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## DISCERNING WHY PATIENTS DIE:

## LEGAL AND POLITICAL CONTROVERSIES IN JAPAN, THE UNITED STATES, AND TAIWAN

Robert B Leflar<sup>\*</sup>

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### I. INTRODUCTION AND BACKGROUND

Reviews of cases of suspected medical error resulting in death or injury take place for various purposes – quality-of-care improvement, compensation entitlement ascertainment, and criminal responsibility determination among others. Those reviews take different forms in different societies, depending on their respective legal, institutional, and cultural arrangements.<sup>1</sup>

<sup>\*</sup>Ben J. Altheimer Professor of Legal Advocacy, University of Arkansas School of Law, Fayetteville; Professor, University of Arkansas for Medical Sciences, Little Rock; frequent visiting professor / visiting researcher, University of Tokyo Faculty of Law and Keio University School of Medicine; rbleflar@uark.edu.

Portions of this article draw on the author's *The Law of Medical Misadventure in Japan*, first published at 87 CHI.-KENT L. REV. 79 (2012), with an updated

Case-review processes often result in political controversy as well. This descriptive essay sets out, in broad-brush fashion, some aspects of medical case-review processes and their outcomes in Japan, the United States, and Taiwan.

The incidence of medical error is surprisingly high in every advanced society. Epidemiological studies in seven Western nations found in-hospital adverse event rates ranging from three percent to sixteen percent of hospital admissions.<sup>2</sup> Studies conducted in selected Japanese hospitals place Japan squarely within this range, at six to eleven percent.<sup>3</sup> The U.S. Institute of Medicine, drawing on studies of medical records sampled in the states of New York, Colorado, and Utah, famously estimated in its 1999 report To Err Is Human that nationwide, between 44,000 and 98,000 preventable deaths occur annually in U.S. hospitals.<sup>4</sup> Those figures are now criticized as too conservative: it is credibly estimated that just from contaminated catheters, hospital

1. Medical injury review and compensation systems worldwide are analyzed and compared in a recent collection of single-country chapters with a useful comparative overview. MEDICAL MALPRACTICE AND COMPENSATION IN A GLOBAL PERSPECTIVE (Ken Oliphant & Richard W. Wright eds., 2013).

2. See CHARLES VINCENT, PATIENT SAFETY 42 (2006) (summarizing studies). The definition of an "adverse event" varies from one study to the next, but a typical definition is "an injury caused by medical management rather than the underlying condition of the patient." INST. OF MEDICINE, TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 28 (Linda T. Kohn et al. eds., 2000) [hereinafter TO ERR IS HUMAN].

3. HIDETO SAKAI, IRYŌ JIKO NO ZENKOKUTEKI HASSEI HINDO NI KANSURU KENKYŪ [REPORT ON THE NATIONWIDE INCIDENCE OF MEDICAL ACCIDENTS: III] 5, 18 (2006) (Japan) (reporting 6.0 percent adverse event rate); Shunya Ikeda et al., *Identification of Adverse Events in Inpatients: Results of a Preliminary Survey in Japan*, 4 ASIAN PAC. J. DISEASE MGMT., no. 2, 2010, at 49, 53 (finding a 10.0% adverse event rate using Australian criteria and 11.3% using Japanese health ministry criteria).

4. TO ERR IS HUMAN, *supra* note 2, at 31.

version at 35 ZEITSCHRIFT FÜR JAPANISCHES RECHT /J. JAPANESE L. 189 (2013) (with German abstract). I thank the editors of both journals. I also thank Thomas (Chih-hsiung) Chen of Taiwan's National Chiaotung University and Norio Higuchi of the University of Tokyo, without whose help this research would never have seen the light of day.

infections kill as many as 28,000 patients every year,<sup>5</sup> and that adoption of proven quality improvement programs would likely prevent 10,000 to 25,000 deaths from hospital-acquired infections alone.<sup>6</sup> One recent estimate put the likely annual number of premature deaths associated with preventable harm in the U.S. at 210,000 to 400,000.<sup>7</sup>

Medical error issues leapt into public attention in Japan at the turn of the 21st century, as a series of highly publicized mistakes at famous Tokyo-area hospitals from 1999 to about 2004, frequently accompanied by deception of patients, families, and authorities, generated newspaper headlines and intense television news coverage.<sup>8</sup> The contemporaneous release of To Err Is

7. John T. James, *A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care*, 9 J. PATIENT SAFETY 122 (2013), *available at* http://journals.lww.com/journalpatientsafety/Fulltext/2013/09000/A\_New,\_Evi dence\_based\_Estimate\_of\_Patient\_Harms.2.aspx; *see also* Marshall Allen & ProPublica, *How Many Die from Medical Mistakes in U.S. Hospitals*? SCI. AM. (Sept. 20, 2013), http://www.scientificamerican.com/article/how-many-diefrom-medical-mistakes-in-us-hospitals/ (describing James' study with favorable evaluation from "father of patient safety" Dr. Lucian Leape).

8. These developments are addressed in more detail in Robert B Leflar & Futoshi Iwata, *Medical Error as Reportable Event, as Tort, as Crime: A Transpacific Comparison*, 12 WIDENER L. REV. 189, 192-195 (2005), and in Robert B Leflar, "Unnatural Deaths," Criminal Sanctions, and Medical Quality Improvement in Japan, 9 YALE J. HEALTH POL'Y L. & ETHICS 1, 6-7 (2009) [hereinafter Leflar, "Unnatural Deaths"]. For a defendants' perspective, see, e.g., Yoichi Kitamura, *The Case of Tokyo Women's Medical* University from the Standpoint of the Defense Counsel, 55 JAPAN MED. ASSN. J. 144 (2012); Kazuki Satoh, *The Case of Tokyo Women's Medical University* from the Standpoint of the Person Concerned, 55 JAPAN MED. ASSN. J. 149 (2012).

<sup>5.</sup> Peter Provonost et al., *An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU*, 355 NEW ENG. J. MED. 2725, 2726 (2006).

<sup>6.</sup> ASS'N FOR PROF'LS IN INFECTION CONTROL AND EPIDEMIOLOGY [APIC], GUIDE TO THE ELIMINATION OF CATHETER-RELATED BLOODSTREAM INFECTIONS 15 (2009) (citing C.A. UMSCHEID ET AL., ESTIMATING THE PROPORTION OF REASONABLY-PREVENTABLE HOSPITAL-ACQUIRED INFECTIONS (HAIS) AND ASSOCIATED COSTS AND MORTALITY (2009)), available at http://www.apic.org/Resource\_/EliminationGuideForm/259c0594-17b0-459db395-fb143321414a/File/APIC-CRBSI-Elimination-Guide.pdf.

Human legitimated the issue in Japan as one of international significance. Patient safety appeared on the Japanese national agenda – at least for awhile. In Taiwan as well, rising numbers of malpractice claims have focused public and political attention on the medical error problem.<sup>9</sup>

#### II. MEDICAL ERROR DISCERNMENT OUTSIDE AND INSIDE LEGAL FRAMEWORKS

A. Internal Hospital Reviews, Medical Records Access, and Truth-telling

The processes of discerning the causes of patient death and injury take place both outside and within the frameworks of legal institutions. Outside the legal framework, health care facilities conduct internal reviews of adverse events. The thoroughness of those reviews varies considerably from facility to facility, but external pressures from accreditation bodies such as the Joint Commission in the United States<sup>10</sup> and from the health ministry and university hospital leaders in Japan<sup>11</sup> have made competent internal reviews more common and their content somewhat more standardized.

Insights into causes of death and injury are also available to patients and families, without initiating litigation, to the extent that (1) patients' access to their own medical records is permitted by law or custom and (2) health professionals have adopted

<sup>9.</sup> See, e.g., Max Kuo, Op-Ed., Medical Malpractice Is Ruining Healthcare, TAIPEI TIMES, June 1, 2012, at 8, available at http://www.taipeitimes.com/News/editorials/archives/2012/06/01/2003534209; Feng-Jen Tsai, Letter to the Editor, Malpractice Claims in Taiwan, 32 HEALTH AFF. 1173, available at http://content.healthaffairs.org/content/32/6/117 3.2.full.pdf+html.

<sup>10.</sup> See generally ROOT CAUSE ANALYSIS IN HEALTH CARE: TOOLS AND TECHNIQUES (Richard J. Croteau ed., 4<sup>th</sup> ed. 2009); JOINT COMM'N, FACTS ABOUT THE SENTINEL EVENT POLICY (Mar. 2011) (describing sentinel events and medical malpractice claims), *available at* http://www.jointcommission.org/ assets/1/18/Sentinel%20Event%20Policy.pdf.

<sup>11.</sup> See Leflar, "Unnatural Deaths," supra note 8, at 21-22.

practices of truth-telling about adverse outcomes. By law, the right of medical record access is essentially universal in the United States,<sup>12</sup> and has also become the rule in Japan since the beginning of this century<sup>13</sup> and in Taiwan as well.<sup>14</sup> Truth-telling practices, traditionally the exception rather than the rule in all societies, have gained favor in both law<sup>15</sup> and custom<sup>16</sup> but cannot yet be said to permeate medical practice anywhere.<sup>17</sup>

13. A blue-ribbon study commission issued a report in 1998 advocating access by members of the public to their own medical records. MINISTRY OF HEALTH & WELFARE, KARUTE-TŌ NO SHINRYŌ JŌHŌ NO KATSUYŌ NI KANSURU KENTŌKAI HŌKOKUSHO [REPORT OF THE STUDY COMMISSION ON THE USE OF MEDICAL CHARTS AND INFORMATION] (1998) (Japan). Following that report, which formed the basis for health ministry policy, the Japan Medical Association reversed its previous stance and encouraged its members to provide patients with their medical records upon request. JAPAN MEDICAL ASS'N, KOKUMIN IRYŌ NENKAN 1999-2000 [JAPANESE MEDICAL CARE YEARBOOK 1999-2000] 290-291 (2000). The right of access was later made explicit for public facilities in health ministry guidance under Japan's personal data protection law. Kojin jōhō hogo ni kansuru hōritsu, Law No. 57 of 2003 [Act on the Protection of Personal Information], *available at* http://www.japaneselaw

translation.go.jp/law/list/?ft=5&re=02&dn=1&gn=99&sy=2003&ht=A&no=57 &x=51&y=; see generally MINISTRY OF HEALTH, LABOR, & WELFARE, IRYŌ-KAIGO KANKEI JIGYŌSHA NI OKERU KOJIN JŌHŌ NO TEKISETSU NA TORIATSUKAI NO TAME NO GAIDORAIN [GUIDELINES FOR THE MANAGEMENT OF PERSONAL INFORMATION BY EMPLOYEES OF MEDICAL AND ELDERLY CARE FACILITIES] (2004) (providing privacy guidelines for hospital employees for protecting personal information).

14. I LIAO FA [Medical Care Act] art. 71 (Taiwan), *translated in* http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx?PCode=L0020021.

15. In Japan, for example, physicians are held to a contract-based duty of accurate explanation of treatment outcomes, and breach of that duty gives rise to damages independent of any associated physical harm. *See* Robert B Leflar, *The Law of Medical Misadventure in Japan*, 87 CHI.-KENT L. REV. 79, 96 n. 76 (2012) [hereinafter Leflar, *Medical Misadventure*].

16. See generally WHEN THINGS GO WRONG: RESPONDING TO ADVERSE EVENTS (2006) (describing Harvard Hospitals consensus statement), *available at* http://www.macoalition.org/documents/respondingToAdverseEvents.pdf.

17. See generally Lucas Mearian, U.S. Doctors Don't Believe Patients Need Full Access to Health Records, HEALTHCARE IT, (Mar. 7, 2013),

<sup>12.</sup> The right of access to one's own medical records is now codified nationwide in HIPAA regulations. 45 C.F.R. §164.524 (2012). A few exceptions are recognized, such as one keeping psychotherapy notes confidential. *Id.* 

# B. Medical Error Discernment in Civil, Criminal, and Administrative Systems

Within the three nations' legal systems, discernment processes overlap significantly but contain notable variations, arising in considerable part from differences in the systems' legal and institutional structures. For example, in contrast to the common-law and federalist legal background of the United States, Japan's civil and criminal codes draw heavily on continental code systems unified at the national level, and Taiwan's legal structure is still significantly influenced by Japan's colonial legacy. This essay compares case review practices in civil lawsuits, in police investigations and criminal trials, and in administrative proceedings in each of the three countries.

#### 1. Civil Law

In the United States, virtually all medical injury claims are brought under negligence theories. Rhetoric about medical malpractice crises notwithstanding, the number of paid medical malpractice claims has been declining over the past decade or more. As the important empirical studies carried out by Paik, Black, Hyman and their colleagues have demonstrated, this decline is evident from statistics on raw quantities of claims and, even more strikingly, on claims numbers adjusted for population growth, number of physicians, and real health spending.<sup>18</sup> Some

http://www.computerworld.com/s/article/9237428/U.S.\_doctors\_don\_t\_believe \_patients\_need\_full\_access\_to\_health\_records (reporting on Accenture study of physicians in eight nations).

<sup>18.</sup> Myungho Paik, Bernard Black & David A. Hyman, *The Receding Tide of Medical Malpractice Litigation: Part 1 -- National Trends*, 10 J. EMPIRICAL LEGAL STUD. 612, 617 (2013) [hereinafter Paik et al., *National Trends*]; see generally Myungho Paik, Bernard Black & David A. Hyman, *The Receding Tide of Medical Malpractice Litigation: Part 2 -- Effect of Damage Caps*, 10 J. EMPIRICAL LEGAL STUD. 639 (2013) [hereinafter Paik et al., *Effect on Damage Caps*] (describing effect of noneconomic caps on total damages on medical malpractice claims).

of the decline is attributable to liability-limiting state legislation restricting the circumstances under which malpractice claims can be made and the amounts that can be awarded. But much of the decline apparently represents an underlying trend toward diminution of medical injury claims in general, apart from changes in the legal landscape.<sup>19</sup>

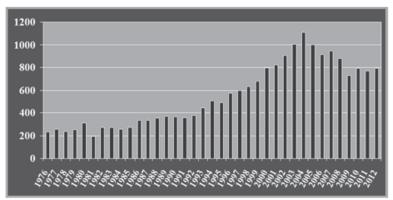


Figure 1. Medical Malpractice Cases Filed in Japanese Civil Courts, 1976-2012.

In Japan, compensation claims for deaths and injuries from medical malpractice are brought under theories of negligence,<sup>20</sup> breach of contract,<sup>21</sup> or both.<sup>22</sup> The number of claims rose gradually from the 1970s to the early 1990s, and then increased dramatically to a peak in 2004, followed by a moderate decline. This trend is evident from public case filing statistics compiled by the Administrative Office of the Supreme Court (Fig. 1).<sup>23</sup>

- 20. MINPŌ [Civ. C.] art. 709.
- 21. Id. art. 415.
- 22. Leflar, *Medical Misadventure*, *supra* note 15, at 91-92.

<sup>19.</sup> See generally Paik et al., *National Trends, supra* note 18; Paik et al., *Effect on Damage Caps, supra* note 18.

<sup>23.</sup> See SAIKŌ SAIBANSHO [SUP. CT.], JJI KANKEI SOSHŌ JIKEN NO SHORI JŌKYŌ OYOBI HEIKIN SHINRI KIKAN [DISPOSITION OF MEDICALLY RELATED LITIGATION AND MEAN DURATIONS OF PROCEEDINGS] [hereinafter SUPREME COURT, MEDICALLY RELATED LITIGATION], *available at* http://www.courts.go.jp/saikosai/ about/iinkai/izikankei/toukei\_01.html.

Cases filed in court, however, represent only a small proportion of all Japanese medical injury claims – only "ten percent plus," according to specialists at Sompō Japan, one of the nation's largest medical malpractice insurance carriers.<sup>24</sup> A true picture of claims trends would incorporate extrajudicial claims handled informally through private negotiations, typically conducted (on the part of physician defendants) following reviews by committees of local and prefectural medical societies that contract with private liability insurers on behalf of their physician members. Such extrajudicial claim data are hard to come by. However, the Tokyo Medical Association graciously provided pertinent statistics on claims handled from 1960 to 2011 (Fig. 2).<sup>25</sup> These statistics indicate that trends for all claims (including extrajudicial claims) have been roughly similar to trends for claims filed in court.

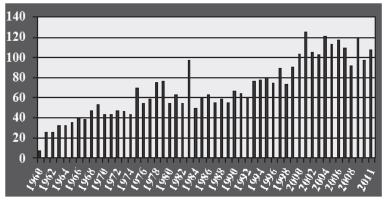


Figure 2: Medical Malpractice Claims Filed with the Tokyo Medical Association 1960-2011 (including claims handled informally out of court).

Employing statistics on court filings and on total malpractice liability insurance premiums in Japan, Mark Ramseyer offered

<sup>24.</sup> Interview with Makoto Hotta, S. Mochida and Y. Ohyama, Sompō Japan, in Tokyo, Japan (May 20, 2013).

<sup>25.</sup> Interviews with Tokyo Medical Association executives and attorneys, in Tokyo, Japan (Mar. 12, Aug. 1, & Aug. 8, 2013).

an estimated range of malpractice claims, whether filed in court or not: between 2,230 and 13,875 claims per year.<sup>26</sup> Comparing that estimated range with U.S. claims estimates from leading researchers,<sup>27</sup> and adjusting for population differences, the American medical malpractice claiming rate would work out to be between 1.5 times and 12 times the Japanese rate. I have suggested that "[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."<sup>28</sup> Damage awards are more standardized in Japan, where professional judges refer to damage tables drawn from the traffic accident compensation system,<sup>29</sup> than in the United States, where jurors have fairly wide discretion. In general, however, the amounts of awards appear to be roughly equivalent for similar injuries.<sup>30</sup>

In Taiwan, the number of medical malpractice civil claims filed in court rose from 35 in 2002 to 127 in 2007:<sup>31</sup> more than a

27. Michelle M. Mello & David M. Studdert, *The Medical Malpractice System: Structure and Performance*, in MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM 11, 13 (William M. Sage & Rogan Kersch eds., 2006) (estimating 50,000 to 60,000 claims per year in the U.S.).

28. Leflar, Medical Misadventure, supra note 15, at 103.

29. SHIGEMI OSHIDA, YASUSHI KODAMA & TOSHIHIRO SUZUKI, JITSUREI NI MANABU IRYŌ JIKO [A REAL-WORLD VIEW OF MEDICAL ACCIDENT CASES] 20-21 (2002) (Japan). For a description of these standardized damage calculations, *see* Eric A. Feldman, *Law, Society, and Medical Malpractice Litigation in Japan*, 8 WASH. U. GLOBAL STUD. L. REV. 257, 266 (2009).

30. See Leflar & Iwata, supra note 8, at 200 nn. 36-40; Ramseyer, supra note 26, at 653.

31. Chun-Ying Wu et al., *The Era of Civil Litigation for Medical Malpractice in Taiwan: Analysis of Trial Cases between 2002 and 2007*, 14 FORMOSAN J. MED. 359 (2010) (Taiwan). Extrajudicial claim statistics for Taiwan were unavailable for this study.

For a few years from 1998, some Taiwanese courts took a detour from negligence principles, deciding medical injury cases under the strict liability standards of the Consumer Protection Act. See Ya-Ling Wu, The Applicability of the Consumer Protection Law in Medical Malpractice Disputes

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<sup>26.</sup> J. Mark Ramseyer, *The Effect of Universal Health Insurance on Malpractice Claims: The Japanese Experience*, 2 J. LEGAL ANALYSIS 621, 665-66 (2010).

threefold increase. Putting the statistics in international perspective, the judicial claiming rate per million population in Taiwan in 2007 was 5.5, approaching Japan's 2007 rate of 7.9<sup>32</sup> but just one-sixth of Canada's 2004 rate of 33.8.<sup>33</sup> Damages were awarded in just 17% of Taiwanese court cases litigated to final judgment from 2000 to 2008,<sup>34</sup> compared with 38%-47% of cases litigated to judgment in Japan during that approximate period.<sup>35</sup> (Cases settled after filing are not included in these figures; including them would increase the proportion of plaintiff recoveries.)<sup>36</sup> Damage awards are considerably lower in Taiwan than in Japan or North America. The median award for death

33. See Ramseyer, supra note 26, at 631, 667-68 (citing CANADIAN HEALTH SERVS. RESEARCH FOUND., MYTH: MEDICAL MALPRACTICE LAWSUITS PLAGUE CANADA (2006)), available at http://www.cfhi-fcass.ca/Migrated/PDF /myth21\_e.pdf.

34. Kuan-Yu Chen et al., *Medical Malpractice in Taiwan: Injury Types, Compensation, and Specialty Risk*, 19 ACAD. EMERGENCY MED. 598, 599 (2012).

*in Taiwan*, 16 PAC. RIM L. & POL'Y J. 805, 807-14 (2007). These decisions must have temporarily encouraged claim filings. However, in 2004 the legislature decreed that liability in medical injury cases must be premised on intent or negligence, not no-fault principles. I LIAO FA [MEDICAL CARE ACT] art. 82, *as amended on* April 28, 2004 [hereinafter MEDICAL CARE ACT OF 2004], *translated in* LAWS AND REGULATIONS DATABASE OF THE REPUBLIC OF CHINA (Dec. 12, 2012), *available at* http://law.moj.gov.tw/eng/LawClass/

LawAll.aspx?PCode=L0020021. *See also* Ya-Ling Wu, *supra* note 31, at 819 (suggesting existence of ambiguity in the 2004 statute's language).

<sup>32.</sup> The Japanese claim filing rate is calculated from the statistics compiled by the Administrative Office of the Supreme Court. SUPREME COURT, MEDICALLY RELATED LITIGATION, *supra* note 23.

<sup>35.</sup> Iji-kankei soshō jiken -- shinjukensū wa zennen-hizō de "sagedomari" ka [Medical Case Filings: Does Last Year's Rise Mean Claim Trends Have "Bottomed Out"?] 4392 NIHON IJI SHINPŌ 10, 11 fig.2 (2008) (Japan) (describing proportion of medical injury cases for which damages were awarded, 1999-2007). These percentages were calculated from statistics compiled by the Administrative Office of the Supreme Court. SUPREME COURT, MEDICALLY RELATED LITIGATION, supra note 23.

<sup>36.</sup> See, e.g., Kazue Nakajima et al., Medical Malpractice and Legal Resolution Systems in Japan, 285 JAMA 1632, 1637 (2001) (indicating that plaintiffs received awards in 32% of cases tried to judgment, but in 60% of cases if settlements were included).

cases in Taiwan during 2002-2007 was about US  $80,000,^{37}$  compared to about 350,000 in Japan in 2004<sup>38</sup> and 195,000 in Florida during 1990-2003.<sup>39</sup>

Responding to concerns about the increasing volume of medical injury claims and the capacity of courts to handle them properly, both Japan and Taiwan set up new judicial structures to address those concerns. In Japan, district courts in selected metropolitan areas in 2001 established iryō shūchūbu (health care divisions), whose judges, trained in medical issues, handle all medical injury cases (reportedly with greater dispatch and perhaps greater accuracy than before) within those district courts' jurisdictions.<sup>40</sup> In Taiwan, the Judicial Yuan (the nation's highest judicial body) was tasked by law in 2004 to set up professional medical courts, in which judges with "related . . . medical knowledge and trial experience" handle medical disputes and litigation at both the district and intermediate appellate court levels.<sup>41</sup> Judges typically commission medical review committees established by local authorities to assess the evidence and report their findings.42 In the United States, by contrast, proposals for health courts on the whole have aroused

<sup>37.</sup> The median award figure is calculated from Chun-Ying Wu et al., *Compensation in Medical Malpractice in Civil Trials: Legal Theory, Court Decisions, and Empirical Study*, 36 TAIWAN L. REV. 13, 32 tbl.1 (2012) (in Chinese).

<sup>38.</sup> Ramseyer, supra note 26, at 653.

<sup>39.</sup> Neil Vidmar et al., Uncovering the "Invisible" Profile of Medical Malpractice Litigation: Insights from Florida, 54 DEPAUL L. REV. 315, 340 tbl.7 (2005).

<sup>40.</sup> See Feldman, supra note 29, at 273-75; Robert B Leflar, Public and Private Justice: Redressing Health Care Harm in Japan, 4 DREXEL L. REV. 243, 256-61 (2011), for descriptions of the workings of the health care divisions of Japanese district courts.

<sup>41.</sup> MEDICAL CARE ACT OF 2004, *supra* note 31, art. 83.

<sup>42.</sup> *Id.* arts. 98-100. At least one-third of the membership of the committees must be composed of "legal experts, scholars, and social personages, excluding legislators/councilors and representatives of medical juridical persons." *Id.* art. 100. In criminal cases, medical review committees may be commissioned by prosecutors. *See* Ya-Ling Wu, *supra* note 31, at 806-07, 814-16 (2007), for a critical view of how medical review committees have operated in Taiwan.

interest merely among academics,<sup>43</sup> but a few experiments are under way putting health court concepts into actual practice.<sup>44</sup>

#### 1. Criminal Law

Criminal law has played a more significant role in the regulation of medical practice in Japan and Taiwan in recent years than it has in the United States, where prosecutions for medical error are rare.<sup>45</sup> In Japan, grounds for prosecution in medical cases are found in both the Criminal Code and in the Medical Practitioners' Law. Article 211 of the Criminal Code makes professional negligence causing death or injury subject to criminal sanctions, so medical malpractice is (as a formal matter) not only a tort and contract breach, but also a crime. Additionally, medical personnel who falsify documents (e.g., altered patient charts) submitted to public authority can be

<sup>43.</sup> See generally Michelle M. Mello et al., "Health Courts" and Accountability for Patient Safety, 84 MILBANK Q. 459 (2006) (describing proposal to remove medical malpractice claims from the tort system to new "health courts").

<sup>44.</sup> New York, for example, recently launched a variation of the health courts concept. In the New York approach, supported by both hospitals and trial lawyers, judges with medical training engage plaintiffs and defendants in "judge-directed negotiations," speeding up the settlement process but (unlike in Japan or Taiwan) retaining jury trial rights if cases fail to settle. *See* Alicia Gallegos, *Medical Liability: Cutting Costs from the Bench*, AMERICAN MEDICAL NEWS (Oct. 31, 2011), http://www.ama-assn.org/amednews/2011/10/31/prsa1031.htm.

<sup>45.</sup> See generally James A. Filkins, "With No Evil Intent": The Criminal Prosecution of Physicians for Medical Negligence, 22 J. LEGAL MED. 467 (2001); Paul R. Van Grunsven, Medical Malpractice or Criminal Mistake? An Analysis of Past and Current Criminal Prosecutions for Clinical Mistakes and Fatal Errors, 2 DEPAUL J. HEALTH CARE L. 1 (1997); Kara M. McCarthy, Note, Doing Time for Clinical Crime: The Prosecution of Incompetent Physicians as an Additional Mechanism to Assure Quality Health Care, 28 SETON HALL L. REV. 569 (1997). Occasionally criminal prosecutions for medical malpractice do gain public attention, as with the conviction of Michael Jackson's personal physician. Jennifer Medina, Doctor Is Guilty in Michael Jackson's Death, N.Y. TIMES, Nov. 7, 2011, http://www.nytimes.com/ 2011/11/08/us/doctor-found-guilty-in-michael-jacksons-death.html? r=0.

prosecuted under other provisions of the Criminal Code.46 Perhaps most controversially, under Article 21 of the Medical Practitioners' Law, a physician who fails to report an "unnatural death" to police within 24 hours has likewise committed a criminal offense.<sup>47</sup> Medical malpractice resulting in a fatality in some circumstances can constitute a reportable "unnatural death." The conviction of a Tokyo hospital CEO who did not timely report the death of a patient killed by evident medical mismanagement (a nurse's careless injection of a toxic disinfectant rather than the intended drug) was upheld in 2004 by the Supreme Court of Japan,<sup>48</sup> causing great consternation in medical circles. Subsequent to that hospital CEO's arrest, in the early years of this century the number of reports to police of medical injuries deaths spiked, as did the number of cases police sent to prosecutors (Fig. 3).<sup>49</sup> The number of prosecutions in medical cases, which had averaged just 2.6 per year during the postwar period 1946-1998, correspondingly jumped to 14.8 per year from 1999 to 2004.50

<sup>46.</sup> KEIHŌ [PENAL CODE] arts. 104 & 156 (Japan).

<sup>47.</sup> ISHI Hō [Medical Practitioners' Law], art. 21 (Japan). Violations are punishable by a criminal fine of up to ¥500,000 (US \$5,000). *Id.* art. 33-2(1).

<sup>48.</sup> Saikō Saibansho [Sup. Ct.] Apr. 13, 2004, 2003(A) No. 1560, 58(4) SAIKō SAIBANSHO KEIJI HANREISHŪ [KEISHŪ] 247, *translated in* http://www.courts.go.jp/english/judgments/text/2004.04.13-2003-A-No..1560.html (Hirō Hospital case).

<sup>49.</sup> 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], Aug. 8, 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.

<sup>50.</sup> See HIDEO IIDA & ISSEI YAMAGUCHI, KEIJI IRYŌ KAGO [CRIMINAL MEDICAL MALPRACTICE] 1-2 (2001); Hideo Iida, *Keiji shihō to iryō* [*Criminal Justice and Medicine*], 1339 JURISTO 60, 61 tbl.1 (2007).

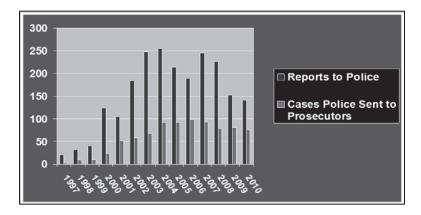


Figure 3. Medical Accidents Reported to Japanese Police; Cases Police Sent to Prosecutors, 1997-2010.

In Taiwan, as in Japan, professional negligence causing death or injury is a crime as well as a tort or contract breach.<sup>51</sup> The number of criminal prosecutions of medical personnel in Taiwan, relative to national population, has been considerably greater than in Japan and far outstrips the United States. As indicated in Figure 4, although Taiwan's population of 23 million is only a fifth of Japan's, medical prosecutions took place on average in more than thirty cases a year from 2002 to 2007,<sup>52</sup> more than double the number of medical prosecutions in Japan. In 2002, Taiwanese courts saw even more criminal malpractice cases filed than civil malpractice cases. One reason for this is that Taiwanese judges may award compensatory damages to victims of medical crime.<sup>53</sup> For patients or families alleging injuries from malpractice, filing a complaint with police

<sup>51.</sup> XING FA [CRIM. CODE] arts. 276(2) & 284(2) (Taiwan), *translated in* LAWS AND REGULATIONS DATABASE OF THE REPUBLIC OF CHINA (June 11, 2013), *available at* http://law.moj.gov.tw/Eng/LawClass/LawAll.aspx? PCode=C0000001.

<sup>52.</sup> Wu et al., *supra* note 31.

<sup>53.</sup> XING SHI SU SONG FA [CODE OF CRIM. PROCEDURE] arts. 487-512, *translated in* LAWS AND REGULATIONS DATABASE OF THE REPUBLIC OF CHINA (June 11, 2013), *available at* http://law.moj.gov.tw/Eng/LawClass/LawSearch Content.aspx?PC=C0010001.

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may be a cheaper and more efficient means of ascertaining the facts (at public expense, taking advantage of public investigative authority) than hiring a private lawyer.

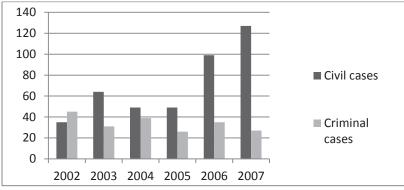


Figure 4. Medical Malpractice Cases Filed in Taiwanese District Courts, 2002-2007.

In Japan, the tide began to turn against the use of criminal law to regulate medical malpractice in 2006, on the occasion of the arrest in humiliating circumstances of an obstetrician at rural Ohno Hospital in Fukushima prefecture, after police learned of the death of one of his patients during a difficult delivery a year and a half earlier.<sup>54</sup> Protests poured in from physicians and medical organizations nationwide. The incident became a cause célèbre for a movement among some physicians protesting the level of legal and governmental constraints on medical practice.<sup>55</sup> This movement, which bore a certain resemblance to the "tort reform" movement in the United States, took as its slogan "iryō hōkai" ("health care's collapse").<sup>56</sup> It had considerable impact on public and editorial opinion, and perhaps also on the perspectives of some of the nation's judges. At any

<sup>54.</sup> See Leflar, Medical Misadventure, supra note 15, at 88-89.

<sup>55.</sup> See Leflar, "Unnnatural Deaths," supra note 8, at 14-15.

<sup>56.</sup> Dr. Hideki Komatsu's book of that title was influential in launching the movement. HIDEKI KOMATSU, IRYŌ HŌKAI [HEALTH CARE'S COLLAPSE] (2006).

rate, in four successive cases culminating in the Ohno Hospital obstetrician's prosecution, judges acquitted medical personnel indicted for malpractice or Article 21 violations<sup>57</sup> – an extraordinary result, given prosecutors' 99%-plus conviction rate in criminal cases generally.<sup>58</sup> That series of acquittals, together with other scandals and embarrassments that contemporaneously undercut the standing of prosecutors and police in the public eye,<sup>59</sup> has resulted in a pullback in prosecutorial aggressiveness in the medical field. Though it has not vanished, criminal law's oversight role in Japanese medicine is in decline.

In Taiwan as well, the extensive employment of criminal law in the medical field has aroused criticism.<sup>60</sup> To channel medical disputes away from the criminal courts and improve the process of resolving medical injury cases, in late 2012 the Executive Yuan proposed a Medical Dispute Resolution and Compensation Act, and two bills have been introduced in the Legislative

<sup>57.</sup> Fukushima Chihō Saibansho [Fukushima Dist. Ct.] Aug. 20, 2008, 16 IRYŌ KAISETSU HANREI 20 (Ohno Hospital case); Tōkyō Chihō Saibansho [Tōkyō Dist. Ct.] Aug. 27, 2007, 1282 HANREI TAIMUZU 233 (Tokyo Women's Medical U. Hospital heart surgery case), *aff'd*, Tōkyō Kōtō Saibansho [Tōkyō High Ct.] March 27, 2009; Nagoya Chihō Saibansho [Nagoya Dist. Ct.] Feb. 27, 2007, 1296 HANREI TAIMUZU 308 (Obstetrics case); Tōkyō Kōtō Saibansho [Tōkyō High Ct.] Nov. 20, 2008, 1304 HANREI TAIMUZU 304 (Kyorin U. *waribashi* [chopstick] case).

<sup>58.</sup> See J. Mark Ramseyer & Minoru Nakazato, Japanese Law: An Economic Approach 178 (1999).

<sup>59.</sup> See, e.g., Current, Former Cops Arrested Over Info Leak, DAILY YOMIURI (July 23, 2011), http://newsonjapan.com/html/newsdesk/article/91058.php; Lead Prosecutor in Muraki Case Arrested: Maeda Admits Tampering with Seized Floppy Disk, JAPAN TIMES, Sept. 22, 2010, http://www.japantimes.co.jp/news/2010/09/22/national/lead-prosecutor-inmuraki-case-arrested/#.Uus-gfldW8B.

<sup>60.</sup> See, e.g., Pyng Jing Lin, Criminal Judgments to Medical Malpractice in Taiwan, 11 LEGAL MED. S376 (2009); Wu Ching-Chin, Op-Ed., Effects of Decriminalizing Medicine, TAIPEI TIMES, July 3, 2012 (Paul Cooper trans.),

http://www.taipeitimes.com/News/editorials/archives/2012/07/03/2003536826/ 1.

Yuan.<sup>61</sup> The proposals aim at enhancing mediation as a dispute resolution technique and at setting up a compensation fund for a limited category of adverse events. As of this writing, the proposals have not been enacted.

#### 2. Japan's Model Project for Peer Review

At the instance of four leading medical specialty societies, Japan's health ministry in 2005 initiated a "Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths."<sup>62</sup> Launched in four urban prefectures and subsequently expanded to ten, the Model Project was an effort to improve the quality of hospital case reviews and regain the public's trust in their objectivity, while channeling the case review function away from police and toward impartial medical professionals with relevant expertise. The Model Project brought in independent specialists to investigate in-hospital deaths upon participating hospitals' request, and to report results to the hospital, the family of the deceased, and (in summary form) to the public.<sup>63</sup> The number of cases submitted by hospitals to the Model Project did not meet expectations, and the case reviews did not proceed as expeditiously as hoped.<sup>64</sup> Nevertheless, the quality of case reviews was sufficiently high and the value of the errorprevention lessons learned, communicated to the nation's hospitals by the quasi-public Japan Council for Quality Health

<sup>61.</sup> Medical Dispute Resolution and Medical Accident Compensation Act, Bill No. 13479 (filed Dec. 26, 2012), II FA YUAN YI AN GUAN XI WEN SHU [Parliamentary journal] 8:2:15 pp. 0271-0288 (Taiwan); Medical Dispute Resolution Act, Bill No. 14520 (filed Dec. 19, 2012), II FA YUAN YI AN GUAN XI WEN SHU [Parliamentary journal] 8:2:14 pp. 0327-0335 (Taiwan) (both in Chinese) (on file with author).

<sup>62.</sup> For descriptions of the Model Project's background, operation, and limitations, see Leflar, "Unnatural Deaths," supra note 8, at 31-39, and Norihiro Nakajima et al., Interim Evaluation of the Model Project for the Investigation and Analysis of Medical Practice-Associated Deaths in Japan, 2009(1) J. MED. SAFETY 34.

<sup>63.</sup> See Leflar & Iwata, supra note 8, at 222-24.

<sup>64.</sup> See Leflar, "Unnatural Deaths," supra note 8, at 35-39.

Care, was sufficiently useful that the health ministry determined in 2008 to try to expand the Model Project's general approach to medical peer reviews nationwide.<sup>65</sup>

For a time, politics got in the way. After negotiations involving the ministries of justice and finance, the Japan Medical Association leadership, patients' rights groups and other health policy interests, the health ministry proposed legislation embodying the Model Project's peer review approach and won the backing of the then-governing Liberal Democratic Party.<sup>66</sup> But the health ministry proposal ran into trouble with antiregulatory physicians' groups influencing the opposition Democratic Party of Japan (DPJ), which criticized it as too bureaucratic and for failing to expunge criminal penalties from the law.<sup>67</sup> The DPJ came into power in 2009, and for four years legislative progress on peer review stagnated. However, the Liberal Democratic Party's overwhelming election victories in December 2012 and August 2013 changed the political calculus, and as of this writing the prospects for legislation expanding some form of peer review nationwide have brightened.

#### 3. Administrative Compensation Systems

In the United States, perceptions of a medical malpractice crisis, driven in considerable part by large verdicts and settlements in birth-related injury cases, led the states of Virginia and Florida to enact no-fault injury compensation systems of limited scope in the late 1980s. Unlike compensation systems in New Zealand and the Nordic countries, whose no-fault principles extend to virtually all iatrogenic injuries,<sup>68</sup> the Virginia and

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<sup>65.</sup> See id. at 39-42.

<sup>66.</sup> *See id.* at 40-42.

<sup>67.</sup> See id. at 39-47 (describing competing proposals of the health ministry and the DPJ).

<sup>68.</sup> See generally Stephen Todd, Treatment Injury in New Zealand, 86 CHI.-KENT L. REV. 1169 (2011) (describing New Zealand's no-fault injury compensation system); Vibe Ulfbeck et al., *Malpractice in Scandinavia*, 87 CHI.-KENT L. REV. 111 (2012) (describing no-fault injury compensation systems in Nordic countries).

Florida systems are restricted to a narrowly-defined set of obstetrical injuries, and the fault-based malpractice system remains in place as an alternative for claimants preferring that route to compensation.<sup>69</sup>

Japan too has initiated a no-fault system for compensation of a limited set of obstetrical injuries. As in the United States, a major impetus for the Japanese system was pressure from the legal world. Pressure came both from the civil law side, with the increase in lawsuits and extrajudicial claims through 2004, and from the criminal law side, with the 2006 arrest of the Ohno Hospital obstetrician and the Supreme Court's 2004 decision confirming that failure to report deaths from medical mismanagement to police might subject physicians to criminal sanctions.<sup>70</sup> The Japanese no-fault system, launched by the health ministry in 2009 at the instance of medical organizations, grants standardized lump-sum payments totaling US \$300,000 per affected child to parents of infants with cerebral palsy as defined by the ministry, without requiring proof of provider negligence.<sup>71</sup> The system is voluntary for both hospitals and parents, and it is administered by private insurers and a nongovernmental entity, so it required no enabling legislation. But virtually all hospitals and birthing clinics have signed up to participate. Of the applications for compensation processed to completion over the first four years since the system's inception,

<sup>69.</sup> See, e.g., FRANK A. SLOAN & LINDSEY M. CHEPKE, MEDICAL MALPRACTICE 280-87 (2008); see also Gil Siegal et al., Adjudicating Severe Birth Injury Claims in Florida and Virginia: The Experience of a Landmark Experiment in Personal Injury Compensation, 34 AM. J.L. & MED. 493 (2008). Except for Denmark, the Nordic nations do allow civil suits for medical malpractice, but "tort law instead of the alternative compensation scheme is seldom used." Ulfbeck et al., supra note 68, at 116.

<sup>70.</sup> See supra notes 48 and 54-57 and accompanying text (Hirō Hospital and Ohno hospital cases).

<sup>71.</sup> MINISTRY OF HEALTH, LABOR, & WELFARE, SANKA IRYŌ HOSHŌ SEIDO NI TSUITE [THE OBSTETRIC MEDICAL COMPENSATION SYSTEM], http://www.mhlw.go.jp/topics/bukyoku/isei/i-anzen/sanka-iryou/index.html (Japan) (last visited Feb. 16, 2014). For an overview of the system, see Leflar, *Medical Misadventure, supra* note 15, at 106-09.

about 90% have been accepted.<sup>72</sup> Although parents of afflicted children may still engage the fault-based civil law system, the number of lawsuits for obstetrical injuries generally has declined since the no-fault program got under way.<sup>73</sup>

Taiwan has also implemented a no-fault obstetrical injury compensation system on an experimental basis. Compensation to parents of afflicted children is set at NT \$2 million, or about US \$60,000.<sup>74</sup> Parents retain the option of filing malpractice actions in civil or criminal courts. Launched at the beginning of 2012, the experimental system is set to run through 2014, and may be extended depending on evaluations of its performance.<sup>75</sup>

#### **III.** CONCLUSION

The processes of discerning the causes of medical injury, and sometimes attributing them to errors by medical professionals, are fraught with legal and political controversy. This short descriptive essay presents several key features of how Japan, the United States, and Taiwan address the discernment process through their respective legal systems. Statistical trends in civil, criminal, and administrative systems for assigning responsibility and determining compensation are set out, and areas of political controversy are identified. Of particular interest are the diminishing number of civil malpractice claims in the United

<sup>72.</sup> KÕEKI ZAIDAN HÕJIN NIHON IRYÕ KINÕ HYÕKA KIKÕ SANKA IRYÕ HOSHÕ SEIDO UN'EI IINKAI [JAPAN COUNCIL ON QUALITY HEALTH CARE OBSTETRICAL CARE COMPENSATION SYSTEM MANAGEMENT COMMISSION], SANKA IRYÕ HOSHÕ SEIDO MINAOSHI NI KAKARU CHŪKAN HÕKOKUSHO [INTERIM REPORT ON RE-EXAMINATION OF THE OBSTETRICAL CARE COMPENSATION SYSTEM] 4 tbl.1 (June 2013).

<sup>73.</sup> *Id.* at 41-43 (app. 5, tbls.1-3).

<sup>74.</sup> Government Considers Setting Up Fund for Birth Risk Compensation, CHINA POST, Mar. 27, 2009, http://www.chinapost.com.tw/taiwan/national/nationalnews/2008/03/06/145823/Gov%E2%80%99t-considers.htm (providing summary of system as proposed in 2008).

<sup>75.</sup> See TAIWAN DRUG RELIEF FOUND., OBSTETRICAL ACCIDENT COMPENSATION SYSTEM (2013), http://www.oirp-tdrf.org.tw/about02.html, for an overview of Taiwan's compensation system.

States, the recent establishment of medical specialty courts and no-fault obstetrical injury compensation systems in Japan and Taiwan, the relative prominence in the 21<sup>st</sup> century (in terms of physician concern, if not in the absolute number of cases) of criminal prosecutions of medical personnel in Japan and especially in Taiwan, and legislative proposals now under consideration in Japan and Taiwan to channel medical disputes away from the criminal law system and to improve peer review, dispute resolution, and patient safety.