The Law of Medical Misadventure in Japan

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All translations are the author's unless otherwise indicated. Japanese as well as non-Japanese names are given surname last, for consistency's sake. Japanese cases are parenthetically denoted by their common sobriquets. Yen amounts are stated in dollars at the approximate prevailing exchange rate for the year in question – in 2011, about US $1 = ¥80.

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I. INTRODUCTION

This article sets out the essential and distinctive features of the Japanese systems – criminal, civil, and administrative – for sanctioning persons causing medically related injury and for compensating the injured.[1] The article seeks to place those systems in historical and social context.

Patients in Japan obtain their health care on a price-controlled, fee-for-service basis. Insurance coverage is virtually universal: since 1961, every legal resident has been entitled to receive care through a mixture of private and public plans.[2] The proportion of GDP that Japan devotes to health care, 8.5 percent as of 2008, is less than almost all other advanced industrial nations, and only about half that of the industrialized world's least efficient health care system, the United States.[3] Yet Japan's longevity and infant mortality statistics are among the world's best,[4] and technological sophistication at Japan's top hospitals parallels that available anywhere.

Nevertheless, iatrogenic harm – injury resulting from medical care – has long been a simmering concern. The number of civil malpractice claims, though relatively small, rose steadily through the 1980s and 1990s.[5] During the same period, dissatisfaction with physicians' paternalistic attitudes, a scandal over HIV-contaminated blood supply, a national debate over brain death issues, and concern over excessive and irrational drug prescriptions combined to undercut the public's previously almost unquestioned faith in medicine's beneficence.[6] These developments fed a growing current of public opinion favoring transparency in medicine, reflecting movements toward greater openness in

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1 The article is not confined to medical malpractice, in the sense of treatment failing to meet the legal standard of due care. The article's scope also encompasses other medically related death and injury; hence the use of "misadventure," a term bequeathed to us in this context by the New Zealanders. See G. PALMER, Compensation for Incapacity: A Study of Law and Social Change in New Zealand and Australia 255 (1979); K. OLIPHANT, Defining "Medical Misadventure": Lessons from New Zealand, 1 Med. L. Rev. 4 (1996).

2 J. C. CAMPBELL & N. IKEGAMI, The Art of Balance in Health Policy: Maintaining Japan's Low-Cost, Egalitarian System (1998) 1–20.

3 OECD.Stat Extracts, *http://stats.oecd.org/index.aspx*; C. PRITCHARD & M. S. WALLACE, Comparing the USA, UK and 17 Western Countries' Efficiency and Effectiveness in Reducing Mortality, 2 J. Royal Soc'y Med. Short Rep. 60 (2011), available at *http://image.guardian.co.uk/sys-files/Guardian/documents/2011/08/07/JRSMpaperPritWall.pdf* (noting inefficiency of US health care system).

4 J. CYLUS & G. F. ANDERSON, Multinational Comparisons of Health Systems Data, 2006 (Commonwealth Fund 2007), available at *http://www.commonwealthfund.org/Content/Publications/ Chartbooks/2007/May/Multinational-Comparisons-of-Health-Systems-Data-2006.aspx*. See generally N. IKEDA et al., What Has Made the Population of Japan Healthy?, 378 The Lancet 1094 (2011) (survey of reasons for Japanese longevity).

5 See *infra* note 53, fig. 2.

6 See R. B LEFLAR, Informed Consent and Patients' Rights in Japan, 33 Hous. L. Rev. 1 (1996) [hereinafter LEFLAR, Informed Consent].

other spheres of society. Marking this trend toward transparency, around the turn of the 21st century, were court decisions advancing principles of informed consent,[7] enactments of information disclosure measures,[8] and provisions for patients' access to their medical records.[9]

Beginning in 1999, reports of a series of errors at hospitals of high repute filled the headlines and newscasts. The first notorious case arose from switched-patient surgeries in Yokohama.[10] Under the eyes of the nation's media, subsequent cases occurred in quick succession in Tokyo itself. A nurse accidentally injected a toxic agent, killing her patient.[11] An inexperienced team of young doctors bungled delicate laparoscopic surgery while insufficiently trained on the equipment, having also neglected to secure an adequate supply of the patient's rare blood type.[12] A child died after an operation at a major pediatric cardiovascular surgery center,[13] one among a series of children's deaths

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7 See, e.g., Judgment of Supreme Court, 29 February 2000, 54 Minshū 582 (damages awarded Jehovah's Witness for violating her blood transfusion refusal, despite transfusion's life-saving effects) [hereinafter Jehovah's Witness case]. The case is available in English translation in C. J. MILHAUPT, J. M. RAMSEYER & M. D. WEST, The Japanese Legal System: Cases, Codes and Commentary (2006) 347–356.

8 *Gyōsei kikan no hoyū-suru jōhō no kōkai ni kansuru hōritsu* [Law on Access to Information Held by Administrative Organs], Law No. 42 of 1999 [hereinafter Information Disclosure Law]. This national law was preceded by various local freedom of information ordinances, a process well described in D. BOLING, Access to Government-Held Information in Japan: Citizens' "Right to Know" Bows to the Bureaucracy, 34 STAN. J. INT'L L. 1 (1998).

9 See Ministry of Health & Welfare (Japan), *Karute-tō no shinryō jōhō no katsuyō ni kansuru kentōkai hōkoku-sho* [Report of the Study Commission on the Use of Medical Charts and Information] (1998); R. B LEFLAR, Law and Health Care in Japan: The Renaissance of Informed Consent, in: Timothy Stoltzfus Jost (ed.), Readings in Comparative Health Law & Bioethics (2d ed. 2007) 154, 159 [hereinafter LEFLAR, *Renaissance*] (summarizing health ministry measures promoting patient access to medical records); and *infra* note 93 and accompanying text.

10 At Yokohama City Medical University Hospital, a lung patient had part of his heart valve removed, and a heart patient with a similar name had part of his lung excised. Three doctors and two nurses were found criminally liable for professional negligence. Judgment of Yokohama Dist. Ct., 20 September 2001, 1087 Hanrei Taimuzu 296 (Yokohama switched-surgery case).

11 After this event at Tokyo's Hirō Hospital, two nurses were convicted of criminal professional negligence, and the hospital director was found guilty of submitting a false death certificate and failing to report the death to police in a timely fashion. Judgment of Supreme Court, 13 April 2004, 58(4) Keishū 247 [hereinafter Hirō Hospital case].

12 See R. B LEFLAR & F. IWATA, Medical Error as Reportable Event, as Tort, as Crime: A Transpacific Comparison, 12 Widener L. Rev. 189, 192–95 (2005), reprinted in: 22 ZJAPANR/J.JAPAN.L. 39, (2006) 43–45 (recounting Aoto Hospital story).

13 See R. B LEFLAR, Unnatural Deaths, Criminal Sanctions, and Medical Quality Improvement in Japan, 9 Yale J. Health Pol'y L. & Ethics 1, 6 (2009), reprinted in: 29 ZJAPANR / J.JAPAN.L. (2010) 5, 9 [hereinafter LEFLAR, Unnatural Deaths] (recounting Tokyo Women's Medical University Hospital story).

at the center. In each of these cases, physicians and hospital personnel altered medical records, gave misleading accounts of events to bereaved families or investigating officials, or engaged in other untrustworthy acts. Many other cases of alleged malpractice surfaced around the country.

Media coverage of these iatrogenic deaths and injuries sparked public questioning of the medical profession's self-policing mechanisms – questioning that the profession was ill-prepared to answer. Institutional structures to monitor the quality of Japan's medical care have historically been weak. Medical licensure and discipline authority, exercised by the Ministry of Health, Labor & Welfare, seldom inquired into failures of patient safety.[14] Hospital peer review was conducted with a soft touch, if at all, and the claimed impartiality of hospitals' internal reviews of adverse events was met with increasing public skepticism. The hierarchical system of medical education and job placement strongly discouraged any open questioning of practices taught by revered professors (who controlled career postings), even if such practices were outmoded or scientifically unproven.[15] The hospital accreditation system fostered good safety practices only marginally; hospitals need not receive accreditation to qualify for reimbursement for examinations, procedures and medications provided to patients, and only 28 percent of hospitals are accredited today.[16] The nation's patchwork death inquiry system functioned with efficacy in only a few urban areas, and even there, seldom focused on medical-practice-associated causes of death and their prevention.[17] Civil litigation over alleged malpractice, as discussed below, provided only a modest and intermittent brake on medical error. Until the 2009 introduction of a no-fault system for compensating obstetrical injuries, administrative compensation systems were confined to a few limited categories of disease sufferers.

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14 See *id.* at 20 & n. 87 (summarizing research of Dr. Etsuji Okamoto and author's interview with health ministry staff concerning work of the Ministry's medical discipline committee, the Medical Ethics Council (Idō Shingi-kai)).

15 See*, e.g.,* CAMPBELL & IKEGAMI, *supra* note 2, at 188–189 (criticizing quality assurance and peer review in Japanese hospitals); H. HASHIMOTO, N. IKEGAMI et al., Cost Containment and Quality of Care in Japan: Is There a Trade-Off? 378 The Lancet (2011) 1174, 1178 ("Physicians' practice patterns tend to be idiosyncratically set by the chair and professor of the university clinical department.").

16 Of Japan's 8,580 hospitals, 2,387 are accredited as of June 2013. Japan Council for Quality Health Care, *Byōin kinō hyōka kekka no jōhō teikyō* [Information on Results of Hospital Evaluations], available at *http://www.report.jcqhc.or.jp.* In any case, accreditation criteria do not address compliance with standards of evidence-based medicine or honesty with patients about adverse events.

17 Tatsuya Fujimiya, Legal Medicine and the Death Inquiry System in Japan: Their Development and a Comparative Study, in: Otsuka / Sakai (eds.) Medicine and the Law: Proceedings of the 119th International Symposium on the Comparative History of Medicine, East and West (1998) 129, 152, 156 (article from a 1994 symposium); LEFLAR, Unnatural Deaths, *supra* note 13, at 25–30.

In short, at the turn of the 21st century, weaknesses in professional self-regulation, administrative oversight, the death inquest system, and civil litigation left Japanese medicine to operate within an accountability vacuum.[18] Attempting to fill part of that gap in public accountability, the criminal justice system – its workings amplified by the media – stepped up its engagement with iatrogenic harm cases.

II. Prosecutions and Their Consequences

1. Prosecutions in Medical Cases

Prosecutors have typically brought charges against health care personnel on any of three grounds. The first, and most common, is "professional negligence causing death or injury."[19] This crime is derived, like most of Japan's Criminal Code, from the German penal code.[20] The mens rea required for conviction, as a formal matter, is simple negligence, although as a practical matter the cases in which prosecutors obtain convictions typically involve acts or omissions amounting to gross negligence or recklessness.[21]

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18 This argument is developed more fully in Leflar, Unnatural Deaths, *supra* note 13, and Leflar & Iwata, *supra* note 12.

19 *Keihō* [Criminal Code] Art. 211 (*Gyōmujō kashitsu chishishō-tō*). The typical defendants charged with this crime are traffic offenders, but other professionals such as architects, pilots, and physicians are sometimes sanctioned as well.

When convicted, such professionals are fined but rarely serve prison sentences. See H. Yamaguchi, *Iryō jiko no keiji shobun to purofuesshonaru ōtonomii* [Criminal Sanctions for Medical Accidents and Professional Autonomy], 695 Niigata-ken ishikaihō 2, 2 tbl.1 (2008) (reporting four cases of imprisonment out of 253 criminal sanctions in medical cases from 1950–2007). However, while under investigation physicians, like other suspects, may languish in police detention for a considerable period. For example, Dr. Kazuki Satō, who was arrested, prosecuted, and acquitted in the Tokyo Women's Medical University Hospital case, Leflar, Unnatural Deaths, *supra* note 13, at 6, was detained and interrogated for three months. Interview with Dr. Kazuki Satō, in Tokyo (7 August 2009). Moreover, even if a convicted professional's ultimate formal sanction is merely pecuniary, the conviction itself is usually enough to force a career change, through either loss of medical license or personal shame, so effectively the punishment is ultimately quite significant.

Although criminal prosecutions and civil damage claims are formally separate, they sometimes proceed in parallel fashion, and the proceedings of each can influence the other. See *infra* note 21.

20 See H. Oda, Japanese Law, 416 (2d ed. 1999).

21 See Leflar, Unnatural Deaths, *supra* note 13, at 16 n. 65 for a discussion of what "negligence" means in criminal law in Japan and France.

Tokyo prosecutors responsible for medical cases informed the author that during the first wave of these prosecutions the most important factors in decisions about whether to prosecute were the bringing of a complaint by the patient or family, the degree of injury, the flagrancy of the medical personnel's acts or omissions, the clarity of proof of negligence, and failure by medical personnel to provide compensation and apologies. Interview with

A second ground for prosecution is concealment or destruction of evidence.[22] Physicians and nurses attempting to cover up medical mistakes by altering patients' medical charts have been found criminally liable for this offense.[23]

The third basis for recent prosecutions of physicians is failure to notify police in a timely fashion of "unnatural deaths." Physicians once assumed that this notification requirement, found in Article 21 of the Medical Practitioners' Law,[24] applied only to violent deaths, suicides, infectious diseases threatening public health, and the like. However, when the CEO of Tokyo's Hirō Hospital in 2000 submitted a falsified death certificate for a patient killed by an accidental toxic injection and delayed reporting the death to police, prosecutors – fully aware of intensified public concern over medical errors – charged the CEO with violating Article 21. The Supreme Court, affirming his conviction in 2004, confirmed that the "unnatural death" notification requirement may encompass deaths causally related to medical management.[25]

The Hirō Hospital CEO's arrest and subsequent conviction placed hospital administrators in a dilemma. For purposes of medical care, no clear definition of "unnatural death" exists. When a patient dies following less-than-optimal care, should the hospital routinely notify police, inviting criminal investigation disruptive of hospital routine and patient care, or avoid notification and risk public condemnation for a cover-up and possible criminal prosecution? The number of reports to police of medically related death and injury, and the number of cases police referred to prosecutors, increased for several years after 1999 (Figure 1). The "unnatural death" notification requirement, and

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Shūji Iwamura, Takayuki Aonuma, and Atsushi Satō, Tokyo District Prosecutor's Office, and Prof. Futoshi Iwata, Sophia University, in Tokyo (July 25, 2001). The prosecutors averred, perhaps disingenuously, that social goals such as deterrence of medical error formed no part of their motivation for bringing charges.

22 *Keihō* [Criminal Code], Art. 104 (*Shōko inmetsu-tō*). A related crime is the creation, with the purpose to use, of false official documents. *Keihō* [Criminal Code], Art. 156 (*Kyogi kō-bunsho sakusei-tō*). The CEO of Hirō Hospital in Tokyo was convicted of this crime. See Hirō Hospital case, *supra* note 11.

23 See, e.g., LEFLAR, Unnatural Deaths, *supra* note 13, at 6 (recounting Tokyo Women's Medical University Hospital case). Plaintiffs' attorneys charge that tampering with patient charts was a frequent practice, at least in the past. See, e.g., H. ISHIKAWA, *Karute kaizan wa naze okiru* [Why Medical Records Are Falsified] (2006); see also J. M. RAMSEYER, The Effect of Universal Health Insurance on Malpractice Claims: The Japanese Experience, 2 J. Legal Analysis 621, 662–663 (2010) [hereinafter RAMSEYER, Malpractice Claims] (citing evidence that chart alteration "commonly happens").

24 *Ishi-hō* [Medical Practitioners' Law], Law No. 201 of 1948, Art. 21.

25 Judgment of Supreme Court, 13 April 2004, 58(4) *Keishū* 247. One observer affiliated with the Japan Medical Association contends that "violation of Article 21 serves only as a hook for the [criminal] investigation of professional negligence resulting in death." R. SAWA, A Healthcare Crisis in Japan: Criminalizing Medical Malpractice, 51 Japan Med. Ass'n J. 235, 240 (2008).

the concomitant (if variable and sporadic) police oversight of medical practice, generated intense controversy.

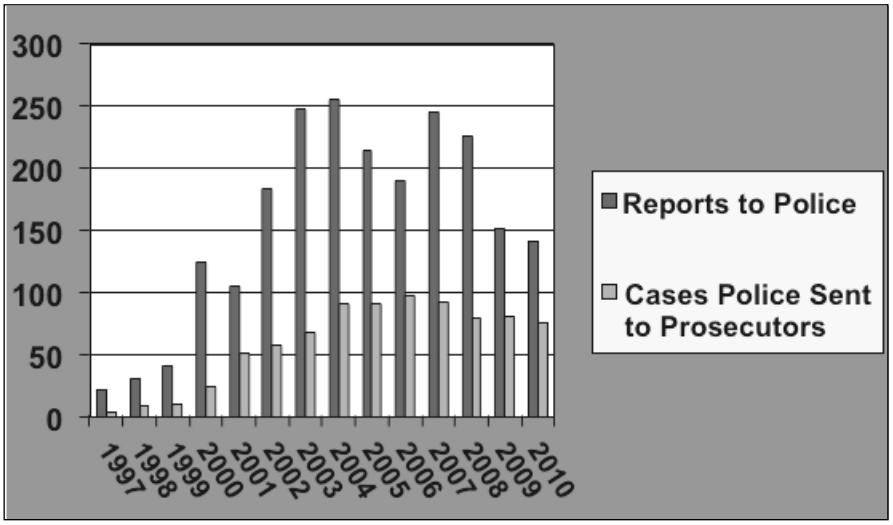

Fig. 1: Medical accidents reported to police; cases police sent to prosecutors, 1997–2010.[26]

Critics of the criminal justice system's involvement in monitoring medical mistakes raise concerns relating to police lack of medical expertise, disruption of patient care by criminal investigations, disproportionality of criminal sanctions to the inadvertence typical of lapses in care, and criminal law's tendency to focus on individual blame rather than addressing more significant problems of system failure.[27] Even granting the substantial merit of these criticisms, criminal law's prominence in regulating medical quality in the early years of this century is understandable in light of these factors: (1) public expectation that the criminal justice system's protective reach does not stop at the hospital doors; (2) police and prosecutors' commitment to professional duty in enforcing the criminal code, applicable by its terms to medical personnel as to everyone else; and (3) the need in a democratic society for public accountability of the medical profession for its errors, a need not adequately fulfilled in Japan by professional self-regulation, administrative oversight, the death inquest system, or civil litigation.

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26 NAT'L POLICE AGENCY, *Iryō jiko kankei todokede-tō kensō no idō, rikken sōchisū* [Trends in Reports of Medically Related Cases and of Cases Sent to Prosecutors] (8 August 2011), reported in: *Iryō jiko todokede genshō tsuzuku; Keisatsu rikken mo 7.4%-gen* [Decline in Medical Accident Reports Continues; Cases Sent to Prosecutors also Decrease 7.4%], Nihon Keizai Shinbun (Aug. 8, 2011) [hereinafter Police Reports on Medical Cases].

27 See LEFLAR, Unnatural Deaths, *supra* note 13, at 14 & n. 53 (summarizing criticisms).

2. Response by the Health Ministry and the Medical Profession

The Ministry of Health, Labor & Welfare (MHLW) had given short shrift before 1999 to patient safety issues. In reaction to the controversy over highly publicized medical errors, the ministry, beginning in 2000, created a small patient safety office, drafted guidance manuals for hospitals to designate risk management staff, set up adverse event tracking systems and review committees,[28] established local "medical safety support centers" to handle patients' complaints and questions,[29] required a class of large specialized hospitals to make reports to a quasi-public entity of accidents causing harm,[30] and launched a study of the incidence of adverse events in Japanese hospitals. In this study 4,389 records were randomly selected from 18 top hospitals that volunteered to participate. Reviewers employing criteria based on a previous Canadian study[31] found an adverse event rate of 6.8 percent, and concluded that of those adverse events, about 23 percent were preventable.[32]

Troubled by the prospect of police investigations and possible criminal liability while also recognizing the importance of clearer accountability in the handling of medical accidents, four major medical specialty societies proposed to MHLW a new system (independent of the criminal process) to review patient deaths possibly connected to

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28 MHLW, *Iryō jiko jōhō shūshū-tō jigyō* [Medical Accident Information Collection Project], *http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/jiko/index.html*; MHLW, *Risuku maneij-imento manyuaru sakusei shishin* [Guidelines for the Creation of Risk Management Manuals] (2000).

29 The medical safety support centers (*iryō anzen shien sentā*) received statutory authorization in a 2006 amendment to the Medical Services Law, *Iryō-hō,* Art. 6(11).

30 This entity is the Japan Council for Quality in Health Care (*Nihon iryō kinō hyōka kikō*). 273 hospitals are required to report adverse events, and roughly 400 others do so on a voluntary basis. See Japan Council for Quality Health Care, Div. of Adverse Event Prevention, Project to Collect Medical Near-Miss / Adverse Event Information: 2009 Annual Report 22 (2010), available at *http://www.med-safe.jp/pdf/year_report_english_2009.pdf* [hereinafter JCQHC Report]. One suspects that many institutions are less than diligent in performing their reporting obligations from the fact that of the 273 hospitals to which the reporting requirement applied in 2009, sixty-one submitted no reports at all. *Id.* at 25.

For an account of these administrative developments, see LEFLAR & IWATA, *supra* note 12, at 208–210.

31 G. R. BAKER et al., The Canadian Adverse Events Study: The Incidence of Adverse Events among Hospital Patients in Canada, 170 Can. Med. Ass'n J. 1678 (2004).

32 H. SAKAI, *Iryō jiko no zenkokuteki hassei hindo ni kansuru kenkyū* [Report on the Nationwide Incidence of Medical Accidents: III] 5, 18 (2006) (reporting 6.0 percent adverse event rate, later corrected by MHLW to 6.8 percent); See also S. IKEDA ET AL, Identification of Adverse Events in Inpatients: Results of a Preliminary Survey in Japan, 4 Asian Pacific J. Disease Mgmt. 49 (2010) (preliminary study reporting 11.3% adverse event rate). Estimates of annual preventable iatrogenic deaths were not given.

Since hospitals experiencing serious quality difficulties were likely underrepresented in the study, the results cannot be deemed representative of Japanese hospitals as a whole.

medical management, inform the parties of facts found, and suggest preventive measures. The health ministry, understaffed and eager to demonstrate progress in addressing patient safety issues, agreed to fund a "Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths." The Model Project, launched in four urban regions in 2005 for an initial term of five years and now continuing on an extended basis in ten regions, is aimed at conducting impartial, high-quality peer reviews of possibly iatrogenic hospital deaths by experts unaffiliated with the hospital in question.[33] Findings are reported to both the family and the hospital; a summary is made public, with names of the patient, medical staff, hospital, and location redacted; and suggestions for prevention of recurrences are offered. The Ministry of Justice and the National Police Agency gave up none of their jurisdiction over medical crime but acquiesced in the Model Project's operation, for the most part holding back from criminal investigations and prosecutions in the regions in which the project operated.[34]

Results from the Model Project are mixed. On the one hand, case uptake and review efficiency have not met expectations. Cooperation from hospitals in participating regions has been uneven – fewer than 100 cases were submitted for review during the project's initial five-year period – and despite the low numbers, delay in issuing case findings has been common.[35] On the other hand, the quality of case reviews has likely been superior to most internal hospital reviews conducted prior to the project's inception, and the project's method – bringing together physicians, nurses, attorneys, academics, and health bureaucrats working toward common goals – has probably improved interdisciplinary cooperation in a society still hierarchically structured, each field generally in silo-like separation from the others.

Data collection and analysis for the Model Project and for the health ministry's other adverse event reporting systems are undertaken by the Japan Council for Quality Health Care (JCQHC), a quasi-public entity that also performs hospital accreditations.[36] To some extent, JCQHC's information dissemination efforts have aided the objective of improving health care quality by encouraging medical facilities' experience-based

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33 See *Nihon iryō anzen chōsa kikō* [Japan Medical Safety Research Organization], *Shinryō kōi ni kanren-shita shibō no chōsa bunseki moderu jigyō* [Model Project for the Investigation & Analysis of Medical Practice-Associated Deaths], *http://www.medsafe.jp*.

34 For a detailed overview of the Model Project, see LEFLAR, Unnatural Deaths, *supra* note 13, at 31–39.

35 Reasons for the low case uptake include physicians' unfamiliarity with the case review process, rules that the process be invoked by hospitals not families, limitation of the Model Project to death cases (excluding nonfatal injuries), and a shortage of pathologists to perform the needed autopsies. See LEFLAR, Unnatural Deaths, *supra* note 13, at 36–39; N. NAKAJIMA et al., Interim Evaluation of the Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths in Japan, in: J. Med. Safety 34 (Union of Risk Management for Preventive Medicine 2009).

36 See JCQHC Report, *supra* note 30, for a description of the information collection program.

learning. However, despite the public's enormous appetite for medical information, neither the health ministry nor JCQHC has made available much hospital-specific health outcomes information.[37] Transparency regarding statistics about adverse events in health care is still a distant goal.

Building on the Model Project's structure, the health ministry and the then-governing Liberal Democratic Party offered a proposal in 2008 essentially to expand the project's methods nationwide, setting up what would have amounted to a national structure for peer reviews of questionable hospital deaths, independent of the criminal justice system. Both patients' rights groups and the Japan Medical Association – usually divided by distrust – supported the proposal. However, the proposal was attacked by a well-organized chorus of antiregulatory critics within the medical profession. These critics were concerned that external reviews of hospital adverse events would be overly centralized and cumbersome,[38] that the Article 21 "unnatural death" reporting requirement would not be abolished, and that police would not be entirely removed in all cases from the monitoring of medical practice. The opposition Democratic Party of Japan issued its own proposal, somewhat closer to the position of the antiregulatory critics.[39] Many thought that the two proposals had enough in common that a compromise could be hammered out. But after the Democratic Party of Japan swept into power after the Summer 2009 elections, other issues took political precedence, among them Japan's continued economic slump and, most recently, the nation's response to the disastrous earthquake, tsunami, and nuclear power plant meltdown of March 2011 in northeast Japan. At this writing (June 2013), however, a new version of a national peer review system is back under consideration. A health ministry advisory group has proposed a system of internal hospital reviews of in-hospital deaths backed up by outside expert reviewers when

37 The health ministry does require hospitals to report the number of operations they conduct annually for various specified procedures. Media outlets obtain this information and compile rankings of hospitals by procedure volume. See, e.g., *Shujutsu-sū de wakaru ii byōin* [Telling Good Hospitals from the Number of Operations] (Shūkan Asahi ed., 2010); *Iryō to kango* [Medical and Nursing Care], in: Yomiyuri Shinbun (2008), updated version available at *http://www.yomiuri.co.jp/iryou/medi/jitsuryoku.* For an analysis based in part on these reports, see J. M. RAMSEYER, Universal Health Insurance and the Effect of Cost Containment on Mortality Rates: Strokes and Heart Attacks in Japan, 6 J. Empirical Legal Stud. 309 (2009) (concluding that price controls diminish availability of sophisticated care, costing lives).

38 Or perhaps too embarrassing. Most physician critics of the health ministry proposal seemed to this observer to be hospital-based, while the JMA, which supported the proposal, chiefly represents smaller doctor-owned clinics. The health ministry proposal would have impacted hospitals far more than clinics.

39 For an explanation and analysis of the two rival proposals, see LEFLAR, Unnatural Deaths, *supra* note 13, at 39–48.

requested.[40] If the Liberal Democratic Party regains control of both houses of the Diet as expected, a political climate favorable to such a proposal would be created.

3. One Prosecution Too Many: The Medical Professionals' Counterattack and the String of Acquittals

Police led obstetrician Katsuhiko Katō in handcuffs out of Ohno Hospital in rural Fukushima prefecture in 2006, after belatedly learning of the 2004 death of one of his patients subsequent to a particularly difficult childbirth. The reaction against Dr. Katō's humiliating arrest (broadcast on national news), detention, and prosecution was intense: petitions and remonstrances poured into the National Police Agency from medical organizations across the country.[41] The fervor of this reaction launched a movement led by physicians employing the slogan "*iryō hōkai*" – "the collapsing health care system."

The "*iryō hōkai*" movement has engineered a significant shift in public opinion. The movement's proponents have called editorial and political attention to the shortage of physicians willing to attend childbirths, particularly in rural areas, and to repeated instances of hospital emergency rooms turning away ambulances for fear of liability exposure.[42] As one chief cause of these problems, the movement has targeted alleged abuses of the criminal justice system, much as medical "tort reformers" attack the civil justice system in the United States. To be sure, other factors have contributed to Japan's shortages in obstetrical care, such as the adoption of a residency matching system undercutting traditional hierarchical job placement practices that once ensured a supply of young physicians to smaller hospitals. Nevertheless, the Ohno Hospital prosecution served as an effective rallying point for critics of the criminal justice system's medical oversight role. The "*iryō hōkai*" movement offers sympathetic portrayals of the plight of overworked, harassed, underappreciated physicians and the importance of protecting them from overreaching prosecutors. The movement appears to have turned media and public attention away, to a considerable extent, from concerns over medical error.

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40 See *Iryō jiko ni kakaru chōsa no shikumi-tō ni kansuru kihonteki na arikata to ronten* [Fundamental Nature and Issues Regarding the Structure of Reviews of Medical Accidents] (materials distributed at 12th meeting of MHLW advisory subcommittee on review of medical accidents, Tokyo, April 18, 2013).

41 For a listing of the protest petitions, see *Fukushima kenritsu ohno byōin no iryō jiko mondai ni tsuite* [The Medical Accident Problem at Ohno Fukushima Prefectural Hospital], *http://www.med.or.jp/nichikara/fseimei/index.html*.

42 The slogan was apparently coined by physician Hideki Komatsu. See H. KOMATSU, *Iryō hōkai* [The Collapsing Health Care System] (2006). For an account of the causes of morale problems among Japanese physicians and structural difficulties within Japanese medicine, see H. YASUNAGA, The Catastrophic Collapse of Morale Among Hospital Physicians in Japan, 2008 Risk Mgmt. & Healthcare Pol'y 1, available at *http://www.dovepress.com/getfile.php?fileID=3935*.

The "*iryō hōkai*" movement's efforts have borne fruit not only on the editorial pages, but also perhaps in the minds of some of the nation's judges. Acquittals in criminal trials are extremely rare in Japan; more than 99 percent of criminal trials result in convictions.[43] But in four successive recent cases, including Dr. Katō's prosecution, medical personnel were acquitted of all charges, and in the two cases that prosecutors appealed,[44] the acquittals were affirmed.[45]

This series of acquittals, in the wake of medical society protests against physicians' arrests, constitutes a major public embarrassment for Japan's procuracy. Police and prosecutors have been further embarrassed by the recent arrests for unprofessional conduct of a top detective in the medical investigation unit of the Tokyo police force[46] and of a top prosecutor for altering evidence in the unsuccessful prosecution of a health ministry official for alleged corruption.[47] These acquittals and scandals, in the author's view, mark a watershed point in Japanese medical jurisprudence. Henceforth, police and prosecutors will be considerably more cautious in targeting health care personnel.[48] Pressures for medical quality improvement must come chiefly from other directions.

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43 See J. M. RAMSEYER & M. NAKAZATO, Japanese Law: An Economic Approach 178 (1999) (overall conviction rate in 1994 of 99.9 percent).

44 Japanese appellate procedure allows prosecutors to appeal not-guilty judgments on grounds of both fact and law without violating the double jeopardy principle. See *id.* at 175.

45 Judgment of Fukushima Dist. Ct., 20 August 2008, 16 Iryō Kaisetsu Hanrei 20 (Ohno Hospital case) (no appeal); Judgment of Tokyo High Ct., 27 March 2009, aff'g Judgment of Tokyo Dist. Ct., 27 August 2007, 1282 Hanrei Taimuzu 233 (Tokyo Women's Medical U. Hospital heart surgery case); Judgment of Nagoya Dist. Ct., 27 February 2007, 1296 Hanrei Taimuzu 308 (obstetrics case) (no appeal); Judgment of Tokyo High Ct., 20 November, 2008, 1304 Hanrei Taimuzu 304, aff'g Judgment of Tokyo Dist. Ct., 28 March 2006 (Kyorin U. *waribashi* [chopstick] case).

46 See, e.g., "Current, Former Cops Arrested over Info Leak," Daily Yomiuri, 23 July 2011, at 1 (arrest of Lt. Shirotori for leaking police documents to cosmetic surgery hospital under investigation for alleged case of fatal malpractice).

47 See "Lead Prosecutor in Muraki Case Arrested; Maeda Admits Tampering with Seized Floppy Disk," Japan Times, 22 September 2010, at 1, available at *http://search.japantimes.co.jp/print/nn20100922a1.html;* "Prosecutors Face Reforms, Restructuring," Daily Yomiuri, 13 August 2011, at 15 ("unprecedented crime" committed by special investigation squad).

48 The number of medical cases police sent to prosecutors peaked in 2006, the year of the Ohno Hospital arrest and subsequent protests, and has since diminished somewhat. See *supra* Figure 1. Police investigations of medical crimes have not ceased, however, and prosecutions continue to be brought. In 2010 police sent papers to prosecutors in seventy-five medical cases, down from the peak of ninety-nine in 2006. See Police Reports on Medical Cases, *supra* note 26; "Lasik Surgeon Held over Infections; Unsanitary Procedures, Lack of Sterilization Alleged at Defunct Ginza Clinic," Daily Yomiuri, 8 December 2010, available at *http://www.yomiuri.co.jp/dy/national/T101207004781. htm?ref=dyolwsj.*

III. CIVIL LIABILITY

Compared to the specter of criminal prosecution with its career-shattering effects, civil liability for medical injury has probably been less worrisome to Japanese physicians in recent years. Civil malpractice insurance is cheap,[49] and in any case hospital-employed physicians – 64 percent of the total number of doctors[50] – are covered by their hospitals' liability insurance policies. Nevertheless, civil liability trends are a matter of concern to the medical profession.

The number of civil claims filed in court far exceeds the number of criminal prosecutions,[51] and rose steadily from the 1980s until the peak year of 2004, following which court filings have declined (Figure 2). In addition, the number of claims settled out of court is doubtless a substantial multiple of the number of court filings.[52]

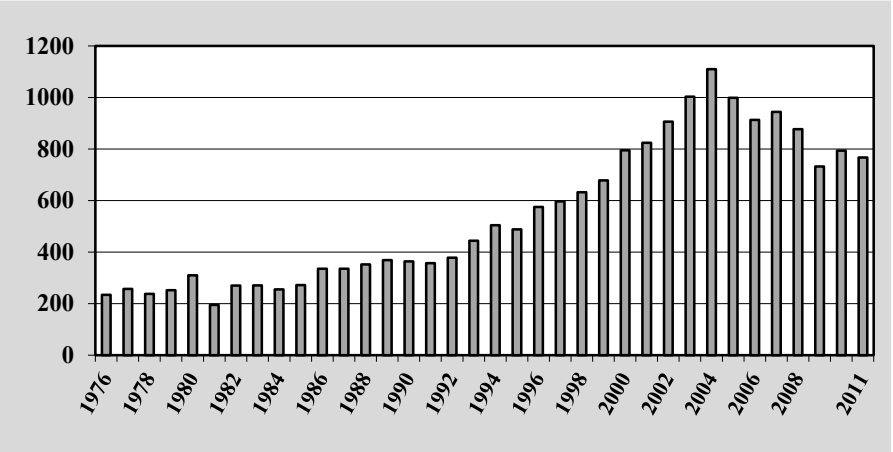

Fig. 2. Medical Malpractice Civil Cases Filed in Court, 1976–2011.[53]

This section of the article first sets out the salient doctrinal features of the substantive civil law of compensation for medical injury. The article then addresses key aspects of

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49 See *infra* notes 116–122 and accompanying text.

50 See YASUNAGA, *supra* note 42, at 2 (2006 data).

51 In 2003, for example, seventeen prosecutions were brought against physicians. See T. HIYAMA et al., The Number of Criminal Prosecutions Against Physicians Due to Medical Negligence Is on the Rise in Japan, 26 Am. J. Emergency Med. 105 (2008). In the same year, 1,003 civil malpractice cases were filed. See *infra* note 56.

52 Rough estimates of the number of settlements are given below. See *infra* notes 106–112 and accompanying text.

53 The Administrative Office of the Supreme Court compiles the yearly number of new medical malpractice filings. See Supreme Court of Japan, *Iji kankei soshō jiken no shori jōkyō oyobi heikin shinri kikan* [Disposition of Medically Related Litigation and Mean Durations of Proceedings] [hereinafter Supreme Court Medical Malpractice Case statistics], *http://www.courts.go.jp/saikosai/ about/iinkai/izikankei/toukei_01.html*.

procedural law and practice, including the institution of health care divisions of trial courts in some metropolitan areas, practices relating to case settlement, estimates of the total numbers of malpractice claims (in court and out) and of medical malpractice premiums and payouts, and information on court filing fees and plaintiffs' attorneys' compensation practices. Finally, the new system for no-fault compensation of certain obstetrical injuries is described.

4. Substantive Law of Medical Malpractice

a) Theories of Recovery

Civil claims for medical injury may be brought under either the Civil Code provision governing tort[54] or the provision governing nonperformance of contract,[55] and there are many examples of each. As a practical matter it generally makes little difference under which theory a claim is brought, for the standards and principles applied are the same in either case. The plaintiff must prove in contract cases a breach of the physician's or hospital's obligation, which is equivalent to proving a breach of the applicable standard of care in tort. In most cases, the plaintiff must prove under either theory that the breach caused ascertainable damages.

b) Standard of Care

The Supreme Court has expressed the legal standard of care to which physicians are held as "the standard prevailing in clinical medical practice at the time of treatment."[56] Physician custom is not invariably congruent with the legal standard of care, however. The Supreme Court has recognized that sometimes adherence to the custom of average medical practitioners does not fulfill the duty of care, as when a defendant doctor, following general practitioners' common practice of ignoring an anesthetic drug's labeled directions for use, failed to monitor the patient's blood pressure in timely fashion.[57]

Japanese courts hold large, sophisticated hospitals and their physicians to a higher standard of care in some respects than doctors in small clinics lacking equivalent resources. To quote the Supreme Court's 1995 decision in a celebrated case involving a premature infant's blindness from retinal injury, in determining the applicable standard of care the court "must consider various circumstances such as the nature of the [defen-

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54 Civil Code, Art. 709, General Principle of Tortious Act: "A person who violates intentionally or negligently the right of another is bound to make compensation for damage arising therefrom." H. ODA, Basic Japanese Laws, 146 (1997).

55 Civil Code, Art. 415, Claim for Damages for Non-Performance: "If an obligor fails to effect performance in accordance with the tenor and purport of the obligation, the obligee may claim damages …" *Id.* at 98.

56 Judgment of Supreme Court, 30 March 1982, 1039 Hanrei Jihō 66, 106.

57 Judgment of Supreme Court, 23 January 1996, 50 Minshū 1, 1571 Hanrei Jihō 57 (perukamin-S case).

dant] facility and the distinctive characteristics of the region's medical environment."[58] This is taken to mean that the standard of care expected of a medical facility and its personnel depends on the facility's size and function.[59] The standard of knowledge (*chiken*) expected of physicians depends on their specialty; non-specialists in a field are not held to the same standard as specialists.[60] However, if a physician or facility is unable to treat a patient's particular condition, whether due to lack of knowledge, skill, or resources, the care provider comes under a legal duty to transfer the patient to a facility that offers the requisite level of services.[61]

c) Level of Proof

The level of proof required of plaintiffs on breach of duty and causation is "a high degree of probability" (*kōdo no gaizensei*).[62] The phrase suggests a level of confidence somewhat higher than the "preponderance of the evidence" standard prevailing in civil cases in common law jurisdictions.[63] Neither the Civil Code nor the case law offers an

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58 Judgment of Supreme Court, 9 June 1995, 1537 Hanrei Jihō 3, 883 Hanrei Taimuzu 92 [hereinafter infant retrolental fibroplagia case].

59 See, e.g., T. SUZUKI et al., *Iryō jiko no hōritsu sōdan* [The Law of Medical Accidents] 36–37 (2009) (commentary on infant retrolental fibroplagia case). This approach is somewhat analogous to the resource-based locality rule applied in some US jurisdictions. See, e.g., *Hall v. Hilbun,* 466 So.2d 856 (Miss. 1985) (the leading case on medical standards of care in B. R. FURROW et al., Health Law: Cases, Materials and Problems 327–336 (6th ed. 2008)).

60 The Court recognized, however, that the time required for the diffusion of medical knowledge from one field to another is "relatively short." Infant retrolental fibroplagia case, *supra* note 58, 1537 Hanrei Jihō at 7–8, 883 Hanrei Taimuzu at 97; SUZUKI et al., *supra* note 59, at 37.

61 *Iryō-hō* [Medical Service Law], Law No. 205 of 1948 as amended, Art. 1, para. 4 no. 3; Judgment of Supreme Court, 11 November 2003, 57 Minshū 1466, 1845 Hanrei Jihō 63 (acute encephalopathy case); SUZUKI et al., *supra* note 59, at 42–43.

62 Judgment of Supreme Court, 24 October 1975, Minshū 1417, 792 Hanrei Jihō 3 (lumbar procedure case, addressing proof of causation). See *infra* note 64. The standard is of judicial rather than statutory origin.

The "high degree of probability" standard is expressed clearly by courts with regard to causation issues, but less clearly with regard to proof of breach of the duty of care. Judges, lawyers, and academics have suggested to the author that in practice, judges actually decide breach-of-duty issues on something like a preponderance standard, but write their opinions as though the evidence as to whether the breach of duty was established was clearly convincing.

63 See T. KOJIMA, Japanese Civil Procedure in Comparative Law Perspective, 46 U. Kan. L. Rev. 687, 708 (1998) ("[M]ere proof by a preponderance of the evidence is not enough.").

Just what "a high degree of probability" means is a matter of debate. Kevin Clermont, while recognizing the existence of controversy, has argued that the standard of proof in Japanese civil cases "requires that facts be proven to a high probability *similar to beyond a reasonable doubt*." K. M. CLERMONT, Standards of Proof in Japan and the United States, 37 Cornell Int'l L.J. 263, 263 (2004) (emphasis added). He linked the Japanese standard to the *intime conviction* standard employed in French civil law. This writer's interviews with

exact prescription of how judges are to decide closely balanced issues of fact. Regarding causation, the Supreme Court has stated that at least something less than a scientific standard of certainty will suffice.[64] The author's interviews with numerous trial judges, from several courts and encompassing the range of judicial seniority, reveal not so much a contrariety of opinion regarding the standard as an insistence that flexible case-by-case determinations are needed.

The ambiguity of the standard of proof inevitably follows from the need for discretion in addressing the subtle factual circumstances presented by many injury claims, and relates both to institutional concern with preserving the court system's legitimacy and to trial judges' personal desire for "cover" when their judgments are reviewed on appeal. Just as US judges, sending factually controverted cases to juries, are disburdened by the lenient standard of appellate review of juries' factual findings, so Japanese trial judges take a certain comfort in the degree of deference that appellate courts usually allow the trial judges' determinations (sometimes written, perhaps, with the same enhanced certainty of an umpire's emphatic call of a close play at the plate) of whether plaintiffs' proofs met the "high degree of probability" standard.[65]

Japanese judges indicate, however, that Clermont's characterization of the Japanese proof standard as "similar to beyond a reasonable doubt" is too stringent.

Ramseyer and Nakazato, relying on an old Tokyo District Court case, fell into the opposite error regarding malpractice claims based on tort. They stated that "[a]lthough tort plaintiffs must usually prove causation and lack of care, in malpractice cases courts deliberately switch the burden. As a result, to defend, a doctor will need to show that he met the standard set by other doctors in his specialty in his community." RAMSEYER & NAKAZATO, *supra* note 43, at 67 (citing Judgment of Tokyo Dist. Ct., 7 June 1967, 485 Hanrei Jihō 21, 25–26). The authors apparently took an atypical case involving facts allowing for a res ipsa-like presumption of negligence, and generalized its ruling to apply to all tort-based malpractice cases. Ramseyer corrected the error in a subsequent article. RAMSEYER, Malpractice Claims, *supra* note 23, at 673–674.

64 See Judgment of Supreme Court, 24 October 1975, 29 Minshū 1417 (lumbar procedure case). Reversing the Tokyo High Court's finding of no proof of causation, the Supreme Court stated:

Proof of causation is to be established not by the standard of natural science admitting of no doubt, but rather by an overall examination of the totality of evidence informed by common experience (*keikensoku ni terashite*). Where specific facts can be shown to have brought about specific results with a high degree of probability (*kōdo no gaizensei*), such that ordinary people could hold a doubtless assurance of the fact of the [causal] relationship, that constitutes necessary and sufficient proof of causation.

Id. at 1419–20. The logically muddled nature of this pronouncement is aptly discussed in S. YONEMURA, *Runbāru shikō-go no nō-shukketsu to inga kankei* [Causation and Cerebral Hemorrhage Following Lumbar Procedure], 183 Jurisuto 154 (2006) (case commentary).

65 Kevin Clermont advanced a similar point in a recent essay. K. M. CLERMONT, Standards of Proof Revisited, 33 Vt. L. Rev. 469, 473 (2009). Appellate review of lower courts' factual findings, however, is more rigorous in Japan than in the United States. The High Court will accept additional evidence on appeal, which may supplement or contradict the District

The potential rigor of the "high degree of probability" standard is also mitigated in three other ways: (1) the application of a res ipsa-like rebuttable presumption of negligence where the facts warrant it;[66] (2) the adoption of "loss of chance" doctrine to justify partial compensation where negligence is proven but its causal consequences are difficult to ascertain;[67] and (3) judges' common practice of pressuring attorneys to settle for partial compensation cases in which negligence is established but proof of causation is hazy.[68]

An indication that Japanese jurisprudence has moved toward a less rigorous stance regarding proof burdens is the 2000 Supreme Court case recognizing a "loss of chance" remedy for negligent failure to diagnose and treat a malady for which timely diagnosis and treatment would have afforded the patient a "considerable possibility" (*sōtō no kanōsei*), but not a "high degree of probability" (*kōdo no gaizensei*), of survival.[69] Given that the preservation of life is a "fundamental value" worthy of legal protection, the Court ruled that the value's invasion by an act of medical negligence required a legal remedy.[70] The Court later expanded the loss-of-chance principle to encompass cases in which medical negligence was followed not by death but rather by serious impairment, but the level of impairment the patient would have suffered absent negligence was not proven to a high degree of probability.[71] Subsequent cases in the lower courts have adopted a principle of proportionate liability, scaling damages in rough accordance with the percentage possibility of survival or full recovery had the defendant acted with due care.[72]

Court's fact-findings. See *Minso-hō* [Code of Civil Procedure], Art. 296–297; RAMSEYER & NAKAZATO, supra note 43, at 145.

66 See, e.g., SUZUKI et al., *supra* note 59, at 55, 193–194 (explaining *ichiō no suitei* (rebuttable presumption)); S. KATŌ, *Iryō kago soshō (I)* [Medical Malpractice Litigation (I)], in: *Minji-hō III* [Civil Law III] 265, 271–273 (K. KAMATA et al. eds., 2005) (same); cf. Judgment of Supreme Court, 23 January 1996, 50 Minshū 1, 1571 Hanrei Jihō 57 (perukamin-S case) (ignoring drug label indications, absent rational reasons, is basis for negligence finding). See also Judgment of Tokyo Dist. Ct. June 7, 1967, 485 Hanrei Jihō 21, 25–26, excerpted in RAMSEYER & NAKAZATO, *supra* note 43, at 67 (early rebuttable presumption case).

67 See *infra* notes 69–71 and accompanying text.

68 Interview with Wataru Murata, C.J. and Nozomu Hirano, J., Tokyo District Ct., 34th Div., in Tokyo (10 August 2010) [hereinafter Tokyo Judges 2010 Interview]; interview with noted plaintiffs' attorney Toshihiro Suzuki and associates, in Tokyo (2 August 2010). See also S. MUTO, Concerning Trial Leadership in Civil Litigation: Focusing on the Judge's Inquiry and Compromise, 12 Law in Japan 23, 28 (1979), reprinted in: MILHAUPT, RAMSEYER & WEST, *supra* note 7, at 185, 189–190 (2006) (judge's similar advice to trainee judges in 1979).

69 Judgment of Supreme Court, 22 September 2000, 54 Minshū 2574, 1728 Hanrei Jihō 31 (myocardial infarction case).

70 *Id.* The plaintiff was awarded a solatium (*isharyō*) of ¥2 million (US $18,000).

71 Judgment of Supreme Court, 11 November 2003, 57 Minshū 1466, 1845 Hanrei Jihō 63 (acute encephalopathy and failure-to-transfer case).

72 Damages may be awarded even if the patient's chance of survival or full recovery was less than 50 percent. Tokyo Judges 2010 Interview, *supra* note 68; interview with Yoshio Katō, noted plaintiff's attorney, in Nagoya (26 July 2010).

d) Informed Consent and Related Actions

Apart from the duty to provide medical care meeting legal standards, physicians also have a duty to obtain from patients what has come to be called (for lack of any equivalent expression in standard Japanese) *infōmudo konsento*. Adapting the Western concept of patient autonomy to established customary patterns and departing from a line of previous cases granting high deference to medical custom, Japanese courts came to recognize that in some circumstances traditional principles of medical ethics, according precedence to the duty to save human life at all costs, must give way to patients' sometimes contrary personal values.[73] A leading Supreme Court case recognizing this principle affirmed a damage award to a Jehovah's Witness who was given a blood transfusion despite her contrary expressed intent. Although the procedure was medically successful – she survived her cancer far longer than was predicted – the Supreme Court nevertheless affirmed a consolation or solatium (*isharyō*) award for "emotional suffering" of the nominal sum of ¥500,000 (US $5,000).[74] This case constituted Japan's recognition – contrary to US informed consent precedents requiring "decision causation"[75] – that a dignitary interest apart from physical harm is worthy of protection in informed consent cases.

Parallel to the physician's duty to obtain the patient's informed consent before treatment is the physician's obligation to explain accurately the results of treatment, including adverse results. This duty of explanation of treatment outcomes (*benmei gimu*) is held to arise from the patient-physician contractual relationship. The principle has been tested in recent years in cases in which patients and families were not given honest explanations of adverse outcomes, and courts have awarded solatium damages for physicians' breaches of this duty.[76]

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73 Detailed examinations of the development of informed consent theory and practice in Japanese medicine can be found in LEFLAR, Informed Consent, *supra* note 6, and LEFLAR, Renaissance, *supra* note 9.

74 Jehovah's Witness case, *supra* note 7. Excerpts of both the High Court and Supreme Court opinions are translated into English in: MILHAUPT, RAMSEYER & WEST, *supra* note 7, at 347–356.

75 The term "decision causation," indicating the requirement that a plaintiff prove that had risk disclosure been sufficient, the plaintiff would have decided on a different treatment course leading to less physical harm, was coined in A. MEISEL & L. D. KABNICK, Informed Consent to Medical Treatment: An Analysis of Recent Legislation, 41 U. Pitt. L. Rev. 407, 438–439 (1980) and popularized in A. TWERSKI & N. B. COHEN, Informed Decisionmaking and the Law of Torts: The Myth of Justiciable Causation, 1988 U. Ill. L. Rev. 60 (1989). For an argument that deprivation of informed choice should give rise to an action for dignitary harm in US medical negligence and prescription drug litigation, see M. A. BERGER & A. D. TWERSKI, Uncertainty and Informed Choice: Unmasking Daubert, 104 Mich. L. Rev. 257 (2005).

76 For example, in a suit 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 cover-up of the facts. In addition to awarding damages and costs of ¥243 million (US $2.2 million) plus interest on the

e) Damages

Apart from solatium awards for intangible and dignitary injury, damages in Japanese medical malpractice cases are standardized in accordance with injury severity levels as defined in the traffic accident compensation system.[77] Once negligence and causation are determined, the plaintiff is entitled to an award within these fairly definite limits. Punitive damages are not available.[78]

Awards for injury in Japanese medical malpractice cases do not seem to differ radically in amount from awards in other advanced nations, and may exceed them.[79] Mark Ramseyer, drawing on a database of actions filed in 2004, observed that in wrongful death cases, for example, median and mean damage awards were respectively ¥ 37.5 and ¥ 40.6 million (roughly US $350,000 at then-current exchange rates)[80] –

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malpractice counts, the court awarded ¥1 million (US $9,000) for the contract breach. Judgment of Kyoto Dist. Ct., 12 July 2005, 1907 Hanrei Jihō 112, 124–125. See *also, e.g.,* Judgment of Tokyo High Ct., 30 September 2004, 1880 Hanrei Jihō 72; SUZUKI et al., *supra* note 59, at 66.

77 S. OSHIDA, Y. KODAMA & T. SUZUKI, *Jitsurei ni manabu iryō jiko* [A Real-World View of Medical Accident Cases] 20–21 (2002). Pain-and-suffering damages in death cases include awards to surviving family members for their grief, and may be adjusted up or down for unusual circumstances. *Id.* Damage amounts for each level of injury severity are set out in publications available not only to judges, lawyers, and liability insurers, but also to the general public. See, e.g., *Minji kōtsū jiko soshō: Songai baishō-gaku santei kijun* [Civil Traffic Accident Litigation: Computation Standards for Damages] (Tokyo 3rd Bar Ass'n ed., 2006) (generally known as "*Akahon*" ["the Red Book"]). For a description of damage calculations using the Red Book, see E. A. FELDMAN, Law, Society, and Medical Malpractice Litigation in Japan, 8 Wash. U. Global Stud. L. Rev. 257, 266 (2009), originally published as E. A. FELDMAN, Suing Doctors in Japan: Structure, Culture, and the Rise of Malpractice Litigation, in: Engel / McCann (eds.), Fault Lines: Tort Law as Cultural Practice, 233.

Damages of a given level of severity in medical malpractice cases may somewhat exceed those in auto accident cases, perhaps taking into account the additional difficulty of proving malpractice liability. Y. KAWABATA, "Health-Related Litigation and Its Reform Through a Practitioner's Eyes," address at Penn State Dickinson School of Law Freeman Symposium on Health, Law, and Justice in Asia (28 April 2006) [hereinafter KAWABATA, Dickinson Lecture] (plaintiffs' attorney's estimation of 10–20 percent damages bonus in malpractice cases).

78 RAMSEYER & NAKAZATO, *supra* note 43, at 89 n. 53.

79 See LEFLAR & IWATA, *supra* note 12, at 200 & n. 40 (observing similar scale of damages in Japanese and US wrongful death cases). By contrast, Eric Feldman views the Japanese scale of damages as both "more predictable and more modest" than US levels. FELDMAN, *supra* note 77, at 266. A caveat: in performing international comparisons over time of malpractice awards (or anything else), yen-denominated sums have grown considerably, relative to other currencies, concomitantly with the rise in the yen's exchange value.

80 RAMSEYER, Malpractice Claims, *supra* note 23, at 653. Awards ranged from ¥200,000 to ¥189 million (US $2,000–$1.6 million). *Id.* Judges arrive at these damage awards by calculating, in addition to out-of-pocket medical and funeral expenses, the present value of

recoveries higher in real terms than those observed on average in the high-award US jurisdiction of Florida.[81]

Most malpractice claims are settled (either extrajudicially or during the litigation process) or dropped, rather than being tried to judgment.[82] Settlement negotiations in any medical malpractice case depend on assessments by plaintiff and defense counsel of the strength of plaintiff's proof of three elements: (1) negligence, (2) causation, and (3) damages. One result of Japan's standardized damages schedule is that prejudgment negotiations become relatively predictable in respect of the damages element. Not only judges, lawyers, and liability insurers, but hospital management and patients and families as well, have access to the formulas for calculating damage amounts.[83] In many US medical malpractice actions, plaintiffs' and defendants' attorneys' widely varying assessments of the plaintiffs' damages obstruct resolution of the case. In Japan, these valuation conflicts are muted. This is a partial explanation for the lower litigation rates for Japanese medical malpractice claims in comparison with the US.[84]

Patients' medical and rehabilitation expenses resulting from medical misadventure are covered, in the main, by the health insurance programs in which virtually all patients

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the decedent's expected earnings, subtracting almost half of that value for foregone living expenses, and adding a standardized amount for pain and suffering – a method drawn from the standardized evaluation of traffic accident damages. See *supra* note 77. Payments from collateral sources are not included in damage awards. For a helpful summary of the law of damage calculations in tort, see E. OSAKA, Reevaluating the Role of the Tort Liability System in Japan, 26 Ariz. J. Int'l & Comp. L. 393, 395–396 (2009).

81 A study of Florida malpractice awards from 1990–2003 found that the median and mean payments for wrongful death claims were $195,000 and $290,000. N. VIDMAR ET AL., Uncovering the Invisible Profile of Medical Malpractice Litigation: Insights from Florida, 54 DePaul L. Rev. 315, 340 (2005) (tbl. 7). See also LEFLAR & IWATA, *supra* note 12, at 200 (similar analysis).

82 Attorneys experienced in medical malpractice have informed the author that the vast majority of settled claims are never filed in court. See LEFLAR & IWATA, *supra* note 12, at 199–200 n. 35, and interviews, *infra* note 106 (characterizing informally settled claims as "the sunken part of the iceberg"). Of claims filed in court, about 40 percent are litigated to final judgment. RAMSEYER, Malpractice Claims, *supra* note 23, at 625–627; A. HAGIHARA et al., Standard of Care and Liability in Medical Malpractice Litigation in Japan, 65 Health Pol'y 119, 125 (2003).

83 For an example of a damage calculation website for traffic accidents, see *Shōgai isharyō jidō keisanki/bengoshi jitsumu-yō* [Automatic Personal Injury Compensation Calculator for Attorneys' Use], *http://www.asahi-net.or.jp/~zi3h-kwrz/law2consocalj.html*. Damage calculations are informed to some extent by the circumstances of each case, however, so repeat players such as experienced lawyers will have a better sense of likely damages than members of the general public consulting the "Red Book."

84 See J. M. RAMSEYER & M. NAKAZATO, The Rational Litigant: Settlement Amounts and Verdict Rates in Japan, 18 J. Legal Stud. 263 (1989) (arguing that clear damage guidelines for traffic accident cases promote out-of-court settlements, largely explaining low Japanese litigation rates); RAMSEYER & NAKAZATO, *supra* note 43, at 90–99 (same).

are enrolled. As a legal matter, the insurance programs have a right of subrogation to patients' claims against providers whose negligence necessitated the expenses. As a practical matter, subrogation claims appear to be rare, although they are not unknown in cases of serious impairment where medical and rehabilitation expenses are very high.[85] One reason for their rarity, according to an experienced hospital defense attorney, is that in settled cases the release agreement frequently contains a clause prohibiting the parties from disclosing the settlement or its amount to anyone, even the social insurance entity.[86] If the insurer that covered the patient's medical expenses never learns of the claim or the settlement, and has no hawk-like monitor examining the case, then its subrogation right never comes into play.

5. Key Aspects of Procedural Law and Practice

a) In General

Japanese civil litigation is conducted by professional judges without juries,[87] in keeping with principles of German law introduced in the late 19th century. Typically two or three judges hear each case. Trials take place in sequential hearings over a period of months or years, and attorneys for all parties submit documentary evidence, testimony, and arguments on a scheduled basis during this period.[88] Medical malpractice trials in particular, with their typically complex and controverted facts, have been notorious for their prolonged duration. One infamous case, Dickensian in its protracted length, required twenty years for its ultimate resolution in the Supreme Court in favor of the injured patient.[89]

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85 Interview with Yasushi Kodama, a leading hospital defense attorney, Miyakezaka Sogo Law Offices, in Tokyo (14 August 2010) (giving examples of patients left in a vegetative state). However, in catastrophic injury cases the social insurance system limits patients' self-pay burden to 1 percent of charges over an income-based ceiling (the "high-cost health care expenses system," *kōgaku ryōyōhi seido*). Since collateral source payments (such as those from the social insurance system) are not recoverable under Japanese tort law, patients' recoverable damages – and consequently, the amounts to which health insurers would be subrogated, standing in injured patients' shoes – tend to be much smaller than in most US catastrophic injury cases.

86 *Id.* Kodama memorably characterized this phenomenon as "the puzzle of the Sphinx."

87 Under a recently introduced reform, non-professional "lay assessors" (*saiban-in*) sit with professional judges in hearing certain serious criminal cases. *Saiban-in no sanka suru keiji saiban ni kansuru hōritsu* [Act Concerning Participation of Lay Assessors in Criminal Trials], Law No. 63 of 2004, available at *http://law.e-gov.go.jp/announce/H16HO063.html.* See K. ANDERSON & E. SAINT, Japan's Quasi-Jury (Saiban-in) Law: An Annotated Translation of the Act Concerning Participation of Lay Assessors in Criminal Trials, 6 Asian-Pacific L. & Pol'y J. 9 (2005). This new system does not apply to civil cases.

88 See RAMSEYER & NAKAZATO, *supra* note 43, at 139–141 (describing discontinuous trial system).

89 Judgment of Supreme Court, 23 January 1996, 50 Minshū 1, 1571 Hanrei Jihō 57 (perukamin-S case). For a moving account of the case by the plaintiff's attorney, see

Additional criticisms of the medical injury litigation system have centered on inadequate discovery procedures and the difficulty of coping with the allegedly frequent alteration of medical charts by hospital personnel,[90] making it hard for plaintiffs to obtain accurate evidence about adverse events. These criticisms have been answered to some extent by expansion of discovery procedures in a 1998 reform of the Civil Procedure Code[91] and by the routine availability on demand of patient charts through evidence preservation (*shōko hozen*) actions[92] and direct patient requests to the medical facility.[93]

b) Discovery of Peer Review Findings

An issue that concerns physicians and hospitals in Japan, as it does in the United States, is the availability for litigation purposes of peer reviews of adverse events. Such reviews have become more common in the past decade pursuant to guidance issued by the health ministry,[94] and are standard procedure in cases handled by the Model Project.[95] Three legal grounds support at least partial release of peer review documents: (1) national and local Freedom of Information rules applicable to public hospitals;[96] (2) an implied contractual obligation of hospitals to investigate medical accidents and report the results to patients and families;[97] and (3) liberalized discovery procedures under the revised Civil Procedure Code.[98] In a leading case interpreting the new discovery rules, the Tokyo High Court ruled that the portion of the hospital report containing fact-gathering

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Y. KATŌ, *Kyūsai shisutemu ga jiko bōshi ni kinō suru* [Remedial Systems Prevent Accidents], 18 Iji Hōgaku [Journal of Medical Law] 94, 98–99 (2003).

90 See ISHIKAWA, *supra* note 23 (setting out examples of altered medical charts); RAMSEYER, Malpractice Claims, *supra* note 23 (noting that the practice "commonly happens").

91 Civil Procedure Code, Art. 220 (recognizing general principle of discoverability of specifically identified documents, with some exceptions). See S. OTA, Reform of Civil Procedure in Japan, 49 Am. J. Comp. L. 561 (2001); T. 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).

92 See Minso-hō [Code of Civil Procedure], Art. 234–242 (authorizing and governing evidence preservation actions) (English translation available at *http://www.japaneselawtranslation.go.jp/ law/?re=02* (input "Code of Civil Procedure")).

93 See NIHON ISHI-KAI [Japan Medical Ass'n], *Ishi no shokugyō rinri shishin* [Physicians' professional ethics guide] § 2(7) (2008 rev. ed.), available at *http://dl.med.or.jp/dl-med/teireikaiken/20080910_1.pdf* (recognizing physicians' duty to disclose medical records). The Japan Medical Association expanded its view of patients' right of access to their medical records following the enactment of the Law Concerning the Protection of Personal Information, Law No. 57 of 2003, effective in 2005.

94 See LEFLAR & IWATA, *supra* note 12, at 205–206 (citing guidance documents).

95 See *supra* notes 33–35 and accompanying text.

96 See Information Disclosure Law, *supra* note 8.

97 See, e.g., Judgment of Kyoto Dist. Ct., 12 July 2005, 1907 Hanrei Jihō 112, 124–125. See *also supra* note 76 and accompanying text.

98 See LEFLAR & IWATA, *supra* note 12, at 206–213.

interviews with hospital personnel was non-disclosable in order to protect interviewees' "free formation of ideas," but the portion of the report containing "objective" conclusions about the patient's course, the causes of her death, and proposed corrective measures must be disclosed.[99] Experienced defense attorneys routinely advise hospital clients to prepare for disclosure of anything that goes into such case reports.[100]

c) Judicial Administration Reforms

Responding to criticisms of excessive delays in medical malpractice litigation, the Supreme Court's administrative office instituted several reforms aimed at improving the celerity and efficiency of the judicial process. The most noteworthy of these reforms were (1) clearly delineated time-lines for trials;(2) concentrated evidence gathering; (3) the use of judge-appointed expert witnesses; and (4) the creation of health care divisions (*iryō shūchūbu*) in some metropolitan district courts. The first three reforms were launched in 1998, at the time of a reform of the Civil Procedure Code. The health care divisions began operating in 2001.[101]

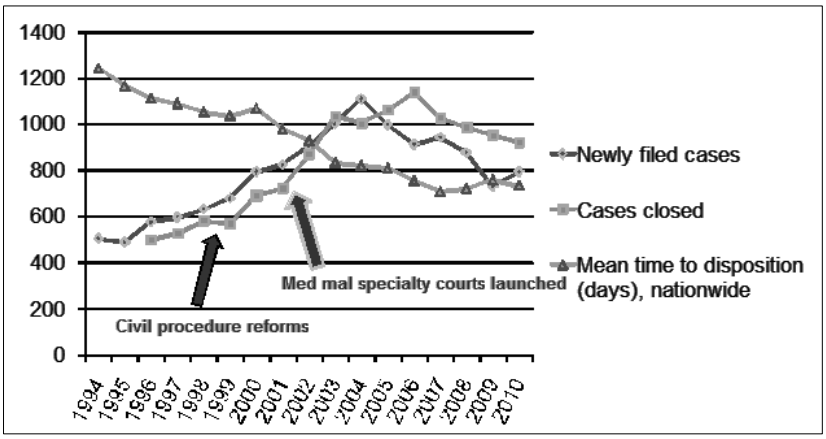

Fig. 3: Disposition of Medical Malpractice Civil Cases Filed in Court, 1994–2010.[102]

As Figure 3 indicates, the duration of litigated medical cases began declining even before these reforms were launched, but the reforms appear to have succeeded in further reducing litigation delays.

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99 Judgment of Tokyo High Ct., 15 July 2003, 1842 Hanrei Jihō 57, 1145 Hanrei Taimuzu 298 (Saitama Medical University case).

100 Tokyo Judges 2010 Interview, *supra* note 68; interview with Yasushi Kodama, a leading hospital defense attorney, Miyakezaka Sogo Law Offices, in Tokyo (30 July 2010).

101 For discussions of these reforms, see FELDMAN, *supra* note 77, at 273–275; R. B LEFLAR, Public and Private Justice: Redressing Health Care Harm in Japan, 4 Drexel L. Rev. 243–264 (2012).

102 Supreme Court Medical Malpractice Case Statistics, *supra* note 53.

d) Settlement Practices, Overall Claiming Levels, and Malpractice Insurance Premiums

Malpractice case filings in court, set out in Figure 2 above,[103] represent only a fraction of all medical injury claims made by patients and paid by medical providers or their liability insurers. Extrajudicial dispute resolution is encouraged both by law[104] and through the activities of entrepreneurial academics.[105] What proportion of all medical injury claims is filed in court is difficult to ascertain, since insurers are famously close with their payout data. Three leading Tokyo attorneys, one representing hospitals, one the Japan Medical Association, and the third plaintiffs, all suggested to the author that court-filed claims constitute merely the "tip of the iceberg" of all claims.[106]

Mark Ramseyer has constructed a useful range of estimates of overall medical malpractice claiming levels, including claims not filed in court, from three sources: (1) court statistics, (2) insurance premiums, and (3) informed observer estimates.[107] Court claims data are firm: 1,110 malpractice claims were filed in court nationwide in 2004, for example, or one lawsuit per 115,000 Japanese residents.[108] Insurance premium data are less precise, and require somewhat speculative manipulations.[109] Estimates from

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103 See *supra* note 53 and accompanying figure.

104 *Saiban-gai funsō kaiketsu tetsuzuki no riyō no sokushin ni kan-suru hōritsu* [Law for the Promotion of the Use of Extrajudicial Dispute Resolution Procedures], Law No. 151 of 2004, as amended, available at *http://law.e-gov.go.jp/announce/H16HO151.html.*

105 See e.g., Y. WADA & T. NAKANISHI, *Iryō konfurikuto manejimento: medieishon no ronri to gihō* [Medical Conflict Management: Mediation Theory and Skills] (2006); Y. WADA, *Iryō ADR* [Medical ADR] (2009).

106 Interview with Yasushi Kodama, a leading hospital defense attorney, Miyakezaka Sogo Law Offices, Tokyo, and Tatsuo Kuroyanagi, Kuroyanagi, Kaneko & Iwamatsu Law Office, Tokyo, in Naha, Okinawa (25 February 2006); interview with Yoshiharu Kawabata, Kasumigaseki Sogo Law Offices, in Tokyo (27 July 2009) [hereinafter Kawabata interview]. Similarly, a 2001 study estimated that only 8 percent of malpractice claims are litigated. K. NAKAJIMA et al., Medical Malpractice and Legal Resolution Systems in Japan, 285 J. Am. Med. Ass'n 1632, 1635 (2001) (drawing on JMA closed-claim data from 1973–81).

It was once a common practice for physicians and hospitals to offer *mimai-kin*, small gifts of money in token of sympathy, to injured patients and families (whether or not they had legal representation) before any lawsuit was filed. See R. B LEFLAR, Personal Injury Compensation Systems in Japan: Values Advanced and Values Undermined, 15 U. Haw. L. Rev. 742, 749 (1993). That practice has become less common since public distrust of medical skill and probity following the publicized disasters of 1999–2004 made the offering of small *mimai-kin* seem "ridiculous." Interview with Yasushi Kodama, a leading hospital defense attorney, Miyakezaka Sogo Law Offices, in Tokyo (4 August 2011).

107 RAMSEYER, Malpractice Claims, *supra* note 23, at 663–668.

108 See Supreme Court Medical Malpractice Case Statistics, *supra* note 53. The population of Japan in 2004 was about 127 million.

109 Ramseyer estimates that annual malpractice insurance premiums total about ¥69 billion (US $860 million). RAMSEYER, Malpractice Claims, *supra* note 23, at 664. A recent estimate from Sompo Japan, a major liability insurer, puts the total somewhat lower, at ¥41 billion (US $510 million). Sompo Japan Insurance Inc., *Ishi baishō sekinin hoken ni tsuite*

knowledgeable Japanese observers of the claims made / court claims filed ratio, while worthy of respect, are unverifiable.

Employing each of these sources in turn, Ramseyer provides a range of estimates of annual medical malpractice claims in Japan based on 2004 data: between 2,230 and 13,875 total claims per year, *in court and out,*[110] with the likely truth somewhere between. Japan's population is 127 million, so that represents a range of one malpractice claim annually per 9,000 to 60,000 residents. To give international perspective to that range, annual malpractice claims (in court and out) in the US, with its population of about 300 million, were credibly estimated in 2006 as 50,000 to 60,000, that is, one claim per 5,000 to 6,000 residents,[111] or between 1.5 and 12 times Ramseyer's estimated Japanese claiming rate. Annual medical malpractice claims filed in court (not extrajudicially) in 2004 in Canada, with a population of 32 million, amounted to 1,083 claims,[112] or one lawsuit per 30,000 residents, about four times Japan's per capita lawsuit filing rate of one lawsuit per 115,000 residents.[113] A reasonable approximate estimate would be that a Japanese patient is one-fourth to one-sixth as likely to make a claim against a medical provider as a North American patient.[114]

Malpractice liability insurance to cover these claims is provided to clinic physicians in private practice chiefly through private insurance plans organized by national and prefectural medical associations, and to private and many public hospitals through

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[Physicians' Liability Insurance] (3 August 2011) (on file with author). Of this sum, roughly 60 percent is paid out to claimants. RAMSEYER, Malpractice Claims, *supra* note 23, at 664.

110 *Id.* at 667.

111 M. M. MELLO & D. M. STUDDERT, The Medical Malpractice System: Structure and Performance, in: Sage / Kersch (eds.) Medical Malpractice and the U.S. Health Care System (2006) 11, 13, cited in: RAMSEYER, Malpractice Claims, *supra* note 23, at 667.

112 Canadian Health Services Research Foundation, Myth: Medical Malpractice Lawsuits Plague Canada (2006), available at *http://www.chsrf.ca/publicationsandresources/Mythbusters/ArticleView/06-03-01/70e601b8-487a-44d0-b390-4e4a0a453493.aspx*, cited in: RAMSEYER, Malpractice Claims, at 667–668.

113 For an earlier comparison of malpractice claim filing rates in Japan and several Western nations, see NAKAJIMA et al., *supra* note 106, at 1638.

An extensive literature, unnecessary to explore here, seeks to explain the difference in propensity to litigate between Japan and the US. For overviews of the debate, see, for example, J. O. HALEY, Authority without Power: Law and the Japanese Paradox (1991) 108–111; MILHAUPT, RAMSEYER & WEST, *supra* note 7, at 141–176 (2006); A. D. FELD, Culture and Medical Malpractice: Lessons from Japan. Is the "Reluctant Plaintiff" a Myth? 101 Am. J. Gastroenterology 1949 (2006).

114 Adding some credence to this estimate are statistics from major liability insurer Sompo Japan indicating that physician and hospital liability insurance, as a proportion of all casualty insurance, is 0.37 percent in Japan and 1.52 percent in the U.S., approximately a 1 to 4 ratio. See Sompo Japan Insurance Inc., *supra* note 109, at 9 (calculated from figures given in table).

commercial carriers such as Sompo Japan and Tokyo Marine.[115] Private physicians' standard insurance policies come with a ¥1 million (US $13,000) deductible and cover liability up to ¥100 million (US $1.3 million). Standard hospital policies cover the same liability level, but typically with no deductible.[116] Physicians employed by hospitals receive standard coverage under their hospitals' policies, but some physicians purchase additional personal coverage.[117] Excess liability insurance covering large-claim liability above standard policy limits, considered "vitally important" to self-insured hospitals in the US,[118] is available in Japan for liability in the range of ¥100–200 million (US $1.3–$2.5 million). However, there are so few large claims that marketing reinsurance for claims exceeding these amounts is uneconomical.[119]

Liability insurance does not constitute a significant part of ordinary practitioners' daily concerns, although hospital administrators must keep the issue in mind. Liability insurance is regulated nationally by the Financial Services Agency, which has control over rate-setting. For physicians in private practice, premiums are uniform nationwide: ¥70,000 annually (US $875, tax-deductible), with no differentiation based on practice specialty or location.[120] Hospital-employed physicians pay somewhat less.[121] Since a 2004 premium revision, hospitals' insurance premiums, once also uniform, have varied somewhat depending on their bed count and treatment levels. Hospitals insured by the Japan Hospital Federation with more than 500 beds, for example, pay ¥23,160 (US $290)

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115 Some national hospitals and national university hospitals cover liability costs through taxpayer-funded operating budgets or through a quasi-public entity, *Kokuritsu byōin kikō* [National Hospital Organization], rather than by purchasing liability insurance from private firms. See *http://www.hosp.go.jp/* (National Hospital Organization website).

For a useful description of the structure and operation of Japanese malpractice insurance systems at the turn of the 21st century, see NAKAJIMA et al., *supra* note 106.

116 Sompo Japan Insurance Inc., *supra* note 109, at 3–4.

117 RAMSEYER, Malpractice Claims, *supra* note 23, at 664–665; Kawabata interview, *supra* note 106.

118 F. A. SLOAN & L. M. CHEPKE, Medical Malpractice (2008) 247.

119 Interviews with Satoko Nishimura, insurance policy specialist, in Tokyo (19 July and 3 August 2011); see *also* Kodama interview, *supra* note 85 (effect of "high-cost health care expense system" on liability for catastrophic injury).

120 This ¥70,000 premium is charged to JMA members owning clinics or small hospitals. Physicians may also purchase additional insurance to cover the ¥1 million deductible and liability for injuries resulting from non-medical acts, such as slip-and-falls at physician-owned hospitals. This additional insurance sells for ¥8,620 (US $110). Sompo Japan Insurance Inc., *supra* note 109, at 3–4.

121 Non-JMA members (mainly hospital-employed physicians) can purchase a standard policy for ¥55,000 (US $700), and physician trainees for ¥34,000 (US $400). *Id.* These doctors are typically covered by the hospital's liability insurance anyway, so it is unclear to the author why many of them purchase it.

per bed per year, while hospitals with 200–299 beds pay ¥21,536 (US $270).[122] Hospitals' premiums are experience-rated, to some extent;[123] physicians' premiums are not.[124]

e) Plaintiffs' Attorney Fees and Court Filing Fees

One barrier confronting patients considering medical malpractice lawsuits, identified by numerous scholars and critics of the Japanese court system, has been plaintiffs' attorneys' fee structure.[125] In contrast to the United States, in which pure contingent fee arrangements with no up-front payments are standard, in Japan plaintiffs customarily had to pay lawyers a substantial up-front retainer according to a standardized schedule enforced by the bar association, plus a filing fee to the court based on the amount claimed. Together, these payments amounted to the yen-equivalent of several thousand dollars, closing the courthouse door to most seriously injured patients without substantial means.[126] Recent reforms have lowered these barriers somewhat: court filing fees in high-damage cases substantially decreased in 2003,[127] and the bar association

122 *Zenkoku kōshi byōin renmei no byōin baishō sekinin hoken-tō no go-annai* [Japan Hospital Federation Guide to Hospital Liability Insurance] 5–8 (2010); interview with Mitsugu Ikeda, Japan Hospital Federation, in Tokyo (29 July 2010). The Japan Hospital Federation (JHF) includes a selection of public and private hospitals including the Japan Red Cross hospital group. University hospitals carrying out high-risk procedures on a frequent basis, non-JHF members, are reported to pay higher premiums in the range of ¥30,000 (US $375) per bed. See LEFLAR, Unnatural Deaths, *supra* note 13, at 8 n. 28. Smaller hospitals of less than 100 beds, where fewer high-risk procedures are performed, are charged only ¥16,000 (US $200) per bed. Sompo Japan Insurance Inc., *supra* note 109, at 4.

123 Ikeda interview, *supra* note 122; Nishimura interviews, *supra* note 119.

124 Nishimura interviews, *supra* note 119; NAKAJIMA et al., *supra* note 106, at 1635. Claims experience for individual physicians is too limited to warrant the expense of compiling experience ratings. Cf. SLOAN & CHEPKE, *supra* note 118 (explaining limitations of experience rating in the US medical malpractice insurance market). The actuarial difficulty of rating individual physicians' likely future claim exposure is even greater in Japan, with its low litigation rates, than in the US.

125 See, e.g., S. MAEDA et al., The Problems of Medical Malpractice Litigation in Japan: The Significant Factors Responsible for the Tendency of Patients to Avoid Litigation, 3 Legal Med. 56 (2001) 59–61 (retainer and filing fees as significant barriers to litigation); E. A. FELDMAN, Why Patients Sue Doctors: The Japanese Experience, 37 J. L. Med. & Ethics 792, 796–797 (2009) (same); R. B LEFLAR, The Regulation of Medical Malpractice in Japan, 467 Clinical Orthopedics & Related Res. (2009) 443, 445 (same).

126 See MAEDA et al., *supra* note 125, at 61 tbl. 9 (noting start-up fees of ¥3 million – then about US $24,000 – for cases involving minor plaintiffs claiming lifelong earning deprivation). Occasionally patients do file pro se claims, however, and once in a while, they win. *Id.* at 59–60; interview with Shunsuke Funase, successful pro se plaintiff, in Naguri, Saitama-ken (9 August 2009).

127 FELDMAN, *supra* note 125, at 797 n. 45. Filing a claim for ¥10 million (US $125,000) now requires a filing fee of ¥50,000 (US $625); a claim of ¥100 million (US $1.25 million) requires a fee of ¥320,000 (US $4,000). For the current filing fee schedule, see *http://www.courts.go.jp/saiban/ tetuzuki/tesuuryou.html*.

withdrew its attorney fee schedule as contrary to antimonopoly law.[128] Currently, some attorneys handling malpractice cases for plaintiffs offer potential clients a degree of flexibility in payment arrangements. For example, the attorney may charge a fee for preliminary case evaluation smaller than the standard retainer and, if the attorney takes the case, a discounted retainer amount may be paid in installments; or the retainer may be decreased while the attorney's share of the recovery, contingent on success, is increased. A contingency arrangement of 15–25 percent of the total recovery, with various adjustments, is common.[129] Still, most attorneys are said to work within the basic framework of the former customary fee schedule.[130]

IV. THE NO-FAULT COMPENSATION SYSTEM FOR OBSTETRICAL INJURY

Japan has a notable history of enacting no-fault administrative compensation systems providing relief for injured persons apart from that available under the civil law, whose various limitations made compensation in circumstances of high social concern difficult or impossible. These compensation systems include schemes aiding people injured by environmental pollution, vaccinations, adverse drug reactions, infections from biological products, blood transfusions, and asbestos exposure.[131] The most recent of these no-fault administrative compensation systems provides relief to parents of a limited class of newborn infants with severe brain damage.

Birth injury cases are among the most serious in every legal system. Profound brain injuries compounded with lifelong rehabilitative needs add up to enormous potential damages. Obstetricians face the prospect that even a minor slip may subject them and their insurance carriers to vast damage judgments.[132]

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128 KAWABATA, Dickinson Lecture, *supra* note 77.

129 Katō interview, *supra* note 72; Suzuki and associates interview, *supra* note 68. Katō and Suzuki are both leaders of cooperating groups of plaintiffs' attorneys specializing in medical malpractice cases.

130 Katō interview, *supra* note 72; Suzuki interview, *supra* note 68; FELDMAN, *supra* note 77, at 264 & n. 24

131 See OSAKA, *supra* note 80, at 400 (listing laws); T. TANASE, The Role of the Judiciary in Asbestos Injury Compensation in Japan, in: Engel / McCann (eds.) *supra* note 79, 233, 247–248 (noting centrality of administrative compensation rather than private litigation as Japan's "archetype"); A. MORISHIMA & M. SMITH, Accident Compensation Schemes in Japan: A Window on the Operation of Law in a Society, 20 U. Brit. Colum. L. Rev. 491 (1986) (early analysis of development of no-fault systems). This significant phenomenon has received scant attention in many respected English-language treatises on Japanese law. See, e.g., MILHAUPT, RAMSEYER & WEST, *supra* note 7; RAMSEYER & NAKAZATO, *supra* note 43, at 125 & n. 58 (sole mention); ODA, *supra* note 20.

132 The subtleties of the litigation process in a birth-damaged baby case, and their impact on the lives of plaintiffs, defendants, and their attorneys, are set out in memorable fashion in B. WERTH, Damages (2008) (first published1988).

Litigation over birth-related injuries has generated considerable concern among Japanese obstetricians. Among civil malpractice actions, suits over obstetrical injuries have apparently resulted in a higher-than-average proportion of plaintiffs' judgments.[133] Of perhaps even greater concern, prosecutors instituted criminal proceedings in 2006 (intensely publicized, but ultimately unsuccessful) against an obstetrician who lost a patient during a difficult delivery, casting a shadow of fear over the profession and giving impetus to the antiregulatory *iryō hōkai* movement described above.[134]

At the instigation of the Japan Medical Association, the Japan Society of Obstetrics & Gynecology, and the then-governing Liberal Democratic Party, the health ministry initiated a no-fault compensation system for a limited class of obstetrical injuries.[135] Launched on January 1, 2009, the system is modeled in some respects on Florida's neurological injury compensation system.[136] It is administered by the quasi-public Japan Council for Quality Health Care (JCQHC), and is financed through a fixed per-birth levy from the social insurance system paid to private insurance companies that stand to reap profits (or possibly suffer losses) from the system's operation.[137]

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133 See N. UESUGI et al., Analysis of Birth-Related Medical Malpractice Litigation Cases in Japan: Review and Discussion Towards Implementation of a No-Fault Compensation System, 36 J. Obstetrical & Gynæcological Res. 717 (2010) (69 percent of sixty-four cases in database of reported birth defect cases resulted in some recovery); compare RAMSEYER, Malpractice Claims, *supra* note 23, at 626–627 (some recovery in 30–40 percent of all medical malpractice cases litigated to final judgment). It is possible, however, that the publishers' selection of cases to be reported biased the database used by Uesugi et al. in favor of cases in which plaintiffs recovered. See *id.* at 642–644.

134 See *supra*, text pt. I.3.

135 Criteria for compensation are rather strict. Infants must be diagnosed with cerebral palsy of the first or second degree of severity, must weigh more than 2000 grams at birth, and with few exceptions must be born after thirty-three weeks of pregnancy. Infants who die within six months and those whose anomalies are congenital are excluded from compensation. Eligibility determinations are performed by expert panels. The level of compensation is fixed: a one-time payment of ¥6 million (US $75,000), plus ¥24 million (US $300,000) paid out over the first twenty years of the child's life, for a total of ¥30 million (US $375,000) per child. MHLW, *Sanka iryō hoshō seido ni tsuite* [The Obstetrical Compensation System], *http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/sanka-iryou/index.html*.

136 The Florida system, like Virginia's Birth-Related Injury Fund, is a no-fault system for compensation of some serious neurological injuries sustained during or close to childbirth. For an overview of the two systems, see SLOAN & CHEPKE, *supra* note 118, at 280–287.

137 The cash flow is circuitous. Funding for the system is generated by a levy of ¥30,000 (US $375) on each birth. JCQHC collects this amount from hospitals and maternity clinics that choose to participate, and channels the money to the private insurers. The hospitals and clinics in turn collect an identical amount from each expectant mother. By Cabinet Order, the amount of the lump-sum childbirth subsidy that each mother receives from her health insurance plan was increased by the same ¥30,000 at the time the compensation system was launched. See T. TOMIZUKA & R. MATSUDA, Introduction of No-Fault Obstetric Compensation, Health Pol'y Monitor (Oct. 2009), available at *http://hpm.org/survey/jp/a14/4*.

The system's stated goals are to provide prompt compensation, without the need for legal proceedings, to parents of infants suffering cerebral palsy related to brain injuries during childbirth, and to improve the quality of maternal care and prevent future cases.[138]

Of particular note, Japan's obstetrical injury compensation system was instituted in a manner that required no legislation. It is a voluntary system – no childbirth facility is obligated to participate. It is operated outside of government by JCQHC. Social insurance funds finance the system, and no specific legislative appropriation is needed. Parents still have a right to sue medical providers for negligence, as before the system was instituted.

Although it is premature to evaluate the new compensation system, it does appear to have gained traction. Essentially all childbirth facilities in the nation (99.7 percent) have signed up to participate.[139] For births occurring from 2009–2011, the first three years of operation, as of November 2012 the system had received 370 applications for compensation and accepted 336.[140] This appears to exceed by a substantial margin the proportion of cerebral palsy cases compensated by the Florida system.[141] For a recently launched program, the new system seems to be capturing a substantial proportion of cerebral palsy cases. It remains to be seen whether the system's financing will suffice in the long term, but it is running a considerable surplus at present, greatly benefitting participating private insurers (and imposing a substantial cost onto the social insurance system).[142] The new system's effects on the quality of obstetrical care and on malpractice claiming practices remain to be researched.

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138 TOMIZUKA & MATSUDA, *supra* note 137.

139 *Dai-16-kai sanka iryō hoshō seido un'ei iinkai shidai* [Agenda for 16th Meeting of Obstetrical Compensation System Management Committee], at 2 (11 December 2012) (table 1 materials), available at *http://www.sanka-hp.jcqhc.or.jp/pdf/obstrics_meeting_08.pdf.* The high participation rate is chiefly explained by the fact that neither the hospital or clinic, nor the expectant mothers for whose custom the hospitals and clinics compete, bear any financial risk from participation, due to the cost pass-through explained in note 137 *supra*. Interview with Naoki Ikegami, Chair, Dep't. of Health Policy & Management, Keio U. Sch. of Medicine, in Tokyo (8 August 2011).

140 Compensation System Committee Agenda, *supra* note 139, at 4 (table 2).

141 The Florida compensation system, and a similar system operating in Virginia, are reported to be compensating no more than 2 percent of cerebral palsy cases in those states. See SLOAN & CHEPKE, *supra* note 118, at 282. One estimate placed the annual incidence of cerebral palsy cases in Japan at about 630, TOMIZUKA & MATSUDA, *supra* note 137, although it is unclear whether that estimate is based on a disease definition congruent with the standards for compensation applied in the new Japanese system. Supposing the estimate of 630 cases is not far off the mark, and well over 100 of them are accepted for compensation in a year, it is clear that the Japanese system is capturing a far higher percentage of cases for compensation than the Florida system.

142 In 2009, the system's first full year of operation, it collected ¥31.5 billion (US $340 million) in premiums (¥30,000 x 1,054,340 births). Through the end of 2010, the system had accepted compensation claims for ninety-nine applications regarding those 2009 births,

The success or failure of the no-fault obstetrical compensation system may also have implications for the future of Japan's medical malpractice system as a whole. Support for no-fault compensation comes from what some outside observers might consider unlikely quarters. For example, the Japan Medical Association has long espoused the merits of a national no-fault compensation system for medical injures in general.[143] The Japan Federation of Bar Associations has likewise come out in favor of a no-fault system, albeit of a different nature.[144] The Ministry of Health, Labor & Welfare has just launched a blue-ribbon study commission on no-fault compensation for medical injury.[145] Administrative compensation systems based on no-fault principles have a solid grounding in Japanese legal tradition over several decades.[146] If the obstetrical injury compensation system proves successful, it is not beyond contemplation that broad-based support for a general no-fault compensation system for medical injury could emerge.

V. CONCLUSION

Distinctive features of Japanese law and society relating to medical misadventure include the following:

Criminal law: In the early years of the 21st century, after a series of publicized errors at hospitals of high repute focused public attention on slipshod practices and dishonesty

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thereby incurring payment obligations over twenty years totaling just ¥3 billion (99 x ¥30 million, See *supra* note 135) – only a tenth of premiums collected. Compensation System Committee Agenda, July 6, 2011 (8th meeting), at 17.

143 See, e.g., *"Bunben ni kansuru nōsei mahi ni tai-suru shōgai hoshō seido" no sōki jitsugen o* [Toward Prompt Institution of an "Injury Compensation System for Birth-Related Cerebral Palsy,"], 1080 Nichi-i Nyūsu 1 (5 September 2006) (JMA publication quoting former JMA president Tarō Takemi as favoring no-fault compensation for medical injury in 1972), available at *http://www.med.or.jp/nichinews/n180905a.html; Nihon ishikai* [JMA], *Iryō jiko chōsa seido no sōsetsu ni muketa kihonteki teigen ni tsuite* [Basic Proposal for the Establishment of a Medical Accident Investigation System] 15–16 (June 2011) (favoring no-fault compensation system), available at *http://dl.med.or.jp/dl-med/teireikaiken/20110713_2.pdf*.

144 Japan Federation of Bar Associations, *"Iryō jiko mukashitsu hoshō seido" no sōsetsu to kihonteki na wakugumi ni kansuru ikensho* [Proposal Concerning the Establishment and Fundamental Framework of a "No-Fault Compensation System for Medical Accidents"] (2007), available at *http://www.nichibenren.or.jp/library/ja/opinion/report/data/070316_2_000.pdf*. Attorney Yoshio Katō, leader of a distinguished group of plaintiff-side malpractice specialists, has long advocated a no-fault system. See, e.g., Y. KATŌ, The Center for Patient Safety and Medical Victims' Relief: A Plan, *http://homepage2.nifty.com/pcmv/PCMV.html*. Katō has been influential in persuading the bar association to support a no-fault system.

145 *Iryō no shitsu no kōjō ni shi-suru mukashitsu hoshō seido-tō no arikata ni kan-suru kentō-kai* [Commission for the Study of No-Fault Compensation Systems Conducive to Health Care Quality Improvement], *Kaisai yōkō* [Outline of First Meeting] (26 August 2011), available at *http://www.mhlw.go.jp/stf/shingi/2r985200000ln6bl.html* (click first attached file).

146 See *supra* note 136 and accompanying text.

in the medical world, the criminal justice system, amplified by media reportage, sounded a wake-up call to a medical profession previously lacking in accountability mechanisms. The health ministry and organized medicine responded with various measures to improve patient safety; the extent to which those measures may have been effective is unknown. Prosecutors' sometimes-excessive involvement in policing medical quality, however, has recently provoked a reaction from the medical profession eliciting media and public sympathy, perhaps contributing to an unusual string of acquittals of medical defendants, and clipping the prosecutors' wings.

Civil law: Civil Code provisions governing compensation for medical injury are fault-based and do not differ greatly in principle from rules applied in North America and Western Europe. The burden of proof of causation is relaxed in informed consent and loss-of-chance cases. Procedural reforms, including the institution of health care divisions of district courts in some metropolitan areas, have helped speed up the pace of judicial proceedings, once notoriously glacial. Damage awards appear to be at least as high on average as in the United States, at current exchange rates, and are applied on a more consistent, standardized basis than in the United States. The volume of claims filed in court is considerably lower than North American levels, and has declined since the peak year of 2004. Most compensation payments are made outside, not within, the court system. Even so, overall claiming rates are low relative to North American practices. Malpractice insurance premiums, uniform nationwide for physicians in private practice without regard to specialty or geography, are far cheaper than in the United States.

Administrative compensation programs: Building on a tradition of no-fault administrative compensation schemes for people injured by pollution, defective drugs, vaccines, blood transfusions, and asbestos, Japan instituted in 2009 a nationwide no-fault compensation system for infants with severe birth-related brain injuries. Backed by the medical establishment, financed through public funding, administered by a quasi-public entity and offering substantial profit opportunities (as well as a theoretical risk of loss) to private insurers, the new compensation system has already achieved virtually universal buy-in by childbirth facilities hoping for protection from future litigation. Evaluation of the system's operation is still premature but worthy of scholarly attention. Should the obstetrical compensation system prove successful, it may serve as a springboard for the expansion of no-fault principles to cover a wider scope of medical injuries. Both the Japan Medical Association and the Japan Federation of Bar Associations have taken positions favoring a no-fault compensation system of some sort, but the issue remains fraught with political controversy.

SUMMARY

This paper offers a comprehensive overview of Japanese law and practice relating to iatrogenic (medically-caused) injury, with comparisons to other nations' medical law

systems. The paper addresses criminal sanctions for Japanese physicians' negligent and illegal acts; civil law principles of substantive law and related issues of procedure, practice, and liability insurance; and administrative measures including health ministry programs aimed at expanding and improving the quality of peer review within Japanese medicine, and a recently implemented no-fault compensation system for birth-related injuries.

Among the paper's findings are these. Criminal and civil actions increased rapidly after highly publicized medical error events at the turn of the 21st century, peaked from 2004 (civil cases filed) to 2006 (cases police sent to prosecutors), and have since declined. Civil Code provisions of substantive law governing medical injury compensation differ little from rules applied in North America and Western Europe, although the burden of proof of causation is relaxed in informed consent and loss-of-chance cases. Damage awards appear to be at least as high on average as in the U.S., and are applied on a more consistent basis. Procedural reforms, including the institution of health care divisions of district courts in some metropolitan areas, have speeded up the pace of court proceedings.

The new no-fault compensation system for birth-related injuries, offering substantial profit opportunities (as well as a theoretical risk of loss) to private insurers, has achieved virtually universal buy-in by childbirth facilities hoping for protection from future litigation. Evaluation of the system's operation is still premature but worthy of scholarly attention. Should the obstetrical compensation system prove successful, it may serve as a springboard for the expansion of no-fault principles to cover a wider scope of medical injuries – a topic now under study.

ZUSAMMENFASSUNG

Der Beitrag gibt einen Überblick darüber, wie Recht und Praxis in Japan mit ärztlich verursachten Gesundheitsschäden umgehen, wobei die Regelungen in anderen Ländern vergleichend herangezogen werden. Der Verfasser diskutiert unter anderem strafrechtliche Sanktionen für Kunstfehler japanischer Ärzte, zivil- und zivilprozessrechtliche Regelungen, Fragen der Haftpflichtversicherung sowie administrative Maßnahmen, um die Selbstkontrolle innerhalb des japanischen Medizinwesens zu verbessern, und das neu eingeführte Regime einer verschuldensunabhängigen Gefährdungshaftung für geburtsbedingte Gesundheitsschäden.

Der Verfasser zeigt auf, dass die Zahl straf- und zivilrechtlicher Gerichtsverfahren zu Beginn des 21. Jahrhunderts rapide zugenommen hatte, nach dem zuvor etliche Fälle medizinischer Kunstfehler in den japanischen Medien bekannt gemacht worden waren. Die Verfahrenswelle erreichte ihren Höhepunkt zwischen 2004 (Zivilklagen) und 2006 (Strafverfahren) und ist seitdem wieder abgeebbt. Diejenigen Vorschriften des japanischen Zivilgesetzes, nach denen sich die Haftung für Kunstfehler richtet, unterscheiden sich nur wenig von den einschlägigen Regelungen in den USA und Westeuropa, auch

wenn die Anforderungen an den Nachweis der Kausalität in bestimmten Fällen weniger hoch sind. Die Schadensersatzzahlungen dürften in Japan mindestens so hoch wie in den USA sein und werden durchgängig einheitlicher gehandhabt. Verfahrensrechtliche Reformen wie die Einrichtung von medizinrechtlichen Kammern bei den Distriktgerichten einiger Metropolregionen haben dazu beigetragen, dass die Verfahren zügiger durchgezogen werden können.

Das neu eingeführte Regime einer verschuldensunabhängigen Gefährdungshaftung für geburtsbedingte Gesundheitsschäden, das für private Versicherer ein neues Geschäftsfeld mit einem erheblichen Gewinnpotential (aber auch Risiken) mit sich gebracht hat, hat sich bei den auf Geburten spezialisierten Einrichtungen flächendeckend durchgesetzt, die sich gegen das Risiko künftiger Schadensersatzklagen absichern wollen. Auch wenn es für eine abschließenden Evaluierung noch zu früh ist, verdient dieses System weitere wissenschaftliche Aufmerksamkeit. Sollte sich dieses geburtsspezifische Schadensersatzregime als Erfolg erweisen, könnte es die Blaupause für die Einführung einer verschuldensunabhängigen Haftung in anderen Fällen von ärztlich verursachten Gesundheitsschäden dienen – was Gegenstand einer anderen Studie ist.

(Übersetzung durch die Redaktion)