpractice litigation rates). That ratio is more than two orders of magnitude higher for Japan than for the United States, suggesting the greater relative importance of criminal law in the medical injury field in Japan.

n115 Keih art. 211 (Gy muj kashitsu chishish -t - zai), providing a prison sentence of up to five years and a fine of up to 500,000 (US $ 4500). This crime is most commonly charged in connection with traffic offenses. Articles 209 and 210 also criminalize negligence causing injury and negligence causing death respectively, but they are seldom used in medical prosecutions. Medical personnel convicted under Article 211 typically receive fines and often suspended sentences, but they rarely serve prison time. See Iida & Yamaguchi, supra note 113, at 435- 82 (collecting cases; summary chart on file with the authors).

n116 See supra note 110 and accompanying text.

n117 Keih art. 104 (Sh ko inmetsu). This provision formed the basis for the indictment of one of the physicians in the recent Tokyo Women's Medical University case. See supra note 19 and accompanying text.

n118 See, e.g., Karute kaizan 109-ken: Iry kago sosh no bengoshi ch sa [109 Cases of Altering Patient Charts - Survey by Medical Malpractice Attorneys], Yomiuri shimbun (Osaka edition), July 7, 2004, at 1; Tokyo Women's Medical University case, supra note 19; Leflar, supra note 3, at 35 & n.127.

n119 Ishih [Physicians' Law] art. 21.

n120 The most well-known Article 21 prosecution involved a charge brought against the director of Hiroo General Hospital in Tokyo for failing to report a patient's accidental death. See supra note 18 and accompanying text. The administrator was convicted, and his conviction was affirmed by the Supreme Court. 58(4) Keish 247 (Sup. Ct. April 13, 2004) (rejecting argument that criminal sanction for failing to make required report violated constitutional protection against self- incrimination). The authors are aware of only three other prosecutions under this provision: Judgment of Tokyo Summary Ct. (Sept. 5, 2001); judgments of Morioka Summary Ct. (Dec. 27, 2002) (2 cases).

n121 This expansive interpretation was originally offered in a 1994 position paper of the Japanese Society of Legal Medicine (Nihon h i gakkai), an association of forensic medicine specialists. Nihon h i gakkai, "Ij shi' Gaidorain" [Guidelines on "Unusual Death"] (1994), reprinted in Toshiharu Furukawa, Shinry k i ni kanren shita kanja no shib , sh gai no h koku ni tsuite [Reporting to Police of Patients' Deaths and Injuries Connected with Medical Acts], 104 Nihon geka gakkai zasshi 9, 13- 14 (2003). For a discussion of the uncertainty engendered by the law, see Yasushi Kodama, Ishih 21-j o meguru konmei [The Confusion Surrounding Article 21 of the Physicians' Law], 1249 Jurisuto 72 (2003).

n122 See, e.g., Teruyuki Yamamoto, Iry jiko e no keijih no kainy [Criminal Sanctions for Medical Accidents], 18 Ijih gaku [J. Med. L.] 85 (2003); Sh ichi Maeda, Iry jiko keiji sekinin ni kansuru kenky [Criminal Liability for Medical Accidents] 30-34 (JMA General Research Institute Working Paper No. 93, 2004).

n123 In fact, the Japan Surgical Society [Nihon geka gakkai] issued a position paper contesting the idea that Article 21 of the Physicians' Law requires the reporting to police of deaths potentially connected to medical error, but nevertheless calling on its members to voluntarily report to police both deaths and serious injuries resulting from clear breaches of the standard of medical care, as a matter of medical ethics. Nihon Geka Gakkai, Shinry k i ni kanren shita kanja no shib , sh gai no h koku ni tsuite [Reporting to Police of Patients' Deaths and Injuries Connected with Medical Acts], reprinted in Hiroyuki Kat , Iry jiko j h no h koku no mondaiten [Issues in Reporting Medical Accidents to Police], 1249 Jurisuto 69, 70-71 (2003), and Furukawa, supra note 121, at 16-18. This position, like the position paper of the National University Hospitals Presidents' Conference which preceded it, supra note 68, in effect, acknowledges the importance of reporting to a public entity as an accountability mechanism in a time of shaken public confidence in physicians' skill and candor. Interview with attorney/physician Toshiharu Furukawa, Tokyo (July 16, 2003). Similarly, the prestigious Science Council of Japan recently issued a report opining that deaths clearly the result of medical negligence must be reported to police, even if doing so would disadvantage medical providers, in order to promote the transparency in health care that the public expects. With regard to deaths whose cause is less clear, the Council suggested a process of expert review before determining whether a report must be submitted to the police. Nihon gakujutsu kaigi [Science Council of Japan], Ij shi-t ni tsuite - Nihon gakujutsu kaigi no kenkai to teigen [Unusual Deaths: Opinion and Proposal of the Science Council of Japan] 6-7 (2005).

n124 See supra note 120.

n125 Iry jiko, jiken todokede 200-ken toppa - Keisatsuch matome, sakunen 35% z [Reports of Medical Accidents, Incidents Top 200, 35% Increase from Last Year - Police Agency Study], Nihon keizai shimbun (2004). These figures include reports of injuries as well as deaths. The number of investigations (rikken) of medical incidents that police opened on the basis of these reports increased dramatically from 1999 (twenty-one) to 2000 (seventy-one), but has fallen off since. Id.

n126 We are indebted for this latter point to Prof. Norio Higuchi and Dr. Sakai Iwasaki.

n127 See supra notes 88-90 and accompanying text.

n128 Interview with Sh ji Iwamura, Takayuki Aonuma, and Atsushi Sat , Tokyo District Prosecutor's Office (July 25, 2001) [hereinafter Prosecutors' Interview].

n129 See **Futoshi Iwata,** Kashitsu ni yoru iry kago ni taisuru keijiteki kisei: Nichibei hikaku-k [Regulation of Medical Malpractice through Criminal Negligence Actions: Japan- U.S. Comparative Research], in Iry anzen suishin ni kansuru h teki mondai ni kansuru kenky : Heisei 14-nendo kenky seika h kokusho [Research Report on Legal Problems in the Promotion of Medical Safety] 6 (Yasushi Kodama ed., 2003) (on file with authors). The prosecutors whom we interviewed declined to say that social goals such as the deterrence of medical error formed part of their motivation for selecting cases. Prosecutors' Interview, supra note 128. But at least one of us found their restraint in this respect disingenuous.

n130 See supra notes 3-5 and accompanying text.

n131 See supra notes 6-7 and accompanying text.

n132 See supra notes 31-44 and accompanying text.

n133 For a classic exposition of this view, accompanied by a certain skepticism about its continued explanatory power, see Hideo Tanaka & Akio Takeuchi, The Role of Private Persons in the Enforcement of Law: A Comparative Study of Japanese and American Law, 7 Law in Japan 34 (1974).

n134 The mean duration from filing of a medical malpractice case to its conclusion by trial judgment or settlement in 2002 was about two and a half years, compared to 8.3 months for civil cases generally. Administrative Office of the Supreme Court, Iji kankei sosh jiken no heikin shinri kikan [Average Trial Duration in Medical Litigation] (2004), available a t http://courtdomino2.courts.go.jp/home.nsf/topframe?OpenFrameSet (last visited Nov. 28, 2005). However, this represents a significant decrease in trial duration compared with 1993, when the mean duration was about three and a half years. Id.

n135 See David T. Johnson, The Japanese Way of Justice: Prosecuting Crimes in Japan (2002).

n136 An important study of the significance to patients of candor, apology, and willingness to undertake safety corrections is Steven S. Kraman & Ginny Hamm, Risk Management: Extreme Honesty May Be the Best Policy, 131 Annals Internal Med. 963 (1999) (describing Lexington, Ky. Veterans Administration Hospital's successful policy of openness toward patients and apology in cases of error); see also Cohen, supra note 103 (same; legal analysis); Cherri Hobgood et al., Parental Preferences for Error Disclosure, Reporting, and Legal Action after Medical Error in the Care of Their Children, 116 Pediatrics 1276 (2005) (questionnaire survey).

n137 For an English-language treatment of a Japanese parent/physician's journey through a medical malpractice dispute over her daughter's death, illustrating most of the motivations noted herein, see Tsuneko Kunou, A Promise to Akiko: A Mother's Notes (1998). Experiences of families of American patients who died from malpractice are well portrayed in, e.g., Sandra M. Gilbert, Wrongful Death: A Memoir (1995), and see Blunt Instruments: Medicine, Law and the Death of Nancy Lim, available at http://www.nancylim.org (last visited Feb. 10, 2006). Japanese-language victims' accounts range from, e.g., Kuniko Nagao, Musume kara no shukudai [Homework from My Daughter] (1988) to Fumie Sugino, "Waribashi ga n ni sasatta wagako" to "daiby in no taido" [The Chopstick Stuck in Our Child's Brain, and the Giant Hospital's Attitude] (2000). A criminal prosecution is ongoing in the latter case. 1-Year Term Urged for Boy's Chopstick Death, Int'l Herald Tribune/Asahi Shimbun, Nov. 15, 2005, at 24 (doctor allegedly failed to notice 7.6 cm portion of chopstick embedded in four-year-old's brain).

n138 See Johnson, supra note 135, at 99-101, 112-16, 189.

n139 See supra note 128 and accompanying text.

n140 Although law enforcement officials have recently been criticized for inattention to victims' needs, see, e.g., Higaisha no tachiba ni tatta shih o: Hikinige jiko de musuko o nakushite [Toward a Justice System That Stands on the Victims' Side: Son Lost in Hit-and-Run], 2 Gekkan shih kaikaku 15-17 (1999), available at http://www2.tky.3web.ne.jp/norin/katayama.html, prosecutors claim to be responding to these criticisms.

n141 See Johnson, supra note 135, at 21-27.

n142 Cf. Stephanos Bibas & Richard A. Bierschbach, Integrating Remorse and Apology into Criminal Procedure, 114 Yale L.J. 85, 134-35 (2004) (advocating greater role for remorse and apology by defendants in American prosecutors' decisionmaking).

n143 The ready availability of personal injury lawyers throughout the United States, whose advertising is ubiquitous and who populate almost every county courthouse, stands in sharp contrast to the paucity of similarly motivated attorneys in Japan. Although the number of private attorneys doing medical malpractice work in Japan has been rising, see supra note 46, it is still far smaller on a per capita basis than the corresponding number of medical malpractice attorneys in the United States.

n144 See, e.g., "Iry kanren-shi" hatsu no kaib jisshi - Tokyo-to-nai no daigaku by in de [First "Medically-Related Death" Autopsy - Tokyo-Area University Hospital], Asahi shimbun, Nov. 13, 2005 (reporting first case investigation under "model project," and setting out the project's goals).

n145 MHLW Aug. 2004 Interview, supra note 5; MHLW, Shinry k i ni kanren shita shib no ch sa bunseki ni kakaru moderu jigy ni tsuite [Model Project for the Investigation and Analysis of Deaths Related to Medical Acts], available at http://www.mhlw.go.jp/houdou/2005/08/h0810-1.html (last visited Nov. 22, 2005) [hereinafter MHLW Model Project].

n146 The medical specialty societies are the Japan Surgical Society (Nihon geka gakkai), the Japanese Society of Internal Medicine (Nihon naika gakkai), the Japanese Society of Pathology (Nihon by ri gakkai), and the Japanese Society of Legal Medicine (Nihon h l gakkai).

n147 This description of the project is taken from MHLW Model Project, supra note 145; MHLW Aug. 2004 Interview, supra note 5; and Iry -naka no shi, dai-3-sha kensh - Senmon-i ga bunseki, k hy [3rd-Party Investigations of Deaths During Medical Treatment - Specialists to Analyze, Report Publicly], Asahi shimbun, Aug. 22, 2004.

n148 See supra notes 68-69 and accompanying text.

Composition of the House

Officers of the House
Strength of the In-House Groups in the House of Representatives
List of Members

Strength of the In-House Groups in the House of Representatives

(as of May 9, 2018)

Liberal Democratic Party	283 (22)
The Constitutional Democratic Party of Japan	55(13)
Democratic Party For the People	39(2)
Komeito	29 (4)
The Group of Independents	13 (1)
Japanese Communist Party	12 (3)
Nippon Ishin (Japan Innovation Party)	11 (1)
Liberal Party	2 (0)
Social Democratic Party	2 (0)
The Party of Hope	2 (0)
Independents	17(1)
INCUMBENTS	465 (47)
Vacancies	0
MEMBERSHIP	465

Note: Figures in parentheses show the number of women members.

In-House Group: A group of House Members who engage in joint activities within the House. Usually, a political party forms an in-House group inside the House, but occasionally there are cases where a group is formed by (1) House Members who do not belong to a particular political party, (2) a political party and a House Member or Members who do not belong to any political party, or (3) two or more political parties.

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Strength of the Political Groups in the House of Councillors

(As of May 25,2018)

Political Groups in the House	Number of Members	Abbreviation
Liberal Democratic Party and The Party for Japanese Kokoro	125 (19)	LDP･PJK
Komeito	25 (5)	KP
Democratic Party For the People and The Shin-Ryokufukai	24 (5)	DPFP-SR
The Constitutional Democratic Party of Japan and Minyukai	23 (6)	CDP
Japanese Communist Party	14 (5)	JCP
Nippon Ishin(Japan Innovation Party)	11 (2)	JIP
Hope Coalition(Kibou)	6 (3)	HC
The Party of Hope	3 (2)	TPH
Independents Club	2 (1)	IC
Okinawa Whirlwind	2 (1)	OW
Voice of The People	2 (1)	VP
Independents	5 (0)	None
INCUMBENTS	242 (50)	-
Vacancies	0	-
MEMBERSHIP	242	-

Notes: Figures in parentheses show the number of women members.

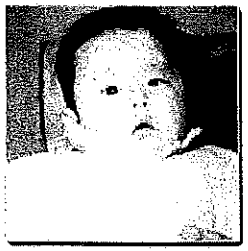
Most house members belong to political groups, which is formed based on their political parties. On this Web site, the names of the political groups are abbreviated as listed above for layout reasons. These abbreviations are not the official abbreviations for the various political groups.

Prime Minister of Japan and His Cabinet

Profile of Prime Minister Abe

TOP ▲

TOP



Childhood

1954	Born
1977	Graduated from the Department of Political Science, Faculty of Law, Seikei University
1979	Entered Kobe Steel, Ltd.

As the Executive Assistant to the Minister for Foreign Affairs, Mr. Shintaro Abe

1982	Executive Assistant to the Minister for Foreign Affairs
1993	Elected for the first time to the House of Representatives
1999	Director of the Committee on Health and Welfare, House of Representatives Director of the Social Affairs Division, Liberal Democratic Party (LDP)

First attendance at the House of Representatives

2000	Deputy Chief Cabinet Secretary, Second Mori Cabinet Deputy Chief Cabinet Secretary, Reshuffled Second Mori Cabinet
2001	Deputy Chief Cabinet Secretary, Reshuffled Second Mori Cabinet Deputy Chief Cabinet Secretary, First Koizumi Cabinet

With Ms. Condoleezza Rice, then the US National Security Adviser

2002	Deputy Chief Cabinet Secretary, Reshuffled First Koizumi Cabinet
2003	Secretary General, LDP
2004	Acting Secretary General and Chairman of Reform Promotion Headquarters, LDP

With his wife, Mrs. Akie Abe, during a visit to India

Photos presented by the Shinzo Abe Office

2005	Chief Cabinet Secretary, Reshuffled Third Koizumi Cabinet
2006	90th Prime Minister of Japan
2007	Resigned Prime Minister
2012	President of LDP Prime Minister

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