

**MEDICAL MALPRACTICE IN THE PEOPLE'S REPUBLIC OF CHINA:
THE 2002 REGULATION ON THE HANDLING OF MEDICAL ACCIDENTS**

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In China, there have been numerous reports that doctors or other health care workers have been attacked by patients or members of patient's families. Those acts of violence have been attributed, in part, to the inadequacy of the legal system for handling medical disputes that was in effect prior to 2002. On February 20, 2002, the State Council of the People's Republic of China adopted the Regulation on the Handling of Medical Accidents. The 2002 regulation replaces the previous 1987 regulation, and was designed to remedy perceived deficiencies in the previous regulation. To some extent, that effort was successful. The new 2002 regulation increases the adequacy and fairness of compensation, makes some improvements in the procedure for resolving medical disputes, and has the potential to reduce medical errors and improve quality of care. Therefore, the 2002 regulation was an important step in the right direction, but some problems remain to be solved in the continuing process of reform. Part of the motivation for the 2002 regulation was the desire to establish a credible system of medical liability. Despite its improvements, the 2002 regulation has not yet created a system in which the people can fully place their trust. We summarize the 2002 regulation, evaluate its strengths and weaknesses, and address some of the unresolved issues. We also make specific recommendations for further reform, and identify the lessons that the United States and China can learn from each other in regard to the law of medical malpractice.

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MEDICAL MALPRACTICE

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ON THE HANDLING OF MEDICAL ACCIDENTS

In China, there have been numerous reports that doctors or other health care workers have been attacked by patients or members of patient's families.¹ From 2000 to 2003, there were 502 reports of violence against health care workers in the city of Beijing, in which 90 health care workers were wounded or disabled. From January 1991 to July 2001, in Hubei Province, 568 attacks on health care facilities and workers were reported, and some health care workers were even killed.² In Jiangsu Province, from 2000 to 2002, violent events against health care facilities and workers increased by 35% every year, with an average of 177 such events occurring each year.³ Those acts of violence have been attributed, in part, to the inadequacy of the legal system for handling medical disputes that was in effect prior to 2002.⁴

In addition, those acts of violence are part of a broader problem in China of a lack of trust, on the part of patients and their families, in the legal system for resolving medical disputes. In China, the "malpractice crisis" is not frivolous or allegedly frivolous litigation, nor is it the cost of professional liability insurance. Rather, China's "malpractice crisis" is the lack of a credible system to deal with medical accidents and related problems in quality of care.

On February 20, 2002, the State Council of the People's Republic of China (P.R.C.) adopted the Regulation on the Handling of Medical Accidents,⁵ which became effective on September 1, 2002. The 2002 regulation replaces the previous 1987 regulation, and was designed to remedy perceived deficiencies in the previous regulation. To some extent, that effort was successful. The new regulation increases the adequacy and fairness of compensation, makes some improvements in the procedure for resolving medical disputes, and has the potential to reduce medical errors and improve the quality of care. Therefore, the 2002 regulation was an important step in the right direction. However, some problems remain to be solved in the continuing process of legal reform. Part of the motivation for the 2002 regulation was the desire to establish a credible system of medical liability, and thereby reduce the incidents of violence.⁶ Despite its improvements, the 2002 regulation has not yet created a system in which the people can fully place their trust.

The 2002 regulation is not merely a mechanism for handling individual cases of medical malpractice. As in the United States, Chinese lawmakers have combined reform of the liability system with efforts to improve the quality of care. Thus, the 2002 regulation describes a comprehensive system of quality assurance, reporting requirements, regulatory supervision, administrative discipline, and compensation for injuries to patients. The regulation includes provisions for civil remedies, administrative punishment, and even criminal punishment in very serious cases. In fact, the 2002 P.R.C. regulation performs a combination of functions that some other jurisdictions address in separate statutes or regulations.

This article explains how the new regulation "works" in the context of the Chinese legal system and the Chinese health care system. After a brief explanation of the modern P.R.C. legal system, we discuss those aspects of the Chinese health care system that are most relevant to quality of care and medical malpractice. We review the prior law on health care and medical errors, including the 1987 regulation and its deficiencies. We summarize the provisions of the 2002 regulation, evaluate its strengths and weaknesses, and address some of the unresolved issues under that new regulation. Finally, we make specific recommendations for further reform, and identify the lessons that the United States and China can learn from each other in regard to the law of medical malpractice.

A BRIEF EXPLANATION OF THE MODERN P.R.C. LEGAL SYSTEM

In order to evaluate the 2002 Regulation on the Handling of Medical Accidents, it is necessary to have at least a basic understanding of the Chinese legal system. In addition, it is important to understand the ways in which the Chinese legal system provides mechanisms for the resolution of private disputes, including disputes involving medical accidents.

1. Established in 1949, the P.R.C. uses a system of civil law that is modeled on Continental Europe and was incorporated to some extent through Japan.⁷ Despite some early reliance on Soviet concepts, the system in place since the late 1970's demonstrates the emphasis on using law as a tool for modernization, economic progress, and the development of the "socialist market economy."⁸

The power to enact laws (falü) is vested in the National People's Congress (NPC) and its Standing Committee. Because the NPC has thousands of members and meets infrequently, its Standing Committee has significant power as a practical matter. Theoretically, the Constitution (xian fa) is the pinnacle of legal authority. However, the NPC may amend the Constitution and the NPC's Standing Committee has authority to interpret it.⁹ Moreover, constitutional provisions are not considered to be self-executing and generally cannot be cited by courts as a basis for deciding specific cases.¹⁰

Aside from the Constitution and the laws enacted by the NPC or its Standing Committee, and below them in the hierarchy of legal authority, administrative regulations (xingzheng fagui) are issued by the State Council. The State Council is the top administrative body, but it is subordinate to the NPC. The 2002 Regulation on the Handling of Medical Accidents was adopted by the State Council as a regulation. In contrast to regulations, administrative rules (xingzheng guizhang) are issued by the ministries or departments under the State Council. Below the national government, local people's congresses and their respective standing committees issue local regulations (difang fagui), and local governments or their agencies issue local administrative rules (difang xingzheng guizhang).¹¹

The judicial system of China is based on a system of people's courts and people's procuratorates. Procuratorates are judicial bodies that have responsibility for supervising the courts and public security agencies, as well as for pursuing criminal prosecutions.¹² The highest court in China is the Supreme People's Court.¹³

However, like the State Council, the Supreme People's Court is subordinate to the NPC, in contrast to the American system of three branches of government with equal status for legislative, executive, and judicial functions.¹⁴ Moreover, there is no clear separation of legislative and judicial powers in the Chinese legal system.¹⁵ As discussed above, the NPC's Standing Committee, rather than the judicial branch, has the power to interpret the Constitution, and the NPC has the power to amend the Constitution.¹⁶ Rather than having three equal and independent branches of government, all of which are subject to the Constitution, the Chinese system places the NPC and its Standing Committee, as the representatives of the people, above the other branches and in control of the Constitution.

Another interesting distinction exists between the American system of federalism and the Chinese system of democratic centralism or centrism. Whereas the U.S. system is based on the divided authority of state and federal governments, in the unitary Chinese system the central government controls and delegates limited powers to local authorities.¹⁷ In China, the national government holds all sovereign power, and provincial governments are not sovereign as in the American system.¹⁸ Thus, the 2002 Regulation on the Handling of Medical Accidents was adopted at the national level by the State Council as a uniform system of malpractice law, in contrast to the American system of different liability laws in each state.¹⁹

Historically, the traditional Chinese legal system was not the primary means of controlling inter-personal relations or resolving disputes.²⁰ Individual duties and prerogatives were determined by a person's social status, rather than by a notion of individual rights.²¹ The traditional legal system was a tool for social and political control, rather than a means of resolving disputes between individuals.²²

Under these circumstances, commentators have noted "the generally hostile attitude towards litigation in Chinese society, which still exists to a certain extent."²³ However, the use of litigation in China has increased in recent years, leading other writers to describe a "surge in civil litigation"²⁴ and even "an explosion in civil litigation."²⁵ Not surprisingly, this includes

litigation involving medical accidents and adverse outcomes in the process of medical care. Just as historical and cultural changes in America led to a greater likelihood of suing for medical malpractice,²⁶ historical and cultural changes in China have made the Chinese people more willing to resort to litigation as a method of resolving various types of disputes.

THE CHINESE HEALTH CARE SYSTEM: IMPLICATIONS FOR QUALITY OF CARE AND MEDICAL MALPRACTICE

Since the creation of the People's Republic in 1949, China has made significant progress in improving the health of its people, such as reducing infant mortality from an estimated 25% or more to only about 3.8%.²⁷ These improvements are attributable not only to better health care but also to progress in a variety of areas such as education and income.²⁸ However, China still has serious health problems and significant disparities in access to care on the basis of income and location.²⁹ Health care facilities and even some government health programs depend on patient revenues to meet their operating expenses, and need to charge user fees for services rendered to patients.³⁰ However, most residents of rural areas have no health insurance coverage,³¹ and need to pay "out-of-pocket" for health care services.³²

In 2000, the World Health Organization (W.H.O.) ranked China's health system at a very low 188 out of 191 with regard to the fairness of financing, as a result of China's inequality in distributing the financial contribution to its health system.³³ As part of its transition to a more competitive market economy since the late 1970's and early 1980's, China abandoned the system of agricultural collectives, and essentially eliminated the rural cooperative medical system that had provided coverage for most rural residents.³⁴ Some efforts have been made to reestablish insurance coverage or other methods of risk pooling, but most people still lack adequate coverage. Even in urban areas, health insurance coverage is subject to significant limitations.

Despite the movement toward a free market economy in many sectors, the vast majority of hospitals in China are public in the sense that they are owned by some agency of government. Governmental or public hospitals may be owned and operated by a variety of different entities, such as municipal governments, state-owned enterprises, public universities, and the military. Therefore, not all governmental hospitals are responsible to the national Ministry of Health. This poses serious problems for the management and regulation of health care facilities in China.³⁵ Originally, government-owned hospitals were part of the state public welfare system, and, therefore, the relationship between the governmental entity and its patient was viewed as administrative or quasi-administrative.

There are relatively few for-profit hospitals in China, although privatization of public hospitals has begun in some locations. Some hospitals are described as “non-profit,” but most of those are owned by a government agency, rather than by a private, non-profit organization as in the United States. Meanwhile, most of the physicians in China work as employees of a hospital, but hospital employees in China are not subject to the same type of control by facility administrators as employees in the United States. In fact, the administrators of hospitals in China generally lack authority to control their hospital personnel, staffing patterns, or operating costs.³⁶

Financial incentives in the Chinese health care system encourage inefficiency and duplication. The government effectively requires hospitals to rely on patient payments for their operating expenses, but fixes the prices for most services below the hospitals’ actual costs. However, the government allows hospitals to charge higher prices for drugs and high technology. In order to meet their costs and make a profit, hospitals tend to overuse drugs and equipment.³⁷ Physicians can receive “commissions” for prescribing drugs,³⁸ and some hospitals even manufacture their own drugs. Not surprisingly, this fee-for-service system encourages excessive utilization, as well as a “medical arms race” for the acquisition of high technology equipment.³⁹

These health care system issues have important implications for quality of care and medical errors in China. Inevitably, China suffers from some of the same problems in health care quality as any other country, including weaknesses in systems of care and weaknesses in the performance of some practitioners.⁴⁰ In addition, as a developing country, China has some health care quality problems that are similar to those in other developing countries, such as wide variations in the training of individual health care professionals,⁴¹ and the lack of effective government regulation of health care professionals and facilities. Finally, China has some problems in quality that are unique to its own system of health care financing and delivery. Quality of care is affected by barriers to effective access, such as the lack of adequate insurance coverage. The overuse of drugs and high technology is not only expensive but also likely to cause physical harm in some cases.⁴²

The nature of the Chinese health care system also has implications for the implementation of medical malpractice law. Because most hospitals are owned by some agency of government, suing a hospital means suing the government. For aggrieved patients or family members, that can pose legal issues and practical issues, including a lack of confidence in the fairness of the system. The unavailability of adequate health insurance also affects the system of medical malpractice, by effectively forcing injured patients to seek compensation through legal means for additional medical expenses that are not covered by health insurance.⁴³ Additional complexities for medical malpractice litigation are caused by the existence of a separate system of Traditional Chinese Medicine (TCM), which is different from modern, high-technology medicine. In China, TCM is used in combination with modern medicine, and not merely as an alternative method of treatment. In the event of a malpractice claim against a practitioner of TCM, there may be a dispute over the standard of care that the court should apply.⁴⁴

In other ways, however, the system of health care in China has simplified and facilitated the development of medical malpractice law. Most physicians are employees of hospitals, rather

than independent practitioners in private practice. Therefore, in order to impose liability on a hospital as an organization, it usually will not be necessary for Chinese claimants to litigate complex issues of vicarious liability and corporate negligence.⁴⁵ Under these circumstances, the health care system of China can provide the context for a system of enterprise liability, in which legal liability is imposed on the health care organization best situated to improve the quality of care. However, as discussed below, Chinese hospitals and their managers do not have the practical ability at the present time to discipline or terminate physicians who fail to meet applicable standards of care.

THE PRIOR LAW ON HEALTH CARE AND MEDICAL ERRORS

The Constitution of the P.R.C. provides a right to health care. Specifically, citizens have “the right to material assistance from the state and society” in the event of illness or disability.⁴⁶ The state has responsibility to develop medical services, health services, and social insurance that are necessary for people to utilize that right. However, the constitutional right to health care is subject to practical limitations, including the government’s lack of financial resources, the lack of an enforcement mechanism, and the need for implementing legislation.

Possibly, the implementing legislation could be found in Article 98 of the General Principles of Civil Law (GPCL), which was adopted by the NPC in 1986 as part of the P.R.C.’s Civil Code.⁴⁷ The GPCL provides that “[c]itizens shall enjoy the rights of life and health.”⁴⁸ However, the GPCL deals with civil relationships, rather than rights to assistance from the government. The GPCL includes provisions on civil liability for breach of contract or infringement of rights. For personal injury, the GPCL uses a negligence standard, and imposes an obligation to pay monetary damages if anyone “infringes upon a citizen’s person and causes him physical injury”⁴⁹ Thus, the rights and obligations in the GPCL provide a basis for legal claims in cases of personal injury and medical malpractice.⁵⁰

In the 1950's, medical disputes in China were handled mainly by procuratorates, although public health officers were also involved to some extent. Criminal penalties were often imposed on negligent doctors.⁵¹ In the 1960's, local administrative departments began to play a more important role in handling medical disputes.⁵²

During the Cultural Revolution from 1966 to 1976, many cases of medical malpractice were mixed with political accusation, and it was not unusual for doctors to be punished severely.⁵³ Laws were almost disregarded or abandoned in handling cases of medical accidents. Even in the early days after the Cultural Revolution, the judicial system was still disorganized.

Since 1978, both procuratorates and local administrative departments have been involved in managing medical disputes.⁵⁴ In the meantime, various administrative regulations and measures were adopted at the local level for handling these cases.⁵⁵ The problem with local regulations was that they led to local variation in court decisions. Gradually, this lack of uniformity came to the attention of the central government, which favored standardized laws and regulations, in order to maintain the order of the market and facilitate economic reform. As an important transaction, medical treatment was part of that trend toward standardization of the law. Thus, since the Cultural Revolution, China has made the transition from essentially no law on medical accidents to a multiplicity of local regulations to a single nationwide regulation in 1987.

On the basis of those local regulations and experiences, the State Council promulgated the Regulation on Dealing with Medical Incidents on June 29, 1987. The purposes of the 1987 regulation were to protect the rights of patients, the rights of medical staff, and the order of medical practice. The 1987 regulation provided that health care facilities and workers could be held liable for "medical incidents" that were caused by negligence or violation of regulations. Before filing a claim in court, the dispute was handled by a local public health department, and medical expertise was provided by technical authentication committees. If patients or their

families were dissatisfied with the conclusion of the technical authentication or the conduct of the health department, they could file claims in court. However, the legal remedy was limited to a one-time economic compensation to be paid by the health care facility, and the amount of compensation was very low.

The 1987 regulation was designed to unify the management of medical disputes, and it inherited the lenient attitude of the local regulations in dealing with medical incidents. For example, Article 24 of the 1987 regulation reserved criminal punishment for those health care workers who were extremely irresponsible and directly caused a patient's death. Thus, the 1987 regulation completed the transition from imposing harsh criminal penalties to imposing more lenient administrative penalties for medical malpractice.

However, as the socialist market economy in the P.R.C. evolved, and as new statutes came into effect in the 1990's, the deficiencies of the 1987 regulation became increasingly obvious. It could neither protect patients' rights nor create a system for improving the quality of care. Numerous Chinese papers and reports have addressed the deficiencies of the 1987 regulation.⁵⁶ Most scholars have criticized the 1987 regulation based on theories of civil liability.⁵⁷ We discuss the deficiencies of the 1987 regulation by separating them into four categories: (1) narrowness in the definition of medical incident; (2) unfair limitations on compensation; (3) weaknesses in the system for expert authentication; and (4) conflicts and lack of integration with other laws.

Narrowness in the definition of medical incident

Treating health care as part of a governmental social welfare scheme, the 1987 regulation established a narrow range of "medical incidents" for which health care facilities and workers were liable. According to Article 2 of the 1987 regulation, health care facilities would only be liable if health care workers' diagnoses, treatments or nursing activities directly caused a patient's "death, disability or tissue-organ functional impairment." This left out injuries caused

by the medical or nursing staff's refusal to treat⁵⁸ or any intentionally harmful acts. If patients were old or had critical conditions, the medical or nursing staff would be less responsible for adverse outcomes that might be attributed to the natural course of disease. Therefore, those vulnerable patients might receive less attention or care.⁵⁹ Moreover, under the 1987 regulation, patients or their families bore the burden of proving negligence and causation.

If medical injuries were caused by personnel other than doctors or nurses, it was unclear whether health care facilities would be liable.⁶⁰ Administrative personnel in health care facilities were omitted from the chain of responsibility in the 1987 regulation. Even if they did not directly cause medical accidents, administrative personnel might have been responsible for the administrative milieu that induced medical accidents.⁶¹ Due to the narrowness in defining liability incidents under the 1987 regulation,⁶² most medical accidents were excluded from the economic compensation scheme.⁶³ Emphasizing the social welfare mission of health care facilities, the 1987 regulation actually required the unfortunate victims to bear the costs of medical accidents for society.

Unfair Limitations on Compensation

The 1987 regulation had its own social and economic background. Since health care was still deemed to be part of the social welfare scheme, health care was funded heavily by the government and priced below the actual cost.⁶⁴ Under the 1987 regulation, the relationship between health care facilities and their patients was treated as quasi-administrative,⁶⁵ rather than as a private relationship between providers and patients. For example, patients and their families could file complaints in court only if they were dissatisfied with the conclusion of the initial technical authentication or with the way in which the local health department had handled the complaint. In addition, health care facilities had to report to--and take orders from--local health departments in handling medical disputes. Some scholars still maintain that the doctor-

patient relationship in the P.R.C. is a type of administrative contract and should be subject to administrative laws and regulations,⁶⁶ but those scholars have become the minority.

The 1987 regulation did provide some financial remedy to the injured patient, but it was only a limited, one-time payment for economic compensation, plus the additional medical expenses incurred as a result of the injury. Under the social and political system in effect at that time, it was assumed that victims of medical incidents would receive economic support and care from their government, local collective enterprise, or business employer.⁶⁷ This was very different from the U.S. system, in which the defendant is the first payer for all of the plaintiff's losses. In all of the provincial regulations adopted pursuant to the 1987 regulation, the amounts of one-time economic compensation for victims of medical incidents were very low.⁶⁸

As the socialist market economy gradually replaced the planned economy of the PRC in the 1980's and 1990's, increasing numbers of employers were no longer offering life-time economic support and care to employees who had been victimized by medical incidents.⁶⁹ In 1986, the State Council adopted regulations that allowed employers to terminate contracts with employees who were disabled due to non-work-related causes.⁷⁰ In the 1995 PRC Labor Law, this measure was applied to all employers and workers.⁷¹ Meanwhile, many government enterprises and collective economic entities encountered financial crises, and could no longer afford to care for victims of medical incidents.

As health care costs escalated, it became more difficult for the P.R.C. government to fund all of the health care facilities and clinics. Health care facilities became increasingly conscious of costs and profits, and the welfare-based health care system began to collapse. The administrative nature of the relationship between government-owned health care facilities and their patients gradually faded away,⁷² and civil law eventually became dominant in the handling of medical accidents. In light of these changes, the limited economic compensation scheme in the 1987 regulation could no longer be justified, and it became an unfair shield for hospitals and clinics.

Weaknesses in the system for expert authentication

Under the 1987 regulation, technical authentication committees provided medical expertise for the resolution of disputes. According to Article 14 and the 1988 supplemental interpretation by the Ministry of Health (MOH), authentication committees could review relevant materials that were offered by health care facilities, patients and their families, and could hear statements by health care practitioners, patients and their families. In addition, technical authentication committees could conduct independent and direct investigation. Theoretically, they were required to base their conclusions on the standard of negligence that was stipulated in Article 2 of the regulation. However, the composition and operation of local authentication committees under the 1987 regulation have been criticized for protectionism, monopoly, and lack of transparency.

According to Article 12 of the 1987 regulation, members of the authentication committees were nominated by local health departments, and were approved by the local governments to which those health departments belonged. Most of the members had to be chosen from among the attending physicians, chief nurses and public health officers. According to the 1988 supplemental interpretation by the MOH, authentication committees were the only “legal” authentication entities for handling medical accidents, and authentication reports by other entities should not be considered by local health departments in handling medical accidents. This created a monopoly status for authentication committees in implementing the 1987 regulation.

However, it is questionable that members of those authentication committees could fairly scrutinize the medical practices of their colleagues and subordinates.⁷³ The problem of biased authentications in China is somewhat similar to the problems encountered in the U.S. under the old locality rule, which perpetuated the so-called “conspiracy of silence.” Moreover, in China, local health departments have their own conflicts of interests when government health

care facilities are involved in medical disputes.⁷⁴ Under those circumstances, there was a danger of departmental protectionism. Findings of negligence on the part of government health care facilities could also constitute evidence of incompetence on the part of health departments in regulating those facilities.

The credibility of authentication committees was also undermined by a lack of transparency. Since no individual signature was required on the authentication reports, it was difficult to hold responsible or cross-examine any individual member of a committee for the quality of their work in performing authentications.⁷⁵ In effect, most authentications were conducted in black boxes. According to Article 15 of the 1987 regulation, the disputing parties or the public could not join the authentication process unless they were invited. Under Article 8, medical charts and other material evidence relevant to medical incidents had to be collected and stored by health care facilities or clinics. Emphasizing the importance of preserving evidence, the 1988 MOH supplemental interpretation prohibited patients or their families from examining stored evidence. Since health care facilities and clinics have their own interests in the outcome of authentications, it was questionable whether they would do an appropriate job of preserving unfavorable evidence.⁷⁶

Conflicts and lack of integration with other laws

The final category of problems with the 1987 regulation is the conflict between that regulation and other laws or regulations that were potentially applicable to cases of medical injury. Those other laws included the GPCL, Civil Procedure Law, Criminal Law, Criminal Procedure Law, Administrative Procedure Law,⁷⁷ State Compensation Law, Consumer Rights and Interests Protection Law, and even judicial interpretations by the Supreme People's Court.

In the hierarchy of legal authority, the 1987 regulation, which was adopted by the State Council, is subordinate to the GPCL and procedural laws that were enacted by the NPC.⁷⁸ One of the fundamental principles of China's civil law system is that legislative enactments of the

NPC supersede administrative regulations adopted by the State Council. However, another principle of legal interpretation dictates that specific provisions preempt more general provisions, assuming that both the specific and general provisions were issued by the same level of authority. Despite these basic principles of legal interpretation, the State Council intended its 1987 regulation for handling medical incidents to preempt the more general GPCL and procedural laws, even though the GPCL and procedural laws had been enacted by a higher level of authority. In addition to language in the 1987 regulation, the 1988 MOH supplemental interpretation implied that the regulation was intended to preempt other laws and regulations in the handling of medical incidents.

The conflict between the 1987 regulation and the GPCL was not merely an abstract theoretical dispute, but rather had a profound effect on the amount of damages that a claimant could recover for medical injuries. The one-time economic compensation scheme in the 1987 regulation was in conflict with Article 119 of GPCL, which authorizes extensive compensation for personal injury.⁷⁹ If claimants were to prevail in court under the GPCL, they usually could be awarded damages that were much higher than the one-time economic compensation under the 1987 regulation.⁸⁰

Gradually, civil law became dominant in the judicial treatment of medical accidents, especially after the 1992 interpretation by the Supreme People's Court to the effect that the GPCL should be applied in adjudicating medical disputes.⁸¹ Although courts gradually shifted to the application of civil, criminal, and procedural laws in handling medical disputes, the health departments and health care facilities, as administrative bodies, continued to apply the 1987 regulation in handling medical disputes before they went to court. To use a Chinese expression, it could be said that the P.R.C. had "one country, but two systems" in the handling of medical injuries.

Even within the judicial system, there was inconsistency in the handling of malpractice cases by various courts. Some courts followed the compensation scheme of the 1987

regulation, but others awarded damages according to the GPCL. Thus, patients suffering similar medical injuries might be awarded very different amounts of compensation.⁸²

There were also conflicts with regard to procedural issues. As discussed above, authentication committees were treated in the 1988 MOH supplemental interpretation as the only “legal” entities for conducting technical authentications. However, nowhere in the procedural laws were authentication committees recognized as the only “legal” entities for conducting technical authentications.⁸³ Some courts treated authentication committees as the only “legal” entities to make authentication conclusions. In some extreme situations, cases were thrown out of court because no medical incident was recognized by the authentication committee.⁸⁴ However, other courts would assign forensic medical experts to conduct independent examinations, and made decisions according to forensic medical reports.

Under Article 11 of the 1987 regulation, handling of the medical incident by a public health department preceded the filing of a claim in court. However, neither the Civil Procedure Law nor the Criminal Procedure Law contains this restriction. According to Article 11 of the 1987 regulation, if patients, families, or health care facilities were not satisfied with the conclusion of the authentication, they could file claims in court. However, no procedural law recognizes disputes over authentication conclusions as a basis for a claim, since they are merely technical evidence in the courts.⁸⁵ According to the Administrative Procedure Law, an aggrieved party may file administrative litigation to challenge a public health department’s decision in handling a medical dispute. However, the 1988 MOH supplemental interpretation directed patients and their families to file claims against health care facilities instead.⁸⁶ According to the Supreme People’s Court, courts should accept cases that dispute the amount of economic compensation, which ultimately might lead to revoking the conclusions of authentication committees. However, complaints that directly challenge the conclusions of technical authentications should be rejected by the courts.⁸⁷

In addition to these procedural conflicts, there were potential conflicts between the 1987 regulation and general laws on consumer protection such as the 1993 Consumer Rights and Interests Protection Law. Scholars in the P.R.C. still have not reached a consensus regarding whether medical accidents should be dealt with according to this consumer protection law.⁸⁸ Nevertheless, at least 11 local regulations have included health care services within the implementation of consumer protection law.⁸⁹ From the American perspective, consumer protection laws or product liability laws are viewed as legal regimes that are separate from ordinary medical malpractice, but the Chinese perspective is that conflicts may exist among these various laws and regulations.

Similarly, the 1987 regulation posed potential conflicts with criminal laws⁹⁰ and with the laws or regulations adopted in the 1990's for licensing of health care professionals and facilities.⁹¹ Although those different laws or regulations might be viewed as merely providing separate and distinct causes of action, there was a potential for confusion in the Chinese civil law system as a result of having different laws or regulations that provided different penalties for the same conduct.

Moreover, there were potential conflicts between the 1987 regulation and the 1994 Law on State Compensation, which applied the principle of limited liability. It was believed that, for the good of the people, the State should be allowed some leniency if its officers make mistakes in their duties.⁹² Thus, under Article 27 of that law, the maximum compensation for a citizen's loss is limited to only 20 times the average annual laborer's income in the past year. If health care personnel were treated as government officers under that law, then conflict between that law and the 1987 regulation was unavoidable.

To summarize, the 1987 regulation gradually lost its foundation, as the concept of health care as a social welfare enterprise collapsed in the booming socialist market economy. Because of its inherent limitations and its conflicts with other laws, the 1987 regulation did not provide adequate or equitable compensation for patients or their families, and did not provide

effective incentives to reduce medical errors and improve the quality of care. As the number of medical malpractice cases rapidly increased,⁹³ courts increasingly disregarded the 1987 regulation in determining the compensation awarded to patients and their families.⁹⁴ Confirming the application of the GPCL and Civil Procedure Law in handling medical accidents, the Supreme People's Court dealt several heavy blows against the already weak 1987 regulation.⁹⁵ Meanwhile, as discussed above, violence against medical workers or health care facilities had increased. That violence was attributed, in part, to the inadequacy of the 1987 regulation in handling medical incidents.

THE NEW 2002 REGULATION

Not long after the adoption of the 1987 regulation, there were requests for its revision. As discussed above, some courts began around 1990 to determine the amounts of compensation for medical injuries according to the GPCL. Those amounts were often much higher than the amounts provided by local regulations adopted pursuant to the 1987 regulation. To deal with that problem, many health care professionals requested the MOH to revise the 1987 regulation, but the MOH put aside those requests in order to maintain the stability of medical malpractice regulation.⁹⁶

In 1996, the MOH began work on a revision of the 1987 regulation.⁹⁷ Based on opinions collected from a symposium on the 1987 regulation in January 2000, the original draft was later revised up to 9 times.⁹⁸ In 2001, the State Council reported the draft to the NPC. Theoretically, the NPC could have taken action on its own to promulgate a new law on medical malpractice. However, the NPC decided not to adopt a new law, because the issue was too urgent and too complex.⁹⁹ Therefore, pursuant to the Legislation Law of 2000, the NPC authorized the State Council to adopt a new regulation on medical accidents. The State Council further revised the draft more than 20 times.¹⁰⁰ Finally, on April 4, 2002, the Regulation on the Handling of Medical

Accidents was adopted by the State Council and it went into effect on September 1, 2002. According to Article 1 of the 2002 regulation, its goals are: (1) properly handling medical accidents; (2) protecting legal rights and interests of patients, facilities, and staff; (3) maintaining an orderly and safe environment for medical practice; and (4) promoting the development of medical science.

Summary of the 2002 Regulation

The 2002 regulation provides various methods for obtaining compensation in cases of medical accidents, including negotiation, mediation, and civil litigation.¹⁰¹ The parties may settle the dispute and agree upon compensation by means of negotiation, in which case the settlement will be set forth in a letter of agreement that is signed by both parties. Pursuant to Article 46, “[i]f the parties concerned refuse to or fail to settle the dispute through negotiations, the parties concerned may file an application to the administrative department of health for mediation or institute a civil action directly to the people’s court.” The parties are not required to use negotiation or mediation, and, therefore, the claimant may commence litigation without exhausting any administrative remedy. However, filing a suit in the people’s court will terminate any efforts at mediation by the department of health. As a practical matter, this allows the claimant to select a method of dispute resolution, but only one method may be used at a time.

With regard to mediation, aggrieved patients or family members may apply to the health department for settlement of a dispute, within one year after the claimant knows or should have known of the injury.¹⁰² If medical expertise is needed to evaluate the claim, the health department can obtain a technical authentication by referring the case to the applicable medical society.¹⁰³ The regulation sets forth detailed procedures for the performance of technical authentications by panels of medical experts, who are selected from databases maintained by medical societies. By majority rule, the panel of experts will reach a conclusion and issue a letter of authentication. The letter will state whether the treatment provided to the patient

violated any legal requirements or medical standards. In addition, the letter will grade the medical accident into one of 4 levels of severity, evaluate the seriousness of the negligent act in relation to the injury, and state whether the negligent act caused the injury to the patient. The fees for technical authentications are set by government agencies. The hospital must pay the fee if the panel determines that a medical accident has occurred, but the claimant must pay the fee if he or she applied for the settlement and the panel determines that there was no medical accident in that case.¹⁰⁴

If a finding is made that a medical accident has occurred, the department of health may also conduct mediation on the issue of compensation, in accordance with standards of compensation that are set forth in the regulation. These standards include the factors that should be considered, such as the severity of the medical accident, and also include methods for calculating various items of damages. The 2002 regulation provides for both economic and non-economic damages, such as lost wages, disability living support, disability equipment, support for dependents, funeral expense, and spiritual injury. When the process of mediation is successful, a letter of mediation will be prepared and the agreed-upon compensation will be paid. However, if the parties fail to agree, or if one of the parties subsequently refuses to perform the agreement, the health department will not make any further effort at mediation.

The same standards of compensation apply if the patient or family members elect to file a civil suit in the people's court. In addition, the court will utilize a similar procedure for technical authentication by a panel of medical experts.¹⁰⁵ Patients cannot obtain another expert opinion without the permission of the court. The conclusion of the expert panel is not technically binding on the court. However, the court is likely to defer to the opinion of the panel on matters of professional expertise, while applying more intensive judicial scrutiny on issues of legal procedure.

The 2002 regulation describes a system in which liability is imposed on the basis of fault, rather than compensating patients under a "no-fault" system.¹⁰⁶ The regulation defines the

term "medical accident" as a negligent act by a hospital or staff members in medical treatment that caused personal injury and violated legal requirements or standards of medical care.¹⁰⁷ Thus, the standard of liability is negligence, and it is the authentication panel, or at least a majority of the panel, that determines whether the treatment violated the standard of medical care. However, the regulation excludes several categories of adverse events from the definition of "medical accident", such as emergency measures that were taken under dangerous circumstances in an attempt to rescue the life of the patient. In addition, injuries caused by illegal medical practices are not considered to be "medical accidents." In accordance with Article 131 of the GPCL, the regulation uses a system of comparative fault, rather than denying all recovery in cases of contributory negligence.¹⁰⁸

In an effort to prevent medical accidents, the regulation requires all licensed medical institutions, such as hospitals, to establish a system of quality control. Hospitals may create their own departments for quality control or arrange for others to take responsibility for the supervision of medical treatment in the hospital. Hospitals are required to develop plans to prevent medical accidents and mitigate injuries. In addition, hospitals have an affirmative obligation to educate their staff members about legal requirements, standards of medical care, and professional ethics.

The regulation requires hospital workers to immediately report to their supervisors when they observe any medical accident, any negligent act that could lead to a medical accident, or any treatment dispute. However, there is no obligation to report unsafe conditions unless those conditions result from a negligent act. After receiving a report from a hospital worker, the supervisor is required to make a timely report to the hospital's department of quality control or to the person responsible for medical supervision. If a medical accident has occurred, the hospital must make a report to the administrative authorities at the local health department. In addition, the hospital must make a report to the local health department whenever a medical dispute is resolved by means of negotiation, mediation or judicial decision. The local health

authorities, in turn, are required to report medical accidents and administrative penalties to higher levels of authority.

The department of health has authority to investigate reports to determine if a medical accident has occurred. It also has authority to impose administrative punishment on both hospitals and staff members who caused the medical accident.¹⁰⁹ Depending on the circumstances of the medical accident, disciplinary actions against a hospital could consist of a warning, an order to take corrective action, or even license revocation if corrective actions are not taken. Staff members who are responsible for medical accidents are subject to administrative or disciplinary punishment, suspension or revocation of license, or even criminal liability in very serious cases.¹¹⁰ The regulation also imposes requirements with regard to the maintenance, preservation, and disclosure of medical records. Hospitals are required to maintain and retain case history materials, and the regulation explicitly prohibits alteration of those materials. Patients have the right to photocopy their medical records at their own expense. In order to assure the accuracy of the copies, the patient will be present during the copying and the hospital will attach a seal to the copies. In the event of a medical dispute, other hospital records, such as peer review materials, must be sealed and only opened in the presence of both parties. Similarly, tangible objects such as blood or medicines will be sealed and opened together by both parties to the dispute. If there is a dispute about the cause of death, an autopsy will be performed with the consent of a relative of the deceased patient.

EVALUATION OF THE NEW REGULATION

The 2002 regulation is an improvement over the 1987 regulation, and it remedies some of the deficiencies in the previous law of medical malpractice. In particular, the new regulation takes steps to strengthen the system of quality improvement in health care facilities, and thereby has at least the potential to reduce medical injuries. In addition, the 2002 regulation contains some procedural improvements, and it authorizes recovery of compensation that is

more adequate and equitable than the prior regulation. However, the 2002 regulation still suffers from some of the same weaknesses and unresolved issues as the 1987 regulation, including conflicts with other sources of law and a system of technical authentication that many patients and their families would not consider to be fair.

Promoting quality of care and preventing medical injuries

Like recent initiatives in U.S. law, the 2002 P.R.C. regulation combines liability reform with efforts to improve patient safety and reduce medical errors. As described above, the 2002 regulation requires hospitals to establish a system of quality control, including mechanisms to report medical accidents or negligent acts that could lead to a medical accident.¹¹¹ In a notice to local health departments and the Chinese Medical Association, dated August 2, 2002, the MOH and the National Bureau of Chinese Medicine and Drug Regulation emphasized that local health departments are required to strengthen the quality management of health care facilities and improve the safety of medical treatments. That notice from the government also insisted that health care facilities strengthen their strategy of prevention and design protocols to prevent and manage medical accidents.¹¹²

The 2002 regulation refines the definition of medical accident to clearly include injuries that are caused by the medical institution itself, and not merely injuries that are caused by individual physicians or nurses. In addition, the obligation to pay compensation rests with the hospital as an organization, rather than with individual physicians. This system of medical malpractice law may be described as a type of enterprise liability.¹¹³

In the U.S., scholars have argued that a system of enterprise liability would be a better way to assure compensation, reduce administrative costs, and prevent medical injuries.¹¹⁴ In particular, enterprise liability places responsibility on the organization that is in the best position to improve systems of medical care.¹¹⁵ Under Article 52 of the 2002 regulation, “compensatory expenses for medical accidents ... shall be paid by the medical institution that is held to be

responsible for the accident.” Similarly, it is the hospital that has the obligation under the 2002 regulation to establish a system of quality control and develop plans to prevent medical accidents, and it is the hospital that is required to report medical accidents and the resolution of medical disputes to the appropriate government agency.

At least theoretically, the 2002 regulation imposes liability on the medical enterprise that is in the best position to supervise its staff physicians as employees and improve the organization’s systems of care. However, the managers of hospitals in China currently do not have the authority to fire staff physicians who provide poor quality of care, because hiring and firing of staff is controlled by government authorities.¹¹⁶ In addition, hospitals operate under severe budgetary constraints, and, therefore, have limited resources to invest in making improvements to their systems of care. Finally, hospitals in China and their managers have little, if any, financial incentive to improve their facility’s quality of care.

Improving the procedure for handling cases of medical injury

The 2002 regulation makes several improvements in the process for handling medical malpractice cases, including the procedure for technical authentication. The 2002 regulation clarifies the process of dispute resolution, provides greater flexibility in choosing a method of resolution, and reduces barriers of access to the courts. At least theoretically, patients have access to more information, and some documents and tangible materials will be sealed to preserve their integrity as evidence. The 2002 regulation uses administrative penalties in an attempt to enforce measures that improve public access to information, the credibility of authentications, and quality control. However, as discussed below, the credibility of the authentication process is still cause for concern.

In addition, criminal penalties are emphasized as reminders for health department officials, health care workers, experts who perform technical authentications, and those who would disturb the order of medical treatment and technical authentication. Using criminal laws

to sanction doctors has been common in civil law countries. Except for medical workers, it appears that most scholars in the P.R.C. support the use of criminal penalties for serious medical accidents.¹¹⁷ Although there are no empirical data on this issue, it is possible that the use of criminal penalties for serious medical accidents could inhibit the reporting of adverse events, and thereby interfere with systems-oriented approaches to reducing medical errors.

The process of mediation under the 2002 regulation may be redundant, and it is questionable whether disputing parties will choose to pursue a process of mediation that gives them little legal protection. According to officials involved in the drafting of the 2002 regulation, the conclusion reached in administrative mediation does not have a legally binding effect. Thus, disputing parties may file civil litigation if they are dissatisfied with the results of mediation.¹¹⁸ On the other hand, if parties decide to pursue both nonbinding mediation and litigation, the use of two procedures could increase total administrative costs for resolving medical disputes.

Various provisions of the 2002 regulation are intended to reduce bias or self-interest in selecting experts and improve the independence, credibility, and efficiency of authentication committees.¹¹⁹ However, there still are some serious concerns about bias, professional protectionism, and departmental protectionism in the selection and operation of authentication committees under the 2002 regulation. Local medical associations are in charge of arranging authentications, and most of the experts in local databanks have local connections. The Chinese Medical Association may arrange authentications in certain cases. However, according to its charter, one of the goals of the Chinese Medical Association is to serve medical science workers and protect their lawful rights and interests.¹²⁰ Thus, professional protectionism may still be a serious problem for the new technical authentication system under the 2002 Regulation,¹²¹ and patients or family members are not likely to have confidence in the fairness or credibility of the system.

The close relationship between medical associations and health departments is also cause for concern. Ordinarily, leaders in medical associations are also officials of health

departments. In addition, local medical associations still rely on local health departments to deal with issues of administration, finance and material resources.¹²² According to Articles 41 and 42, local health departments also have the power to audit technical authentication reports, which raises questions about whether local health departments might inappropriately influence technical authentications. Under these circumstances, departmental protectionism may still haunt the new technical authentication system under the 2002 Regulation.

Under Article 25 of the 2002 regulation, conclusions of technical authentications are reached collegially. The prevailing conclusion shall be the one that is supported by over one-half of the votes of experts in the group. Unfortunately, this organizational structure does not facilitate cross-examination in the courts or outside supervision, since it is difficult to know who actually made the authentication conclusions.¹²³ Cross-examination of medical experts would have both advantages and disadvantages. Eventually, it could lead to what is referred to in the United States as a “battle of experts,” in which decision-makers without medical training must decide which of the competing medical experts is most credible. However, in China, it is imperative to improve the credibility of the overall decision-making process and increase the level of trust in the system for resolving medical disputes. The current collegial decision-making process in China may mask protectionism, rather than increasing the transparency of technical authentications.

Another serious problem persists under the new regulation with regard to the fees for technical authentication, which have turned out to be unaffordable for many people. The fees are set by various government agencies. Fees for city-level technical authentication range from 1,500 to 3,000 RMB (about 180 to 360 U.S. dollars), and fees for province-level technical authentication range from 2,000 to 4,000 RMB (about 240 to 480 U.S. dollars).¹²⁴ According to the P.R.C. Bureau of National Statistics, average annual individual dispensable income in the P.R.C. in 2003 was 8,472 RMB (about 1,050 U.S. dollars), and annual individual net income in rural areas was only 2622 RMB (about 320 U.S. dollars).¹²⁵ Many people cannot afford local

authentication fees, especially people living in rural areas where health care quality is often unsatisfactory. Beyond that, they certainly could not afford the authentication fee that is charged by the Chinese Medical Association of 8,500 RMB (about 1020 U.S. dollars).¹²⁶ For many patients and their families, this may create a financial barrier to access for technical authentication.

Article 34 of the 2002 regulation stipulates that, if technical authentication confirms the occurrence of a medical accident, health care facilities shall pay the authentication fee. Otherwise, the party applying for the authentication shall bear the cost of authentication. Thus, the injured patient or a family member would be obligated to pay the fee if he or she applied for the settlement and the committee concludes that there was no medical accident. However, under the Supreme People's Court's Law Interpretation (2001) No. 33, health care facilities would have to bear the costs of technical authentication regardless of the outcome of the authentication. If that SPC interpretation is followed, there would not be a financial barrier to obtaining a technical authentication. However, if that interpretation is not followed, there would be a barrier to access because patients or family members would bear the risk of paying the fees if they lose their cases.

Under those circumstances, one potential solution is a system of contingent fees that could be similar to the system utilized in the United States. There is no statute or regulation in China at the national level that would prohibit the use of contingent fee arrangements. There may be differences among the provinces in their willingness to permit contingent fees, and some provinces have adopted local regulations that allow the use of contingent fee arrangements.

Increasing the amount and scope of compensation for injured patients

One important area of improvement in the 2002 regulation is elimination of the much-criticized, one-time economic compensation under the 1987 regulation. Article 50 of the 2002

regulation expands the scope of compensation to include a comprehensive list of recoverable damages such as medical fees, lost income, subsidies for disability, living expenses for dependents, and spiritual suffering. According to Article 49, principles of comparative negligence are adopted in determining the amount of compensation.¹²⁷

However, the system of compensation under the 2002 regulation is still unfair in some respects. Living expenses for disabled dependents of an injured patient can only be paid for 20 years, if the disabled dependent is more than 16 years old. That could turn out to be much less than the amount provided by Article 27 of the State Compensation Law, which awards living expenses until the death of a disabled dependent. Since both administrative acts and medical acts are performed for the good of society, there is no valid reason why disabled dependents of victims of medical accidents should be treated worse than disabled dependents of victims of administrative actions. Some scholars argue that this restricted compensation scheme can be justified by the reduction in social costs of health care. However, this system of compensation is inequitable and unfair to the worst-situated people in society.¹²⁸

Continuing conflicts with other sources of law

As demonstrated above, the 1987 regulation failed in large part because of its conflicts with the GPCL and other potentially applicable laws. A similar fate haunts the new 2002 regulation. The Supreme People's Court (SPC) has tried to ease the conflicts between the 2002 regulation and the GPCL and Civil Procedure Law, but some confusion still exists.

In an attempt to clarify the application of laws and regulations to medical disputes, the SPC released the Law (*fa*) (2003) No. 20 Notice to Local High People's Courts and Military Courts on January 6, 2003 (hereinafter the "Law (2003) No. 20 Notice").¹²⁹ According to this notice from the SPC, courts must apply the 2002 regulation when dealing with medical accidents; otherwise, the courts should apply the GPCL. The notice also tries to achieve consistency in the use of expert examinations of medical accidents in the courts. Specifically,

for medical accidents, courts should request medical associations to organize authentications; otherwise, courts should follow the Management Regulation on Entrusting External Forensic Examination by People's Courts.

With regard to applications for and conclusions of technical authentications or forensic examinations, the notice requires courts to follow the SPC's Law Interpretation (*fa shi*) (2001) No. 33, which sets forth rules regarding evidence in civil litigation.¹³⁰ In addition, the Law (2003) No. 20 Notice stipulates that Articles 49, 50, 51 and 52 of the 2002 regulation must be followed in determining the amounts of compensation for medical accidents. This notice from the SPC makes an important contribution to the integration of the 2002 regulation with the GPCL and Civil Procedure Law as applied in the civil courts.¹³¹

As noted by one officer of the State Council Legal Institution Office, as long as the 2002 regulation does not conflict with basic laws, it may be applied in the people's courts.¹³² With the efforts by the SPC to ease the potential conflicts, the consistency of legal application should improve in the people's courts that handle medical disputes. In this respect, the 2002 regulation does have a more auspicious beginning than the 1987 regulation.

However, it is not clear that the SPC's interpretation is constitutional. The P.R.C. Constitution does not authorize the SPC to interpret laws, and the legal status of interpretation by the SPC is actually an unresolved issue. In a 1997 interpretation, the SPC announced that its judicial interpretations have the effect of law.¹³³ However, Article 42 of the Legislation Law (2000) stipulates that the NPC is the only institution with the legal power to interpret laws.

Even if the SPC's interpretation is constitutional, the 2002 regulation still conflicts with the Legislation Law. According to Article 8 of the Legislation Law, crimes and criminal penalties may only be established by laws as opposed to regulations. However, there are several articles in the 2002 regulation that purport to stipulate criminal acts and criminal penalties, and some articles actually modify the scope of criminal acts.¹³⁴

These situations severely complicate the application of the 2002 regulation. For example, the 2002 regulation does not explicitly deal with the issue of assigning the burden of proof in medical accident cases. However, the SPC's Law Interpretation (2001) No. 33 essentially provides, albeit indirectly, that health care facilities bear the burden of proving their lack of negligence and lack of causation.¹³⁵ Literally, the SPC's interpretation merely requires health care facilities to bear the burden of applying for technical authentication. The patient or family member is not even required to apply for an authentication. As a practical matter, patients or their families can establish a prima facie case of medical injury without the need to apply for a technical authentication, and health care facilities would be held liable if they are unable to prove otherwise. In order to avoid liability, health care facilities would need to prove, by means of the technical authentication, that the injury was not the result of negligent treatment.

Although courts are likely to follow the SPC's law interpretation on assigning the burden of proof to health care facilities, local health departments might refuse to follow that interpretation and might instead assign the burden of proof to patients and their families. If health departments require patients and their families to bear the burden of proof, then economically rational patients and their families will choose to file their claims in court.

Finally, the definition of "medical accident" and the categorization of severity in the 2002 regulation may pose other conflicts with the GPCL or other laws. In Article 33 of the 2002 regulation, six conditions are excluded from the definition of medical accidents. These exclusions are intended to exonerate health care facilities and workers from liability for certain unexpected or unavoidable outcomes. Paradoxically, according to SPC's Law (2003) No. 20 Notice, those conditions that are excluded from the 2002 regulation would be covered by the GPCL or even by consumer protection law. Thus, health care facilities and workers may be subject to greater liability for those excluded conditions than they would face under the 2002 regulation.

The 2002 regulation provides that medical accidents should be classified into one of four categories on the basis of severity. Under Article 4 of the new regulation, the most severe accidents in grade 1 are those that have caused death or serious disability, and the least severe accidents in category 4 are those that have merely “caused obvious injury to the body of patients or other consequences.” However, scholars have criticized the vague definition of grade 4 medical accident in the 2002 regulation, because the meaning of “obvious” is not really so obvious. This creates a large grey area with regard to whether certain medical injuries should be handled under the 2002 regulation or the GPCL.¹³⁶

RECOMMENDED REVISIONS AND FURTHER RESEARCH

The revisions recommended in this section are limited to specific changes in the law of medical malpractice, rather than broader reforms to the Chinese legal system or health care system. Some of these specific revisions could be implemented directly by the State Council, whereas other recommendations would require some action by the NPC. For its part, the SPC has apparently already done what it can in an effort to promote clarity and consistency, and the remaining problems are beyond the SPC’s control.

The State Council should amend or clarify the definition of “medical accident” in the 2002 regulation, in order to include all types of injuries that are caused by negligence in the process of medical treatment. In its current form, the regulation excludes certain types of adverse events, such as those resulting from lifesaving emergency care under dangerous circumstances. The intent of those exclusions from the 2002 regulation was to limit the liability of medical facilities and staff. However, the inadvertent result is that cases involving those excluded conditions will be handled under the GPCL and other laws, with a potential for greater liability on the part of health care providers. Although the State Council cannot resolve all of the conflicts between its 2002 regulation and the GPCL, the State Council may be able to solve the problem that was caused by excluding certain situations from the definitional section of its own

regulation. The State Council should also clarify or amend its regulation with regard to the least severe category of medical accidents, in which injury is merely “obvious.”

Another area for potential action by the State Council is further improvement to the system of technical authentication, in order to develop a system in which the people can place their trust. Although the 2002 regulation contains improvements over the previous regulation, serious problems remain with regard to the selection of committee members and the independence of authentication committees. One possible solution is for experts to be selected from a broader geographic area, in order to reduce the potential for local bias or interference by a local health department. Also, it is necessary to address the problem of fees for technical authentication, which may prevent injured patients or their families from seeking redress through legal means. One alternative is to confirm that medical institutions bear the obligation to pay authentication fees as part of their operating costs, regardless of the outcomes of individual cases. Other potential alternatives include the provision of public funds to pay the members of authentication committees, or requiring physicians to provide a limited amount of committee service without compensation as a condition of licensure by the government.

In addition, the State Council should make the amount of compensation under its regulation on medical accidents fully consistent with the amount of compensation that would be available under the GPCL or other laws. In its 2002 regulation, the State Council took an important step toward fairness and consistency by eliminating the inadequate, one-time economic compensation under the 1987 regulation and by providing a comprehensive list of recoverable damages. However, there are still some respects in which the amount of compensation under the 2002 regulation is inadequate or inequitable. For example, the State Council should eliminate the 20-year ceiling on damages for the support of a disabled dependent. By completing the task of raising compensation for medical accidents to the level of the GPCL and other laws, the State Council would eliminate the current inequity and reduce the incentive to seek relief for medical injuries under other sources of law.

Meanwhile, the NPC can help reduce the conflicts and improve the law in a variety of ways. One alternative is for the NPC to enact its own law on the handling of medical accidents, with specific provisions on its integration with the GPCL and other laws. Alternatively, the NPC could formally interpret the GPCL and consumer laws as being inapplicable to cases that fall within the more specific regulation on medical accidents. Under Article 42 of the Legislation Law, the NPC has the legal authority to interpret the laws, whereas the legal effect of an SPC interpretation of law is unclear. As a practical matter, it may be easier for the NPC to issue an interpretation of its own GPCL and related laws than it would be for the NPC to issue an interpretation with regard to the legal effect of SPC interpretations.

In addition to action by government agencies, there is a need for further research with regard to legal methods of handling medical accidents. In light of the concern over potential bias on the part of authentication committees, it would be useful to conduct experiments to determine whether authentication committees composed of local physicians reach the same conclusions on a representative sample of cases as committees composed of physicians from outside of the geographic area. In addition, empirical research is needed with regard to the use of alternative methods of dispute resolution in cases of medical injury. Arguably, administrative mediation should be eliminated from the process for handling medical accidents, because mediation is not legally binding and may increase the time and expense to resolve a dispute. However, if parties tend to be satisfied with the outcome of mediation in a significant percentage of cases, mediation might result in a faster and more economical resolution of medical disputes. These issues and others need to be resolved by means of empirical research and careful analysis of data.¹³⁷

CONCLUSION

By comparing the legal system for medical accidents in China and the United States, we can gain a better understanding of Chinese law, and we can identify the lessons that each

country can learn from the other. In both China and the U.S., lawmakers are combining liability reform with efforts to improve patient safety and reduce the incidence of medical errors. Thus, policymakers in China can take advantage of U.S. experience in continuing their own process of reform. At the same time, policymakers in the United States can learn several lessons from the Chinese experience with medical liability.

In the United States, discussions of medical liability are usually phrased in terms of a “malpractice crisis.” The primary concerns in the U.S. are the effect of medical liability on the cost of care, the expense and availability of professional liability insurance, the inability of the tort system to deter negligence or compensate injured patients in an efficient manner, and the possibility that the liability system interferes with efforts to improve the quality of care.¹³⁸ In addition, some political leaders and interest groups in the U.S. have expressed concern about frivolous or allegedly frivolous claims. In China, those are not the primary concerns, but nevertheless China suffers from a different type of “malpractice crisis.” The crisis in China is caused by the lack of a credible system to deal with medical accidents and related problems in quality of care.

Although commentators have noted an increase in civil litigation in China, there is little evidence of concern about frivolous claims of medical malpractice. Some evidence exists that hospital managers are worried about what they perceive to be an increase in medical errors and medical disputes.¹³⁹ However, it appears that frivolous claims—as well as meritorious claims—are deterred by the lack of trust on the part of patients and their families in the legal system for resolving medical disputes. This lack of trust is the real “malpractice crisis” in China, and it has contributed to multiple incidents of violence against health care professionals.

Experience in the U.S. has shown little evidence that malpractice liability deters negligent conduct in the practice of medicine.¹⁴⁰ However, U.S. researchers have identified some possible ways to increase the deterrent effect, such as promoting a type of enterprise liability.¹⁴¹ In the Chinese context, it may be possible to strengthen deterrence and improve the

quality of care by giving hospitals and their managers greater authority and a different set of incentives. At the present time, Chinese hospitals bear the legal liability for medical errors, but have little practical ability to prevent those errors. The managers of Chinese hospitals need to have the legal authority and the practical ability to discipline or even terminate physicians who fail to provide appropriate care. In addition, hospitals and their managers need incentives, such as effective rewards and sanctions, to take those steps that promote quality and reduce medical errors.

Another important lesson from U.S. experience is that medical liability is only one component of a comprehensive legal structure for promoting the quality of care. Another necessary component of that legal structure is effective government regulation, including licensure controls on medical professionals and facilities. Historically, medical malpractice litigation in the U.S. served as an alternative to government regulation, with litigation expanding to fill the void left by deregulation of the medical profession in the mid-1800's.¹⁴² However, government regulation in the form of licensure is now used in combination with private litigation and other tools as complementary ways to promote the quality of care in the United States.¹⁴³ Although China has adopted licensure laws and regulations for health care providers, the implementation and enforcement of those legal requirements has been limited.¹⁴⁴ In the U. S., state medical licensing boards have been criticized for professional protectionism, but protectionism is even more severe in the health care system of China. This situation makes it difficult to develop an effective system of professional regulation, and also raises questions about the potential effectiveness of peer review and other mechanisms of self-regulation.

In the meantime, the Chinese experience with medical liability provides several lessons for policymakers in the United States. First, the numerous problems with medical authentication committees in China, as discussed above, should provide a cautionary note to those in the U.S. who advocate replacing lay juries with expert panels or specialized courts.¹⁴⁵ Second, those who advocate legal mandates for reporting medical errors in the U.S. should note that China's 2002

regulation already includes comprehensive reporting requirements, but it is not at all clear that physicians and hospitals actually comply with those legal requirements. As others have pointed out, “all error reporting is ultimately voluntary, regardless of whether a mandate to report exists.”¹⁴⁶ Finally, the Chinese experience with violence against health care professionals should serve as a reminder that, despite all of its faults, medical malpractice litigation in the U.S. is a generally credible and relatively peaceful method of resolving disputes in cases of adverse medical incidents.

¹ See, e.g., “Doctor/Patient Conflicts Become More Common,” China Daily, August 8, 2001, available online at <http://www.china.org.cn/english/2001/Aug/17189.htm>, last visited on February 13, 2005.

² See Dehai Jiang, “Thoughts on the Practice of the Regulation on the Handling of Medical Accidents” (*guan yu yi liao shi gu chu li tiao li de shi jian si kao*), *National Judges College Law Journal (fa lu shi yong)*, 2002(11): 53-56, at 55.

³ See First Civil Branch of Jiang Su High People’s Court (*jiang su sheng gao ji ren min fa yuan min yi ting*), “Survey Report Regarding Cases of Disputes of Medical Harm Compensation” (*guan yu yi liao sun hai pei chang jiu fen an jian de diao cha bao gao*), *People’s Judicature (ren min si fa)*, 2002(10), 21-25, at 21.

⁴ Yongtang Song, Hongbing Xiang, and Wujin Luo, “Causes of the Aggravation of Medical Disputes and Their Corresponding Policy” (*yi liao jiu fen ji hua de yuan yin yu dui ce*), *The Chinese Health Service Management (zhong guo wei sheng shi ye guan li)*, 2000(5): 290-291, at 290. Other listed causes included biased mass media reports and inappropriate responses by health care facilities and health care workers. See also Jin Wei, “Thoughts on Medical Disputes and Corresponding Legal System” (*dui yi liao jiu fen ji qi fa lu zhi du de si kao*), *Chinese Medicine Bulletin (zhong hua yi xue cong kan)*, 2001, 1(12): 120-122, at 120; Hong Cheng, “Civil Liability in Medical Accidents” (*yi liao shi gu zhong de min shi ze ren*), *Chinese Lawyer (zhong guo lu shi)*, 1998 (6): 24-25, at 24.

⁵ LEXIS PRCLEG 2276 (March 13, 2003).

⁶ As set forth in Article 1 of the 2002 regulation, one of the purposes of the regulation was maintaining an orderly and safe environment for medical practice. Article 59 of the 2002 regulation provides for criminal penalties or other punishments for anyone who “picks quarrels and stirs up trouble.” Similarly, Article 40 of the Law on Practicing Doctors, which was promulgated on June 26, 1998 by the Standing Committee of the National People’s Congress, provides punishment for “[t]hose who obstruct medical practice by doctors according to law, insult, slander, threat or beat up doctors....”. The adoption of that law in 1998 provides further evidence that violence against doctors was perceived as a serious problem for which a legal solution was required.

⁷ J. Chen, *Chinese Law: Towards an Understanding of Chinese Law, Its Nature and Development* (The Hague: Kluwer Law International, 1999): at 21-22.

⁸ *Id.* at 31, 40-44; C. Wang and X. Zhang, eds., “Introduction to Chinese Law” (Hong Kong: Street & Maxwell Asia, 1997): at 12; G. Wang and J. Mo, eds., *Chinese Law* (London: Kluwer Law International, Ltd. 1999): at 2-3.

⁹ Wang and Mo, *supra* note 8, at 6-8, 19.

¹⁰ Wang and Zhang, *supra* note 8, at 18 (“Although the Constitution is regarded as the paramount law in the country, it nevertheless cannot be quoted in judicial verdicts and administrative decisions as a direct legal ground for solving concrete disputes and problems.”); D. Chow, *The Legal System of the People’s Republic of China in a Nutshell* (St. Paul: West Group, 2003), at 78 (“Many scholars in the PRC view the Constitution as declaratory and as stating policy and doubt whether it has direct legal effect in the absence of implementing legislation.”). But see Kui Shen, “Is It the Beginning of the Era of the Rule of the Constitution?: Reinterpreting China’s First Constitutional Case,” *Pacific Rim Law and Policy Journal*, 12 (2003): 199-231 (discussing the potentially groundbreaking use of a constitutional provision by the Supreme People’s Court in civil litigation involving the right to education.)

¹¹ See Wang and Zhang, *supra* note 8, at 18-20; Wang and Mo, *supra* note 8, at 8-11. Unlike the American use of the term “law” to include all types of binding legal authority at any level of government, English translations of Chinese legal materials generally limit the term “law” (*fa lu*) to enactments of the NPC or its Standing Committee. Chow, *supra* note 10, at 153. But see Wang and Mo, *supra* note 8 at 8 (“The form or title of the

legislation is not significant. What is important is the body which enacts it.”).

¹² Wang and Zhang, *supra* note 8, at 23; Chow, *supra* note 10, at 215-217.

¹³ See generally, Wang and Mo, *supra* note 8, at 15-21; Wang and Zhang, *supra* note 8, at 23-26. Theoretically, judicial decisions do not create binding precedent, but they have a strong impact as a practical matter. Wang and Zhang, *supra* note 8, at 21.

¹⁴ Wang and Zhang, *supra* note 8, at 16-17. See also N. Liu, “A Vulnerable Justice: The Finality of Civil Judgments in China,” *Columbia Journal of Asian Law*, 13 (1999): 35-98, at 60-61 & nn. 89-91. Moreover, as a practical matter, the Communist Party of China has the power to control nominations for positions in government agencies, including the nomination of judges. Wang and Zhang, *supra* note 8, at 25; Chow, *supra* note 10, at 128-29.

¹⁵ N. Liu, *supra* note 14, at 60-61 & nn. 89-91; Chow, *supra* note 10, at 78-81, 142-143. Similarly, there was no separation of powers in traditional Chinese law, in which administrative officials also served as prosecutors and judges. Wang and Zhang, *supra* note 8, at 6; Chen, *supra* note 7, at 16.

¹⁶ See note 9 and accompanying text *supra*. In addition, legislative powers are not limited to the people’s congresses in the legislative branch. Chow, *supra* note 10, at 142-156.

¹⁷ Wang and Zhang, *supra* note 8, at 15-16.

¹⁸ Chow, *supra* note 10, at 86-87.

¹⁹ One exception to uniformity under the 2002 regulation is that military medical facilities will have their own system for handling medical accidents, although that system will be based on the 2002 regulation.

²⁰ See Chen, *supra* note 7, at 3- 17, 30; C. Wang and Zhang, *supra* note 8, at 5-9.

²¹ Chen, *supra* note 7, at 17 (“An abstract concept of individual was conspicuously lacking in traditional Chinese law.”); Wang and Zhang, *supra* note 8, at 5.

²² Chen, *supra* note 7, at 15; Wang and Zhang, *supra* note 8, at 6

²³ Wang and Zhang, *supra* note 8, at 6. See also Vai I. Lo, “Resolution of Civil Disputes in China,” *UCLA Pacific Basin Law Journal*, 18 (2001): 117-156, at 152 (“the general assumption that Chinese are averse to litigation....”).

²⁴ *Id.* at 140.

²⁵ Note, “Class Action Litigation in China,” *Harvard Law Review*, 111 (1998): 1523-1541, at 1523. The current use of litigation in China includes suits against government officials for violation of rights. *Id.* at 139-40, 152. “Together with the surge in litigation involving administrative malfeasance in recent years, the rising incidence of civil litigation largely reflects that Chinese citizens are no longer afraid to go to the court.” *Id.* at 152. See also Chen, *supra* note 7, at 166 (“The idea that a citizen can sue the government and that a government is liable for its maladministration is revolutionary in a legal culture where government officials had the status of parents and parents were perceived to be infallible.”).

²⁶ James C. Mohr. American Medical Malpractice Litigation in Historical Perspective. *JAMA* 283(13)(2000): 1731-1737, at 1732 (“The onset of medical malpractice litigation corresponded with a sharp decline of religious fatalism and a dramatic rise of religious perfectionism, both of which were associated with the revivals of the 1820s and 1830s.”).

²⁷ B.J. Fried and L.M. Gaydos, eds., *World Health Systems: Challenges and Perspectives* (Health Administration Press, 2002): at 345.

²⁸ W.C.L. Hsiao, “The Chinese Health Care System: Lessons for Other Nations,” *Social Science & Medicine*, 41, no.8 (1995): 1047-1055, at 1054.

²⁹ Hsiao *supra* note 28, at 1052. See generally, The World Bank. *CHINA 2020: Financing Health Care: Issues and Options for China* (Washington, D.C. 1997).

³⁰ World Bank, *supra* note 29, at 2-3.

- ³¹ J.S. Akin, W.H. Dow, and P.M. Lance, "Did the Distribution of Health Insurance in China Continue to Grow Less Equitable in the Nineties? Results from a Longitudinal Study," *Social Science & Medicine*, 58 (2004): 293-304, at 295.
- ³² World Bank, *supra* note 29, at 47 ("Nearly 90 percent of farm households now pay out of pocket for almost all their health services.").
- ³³ World Health Organization, *World Health Report 2000—Health Systems: Improving Performance* (2000), 35-39, 188-91(Annex Table 7).
- ³⁴ See G. Henderson, et al, "Distribution of Medical Insurance in China," *Social Science & Medicine*, 41(8) (1995); 1119-1130; Akin et al., *supra* note 31, at 294-95; World Bank, *supra* note 29, at 2.
- ³⁵ See Hsiao, *supra* note 28, at 1051 (noting that neither the national MOH nor the provincial health bureaus have "regulatory jurisdiction" over hospitals operated by state-owned enterprises.) Similarly, civilian health agencies do not have authority over military health care facilities. As Gordon Liu has pointed out, "[s]ince these institutions are not accountable to any single body, their financial and quality performance are poorly monitored and evaluated, resulting in over-billing, over-prescribing, and over-utilization of health services." G. Liu et al., "Urban Health Care Reform Initiative in China: Findings from its Pilot Experiment in Zhengjiang City," *International Journal of Economic Development* (December 1999): 1-13.
- ³⁶ Hsiao, *supra* note 28, at 1051, 1053; Likun Pei et al., "Hospital Management in China in a Time of Change," *Chinese Medical Journal* 115(11)(2002): 1716-1726 at 1722.
- ³⁷ World Bank, *supra* note 29, at 2-3, 19-20, 42-43; Hsiao, *supra* note 28, at 1051, 1053; Pei et al, *supra* note 36, at 1722-23; Ruiping Fan, "Modern Western Science as a Standard for Traditional Chinese Medicine: A Critical Approach," *Journal of Law, Medicine & Ethics* 31(2)(2003): 213-221 at 221 n.6. In addition, it appears that prices for the use of some high technology equipment may have been based on unrealistically low estimates of volume and equipment life in the data that was provided to price-setting agencies. Pei et al., *supra* note 36, at 1722-23; Hsiao, *supra* note 28, at 1051-52.
- ³⁸ Pei et al., *supra* note 36, at 1719, 1723.
- ³⁹ World Bank, *supra* note 29, at 5-6, 22, 42-43, 45-46. According to the World Bank, duplication causes supplier-induced demand, and, therefore, China should impose governmental supply-side controls. *Id.* at 6, 45-46. It is interesting to note that the supply-side controls recommended by the World Bank would be similar to the much-criticized U.S. program of certificate of need (CON) regulation. See, e.g., C.J. Conover and F.A. Sloan, "Does Removing Certificate of need Regulations Lead to a Surge in Health Care Spending?," *Journal of Health Politics, Policy & Law*, 23(3)(1998): 455-481.
- ⁴⁰ See generally, Institute of Medicine, *To Err is Human: Building a Safer Health Care System*, at 4 ("Building safety into processes of care is a more effective way to reduce errors than blaming individuals"); T.S. Jost, "Oversight of the Quality of Medical Care: Regulation, Management, or the Market?," *Arizona Law Review*, 37 (1995): 825-868.
- ⁴¹ See G. Liu et al., "Privatization of the medical market in socialist China: A historical approach," *Health Policy*, 27 (1994): 157-174, at 169 ("Like in most other developing countries, many Chinese private medical practitioners are not well trained or formally educated.").
- ⁴² See Hsiao, *supra* note 28, at p. 1053. In addition, according to Hsiao, "China also lacks a system to monitor quality of services or improve services according to changes in patient preferences." (*Id.*)
- ⁴³ Writing in 1991, Localio et al. suggested that the availability of health insurance in the United States might be one of the reasons that so few injured patients pursue medical malpractice claims. Localio et al., "Relation between Malpractice Claims and Adverse

Events Due to Negligence,” *N. Engl. J. Med.* 325(4) (1991): 245-251, at 249. Thirteen years later, William Sage noted that higher levels of uninsurance and the widespread use of cost containment techniques by health insurers has left liability insurance “as one of the few remaining unconstrained sources of health care financing for severe injury.” William M. Sage, “The Forgotten Third: Liability Insurance and the Medical Malpractice Crisis,” *Health Affairs*, 23(4) (2004): 10-21, at 16.

⁴⁴ See Fan, *supra* note 37, at pp. 215 and 219.

⁴⁵ In contrast, to impose vicarious liability on a hospital for the negligence of a physician in the U.S., the plaintiff ordinarily would need to litigate factual issues regarding the physician’s relationship with the hospital as an actual employee or agent. Alternatively, a plaintiff might need to prove that the hospital held out the doctor to the public as its ostensible agent. A U.S. plaintiff might also need to prove that the hospital breached its own duty to the patient by failing to properly screen independent physicians who were applying for medical staff membership and clinical privileges.

⁴⁶ Constitution of the P.R.C., Art. 45 (China Legal Publishing House, 2004).

⁴⁷ General Principles of the Civil Law of the P.R.C., Art. 98 (Law Press China 2002). See Chen, *supra* note 7, at 51. See generally W.C. Jones, “Some Questions Regarding the Significance of the General Provisions of Civil Law of the People’s Republic of China,” *Harvard International Law Journal*, 28, no. 2 (1987): 309-331. But see J.A. Cohen, “Forward,” *Harvard International Law Journal*, 28, no. 2 (1987): 239-247, at 242-43 (suggesting that Professor W.C. Jones underestimates the significance of the GPCL as a practical matter.) In addition to the GPCL, the P.R.C. has adopted a Civil Procedure Law that became effective in 1991.

⁴⁸ GPCL, *supra* note 47, at Art. 98.

⁴⁹ GPCL, *supra* note 47, at Art. 119.

⁵⁰ Wang and Mo, *supra* note 8, at 160.

⁵¹ Linna Song et al., “The Attribution of Criminal Responsibility in Medical Liability Incidents” (*yi liao ze ren shi gu zhong xing shi ze ren de que ding*), *Chinese Journal of Hospital Administration (zhong hua yi yuan guan li za zhi)*, 1989, 5(3): 161, quoted in Xin Liu and Lin Chang, “Summary of Opinions Regarding Criminal Liability for Medical Liability Incident” (*yi liao shi gu xing shi chu fa guan dian zong shu*), *Journal of Law and Medicine (fa lu yu yi xue za zhi)*, 1996, 3(2): 60-62, at 60.

⁵² *Id.* Though, many patients and their family members were not satisfied with administrative management because administrative officials did not have much legal authority.

⁵³ Qinchu Zhang and Shengli Cai, “Retrospect Survey of the Handling of Medical Incidents in the PRC” (*wo guo chu li yi liao shi gu zhuang kuang hui gu diao cha*), *Chinese Journal of Forensic Medicine (zhong guo fa yi xue za zhi)*, 1999, 14(3): 165-167, at 165.

⁵⁴ Song et al., see *supra* note 51, at p.161. Criminal penalties have been imposed less frequently for medical malpractice since, see Qinchu Zhang, “Concise Summary of the Handling of Medical Incidents in the PRC” (*wo guo yi liao shi gu chu li de jian yao hui gu*), *Chinese Clinical Physician (zhong guo lin chuang yi sheng)*, 2004, (32)3: 61-62, at 61.

⁵⁵ Baozhen Li, “Recommending the Addition of Crime of Severe Medical Liability Incident” (*jian yi zeng she zhong da yi liao shi gu zui*), *Deiking University Law Journal (zhong wai fa xue)*, 1994(2): 52-54, at 52.

⁵⁶ Juan Luo, “Investigation into the Distribution of ‘Medical Accidents and Disputes’ Articles in Journals in Our Country” (*guo nei yi liao shu gu ji jiu fen zai wen qi kan fen bu diao cha*), *China Health Law (zhong guo wei sheng fa zhi)*, 2000, 8(5): 23. From 1995 through 1999, there were 274 articles addressing the 1987 Regulation in the 10 leading journals regarding law and medicine in the PRC.

⁵⁷ Qingwen Guo and Xinshan Chen, “Law of Medical Disputes: Retrospectation and Expectation” (*yi liao jiu fen chu li shi yong fa lu hui gu ji zhan wang*), *Hosp Admin J Chin PLA* (jie fang jun yi yuan guan li za zhi), 2003, 10(2): 182-183, at 182-183. Lingzh Cui i, “Comment on the Reform and Perfection of Medical Law System” (*lun yi liao fa lu zhi du de gai ge yu wan shan*), *Administration and Law* (*xing zheng yu fa*), 2001(3): 63-65, at 63-64. Hongbin Gao and Xuneng Huang, “Legal Study in Medical Disputes” (*yi liao jiu fen de fa lu yan jiu*), *People’s Judicature* (*ren min si fa*), 2001(10): 30-33, at 33.

⁵⁸ P.W. Bates, “The Role of Legislation in Health Services Development” (with Particular Reference to China and Australia), *Medical Law*, 1994 (13): 433-449, at 443.

⁵⁹ Bin Zhang et al., “Exploration of and Suggestion for Current Medical Law System” (*dui xian xing yi liao fa lu zhi du de tan tao yu jian yi*), *Chinese Journal of Hospital Administration* (*zhong hua yi yuan guan li za zhi*), 1999, 15 (4): 222-224, at 222-223.

⁶⁰ The concept of ‘treatment and nursing activities’ was broadened in the May 10, 1988 supplement administrative interpretation on the 1987 regulation by Ministry of Health (*wei sheng bu guan yu yi liao shi gu chu li ban fa ruo gan wen ti de shuo ming*). Accordingly, maintenance and management activities serving diagnostic, treatment and nursing activities were included in the definition of liability accident. Thus, patient death due to power failure during a surgical operation may be regarded as a liability incident. cf. P.W. Bates, *supra* note 58, at 443. Unfortunately, this specific expansion of health care activities was neglected. See Xiaoxiang Hu, “Brief Analysis of Several Questions in Urgent Need of Solutions in Applying the 2002 Regulation” (*qian xi tiao li guan che shi shi zhong qi dai jie jue de ji ge wen ti*), *Journal of Law and Medicine* (*fa lu yu yi xue za zhi*), 2002, 9 (4): 193-196, at 194.

⁶¹ The 1988 supplement interpretation did not state clearly whether administrative staff of health care facilities were included as actors who might cause liability. In addition, the 1988 supplement interpretation re-emphasized the requirement of ‘direct causation’ and ‘direct responsibility’ in imposing administrative penalty. It is dubious whether any administrative staff could be ‘directly responsible’ for medical accidents in their usual administrative activities.

⁶² Bin Zhang, Yongzhang Lu and Yichen Huang, “Current Problems in the Legal System of Managing Medical Disputes and Reform Recommendation” (*xian xing chu li yi liao shi gu jiu fen fa lu zhi du cuen zaide wen ti yu gai ge*), *Chinese Health Law* (*zhong guo wei sheng fa zhi*), 1999, 7(4): 13-15, at 13. According to a survey on 12,815 subjects in 1999 by Chinese Association of Patients and Families (*Zhong Guo Bing Yuan Ji Jia Shu Xie Hui*), 52.76% reported that they were harmed by medical practice in the past year; less than 10% of people were satisfied with either medical service or drugs. See Hailing Chen, “Theoretical Exploration of Further Perfection of the System of Managing Medical Accidents” (*jin yi bu wan shan yi liao shu gu chu li zhi du de li lun tan tao*), *Modern Law Science* (*dang dai fa xue*), 1999(6): 45-47, at 45. It is doubtful that these complaints could be addressed by the narrow definition of liability incident in the 1987 Regulation.

⁶³ On September 20th 1994 in a response to Henan Provincial Health Department’s questions regarding the 1987 Regulation, the PRC Ministry of Health allowed some discretionary compensation for victims of medical negligence that could not be categorized as *medical incident*. However, no practical direction was given on how to implement this breakthrough. See Zhang et al., *supra* note 62, at 13. In a sample of 100 cases from a provincial-wide survey conducted by Jiang Su High People’s Court, only 5 cases were recognized as liability incidents. However, medical negligence was found in most of 100 cases. See First Civil Branch of Jiang Su High People’s Court, *supra* note 3, at 23.

⁶⁴ Xiaoxiang Hu, “Re-discussing the Evaluation of the Regulation on Dealing with Medical Incidents” (*zai lun dui yi liao shi gu chu li ban fa de ping jia – bu ke lan yong min*

fa tong ze), *The Chinese Health Service Management (zhong guo wei sheng shi ye guan li)*, 1998 (7): 364-367, at 365; Xiaojun Zhang, "Research into Several Questions Regarding Medical Accident Liability" (*yi liao shi gu pei chang ze ren ruo gan wen ti yan jiu*), *Journal of the Renmin University of China (zhong guo ren min da xue xue bao)*, 1999(3): 83-88, at 84.

⁶⁵ Yaping Chen and Yuwen Jin, "Discussing Current Legal System in Managing Medical Accident in Our Country" (*lun wo guo mu qian yi liao shi gu chu li de fa lu zhi du*), *Journal of Huaqiao University (Philosophy and Social Science) (hua qiao da xue xue bao (zhe she ban))*, 1999(3): 61-66, at 62.

⁶⁶ Their arguments are as follow: For guaranteeing citizens' right to health care, government healthcare facilities have the obligation to offer affordable healthcare to citizens as part of social welfare administration. It is doctors who actually determine the contents of health care. Civil contract is not suitable for explaining these characteristics. See Hu, *supra* note 64; Xin Liu and Yueping Zeng, "Theoretical Exploration of Principles of Limited Medical Liability" (*the yi liao sun hai xian e pei chang yuan ze de li lun tan tao*), *Journal of Law and Medicine (fa lu yu yi xue za zhi)*, 1999, 6(2): 23-25, at 23.

⁶⁷ Shufa Wei, "Arguments on Establishing Legal System of Compensating Medical Accidents" (*jian li yi liao shi gu sun hai pei chang fa lu zhi du zheng yi*), *Fujian Tribune: An Economics and Sociology Monthly (fu jian lun tan: jing ju she hui ban)*, 1997(9): 62-64, at 62. Shu Lin, "Analysis in and Policy Exploration of Economic Compensation for Medical Accidents" (*yi liao shi gu jing ji bu chang wen ti fen xi ji dui ce*), *Journal of Shandong Medical University (social sciences) (san dong yi ke da xue xue bao (she hui ke xue ban))*, 1998(3): 6-8, at 6.

⁶⁸ The amounts of one-time 'economic compensation' for patients' deaths ranged from 3,000 to 15,000 RMB. See Zhang et al., *supra* note 59, at 224; Wei, *Id.* at 63.

⁶⁹ Wei, *Id.*, at 62; Qiao Shi Ming, "Discussing the Legal Problems of the Regulation on Dealing with Medical Incidents and Its Perfection" (*lun yi liao shi gu chu li fa de fa lu wen ti ji wan shan*), *National Judges College Law Journal (fa lu shi yong)*, 2001(3): 32-34, at 34.

⁷⁰ Wei Shu Fa, *Id.*, at 62

⁷¹ *Id.*, at 62

⁷² *Id.*, at 63; Zhang Bin et al., "Deficits and Policy of Current Medical Law System" (*xian xing yi liao fa lu zhi du de que xian yu dui ce*), *Science Technology and Law (ke ji yu fa lu)*, 1998(3): 54-57, at 56; Liming Wang, "Concept of Consumer and the Management Range of Consumer Rights and Interests Protection Law" (*xiao fei zhe de gai nian ji xiao fei zhe quan yi bao hu fa de tiao zheng fan wei*), *Political Science and Law (zheng zhi yu fa lu)*, 2002(2): 3-12, at 11.

⁷³ Zeyin Gao, "Comments on the Establishment of Relevant Legal System to Manage Medical Disputes" (*lun yi liao jiu fen chu li xiang guan fa lu zhi du jian she*), *The Chinese Health Service Management (zhong guo wei sheng shi ye guan li)*, 2002(4): 223-225, at 223. Chenglong Yang, "Legal Application in Medical Disputes" (*yi liao jiu fen de fa lu shi yong*), *Journal of Shanghai University (Social Science) (shang hai da xue xue bao (she hui ke xue ban))*, 1999, 6(6): 81-85, at 83. Qiao, *supra* note 69, at 33

⁷⁴ Cui, *supra* note 57, 2001(3): 63-65, at 63-64. Gao, *Id.* at 223. Qiao, *Id.* at 33. As Professor Dongdong Sun pointed out in an interview, according to his knowledge, 8 deputy chiefs of provincial health departments were actually the presidents of provincial hospitals. It was hard for them not to consider the interests of these hospitals; available at <http://cul.sina.com.cn/s/2002-04-02/11422.html>, last visit on July 2, 2004.

⁷⁵ Cui, *Id.* at 63-64. Dongdong Sun and Jianfong Wu, "Opinions on the Deficits and Reform of Medical Accident Authentication System" (*wo guo yi liao shi gu jian ding ti zhi de bi duan yu gai ge*), *Deiking University Law Journal (zhong wai fa xue)*, 1998(5): 95-97, at 96. Qiao Shi Ming, *Id.* at 33. Pang Cai Bin, "Opinions on the Regulation on

Dealing with Medical Incidents” (*guan yu yi liao shi gu chu li ban fa de ji dian yi jian*), *Journal of Law and Medicine* (*fa lu yu yi xue za zhi*), 1997, 4(2): 67-68, at 67.

⁷⁶ Ningmin Wang, Yan Wan, Shengli Di and Fongqin Zhang, eds., *An Easy Guide to Help You Understand Law - Medical Dispute* (*fa lu bang zhu yi dian tong- yi liao jiu fen*), Beijing: Zhong Guo Jian Cha Chu Ban She, at 30-31.

⁷⁷ Xueliang Zhao, “Problems in Legislation Inequity and Practice of the Regulation on Dealing with Medical Incidents” (*yi liao shi gu chu li ban fa li fa bu gong han shi jian de wen ti*), *Journal of Liaocheng Teachers University* (*liao cheng shi fan xue yuan xue bao*), 2000(2): 47-51, at 48. According to Article 119 of Criminal Procedure Law, the courts have to power to assign experts to conduct medical examination. According to Article 35 of Administrative Procedure Law and Article 72 of Civil Procedure Law, the courts’ power to assigning experts to conduct forensic examination is restricted only by law, not by a regulation.

⁷⁸ This is explicitly stated in Article 79 of the PRC Legislation Law, which has become effective since 2000.

⁷⁹ In Article 119 of GPCL, compensation for medical injury must include the incurred medical fees, lost income, living fees for those disabled; compensation for death must include the burial fees and the living fees for the dependent of the deceased.

⁸⁰ In 2001, the highest documented damage awarded to victims of medical accidents has reached 2,920,000 RMB. See Xueqian Zheng, “How to Reasonably Compensate for Medical Negligence?” (*yi liao guo shi zen me pei cai he li*), *Legal Daily* (*fa zhi ri bao*), 2001.9.6, at 5. However, the highest one-time economic compensation is only 15,000 RMB (about 1,800 US dollars). See Zhang et al., *supra* note 59, at 224; Wei Shu Fa, see *supra* note 67, at 63.

⁸¹ See March 24, 1992 Supreme People’s Court’s reply to Tian Jin High People’s Court regarding how to apply laws in adjudicating compensations for medical incidents (*guan yu li xin rong su tian jin shi di er yi xue yuan fu she yi yuan yi liao shi gu pei chang yi an ru he shi yong fa lü wen ti de fu han*). Unfortunately, in that reply Supreme People’s Court did not clarify how to reconcile the conflicts among GPCL, the 1987 Regulation and other local regulations. See Bosheng Jiang, “Evaluating and Analyzing Current Legal System of Medical Incident Management in Our Country” (*wo guo xian xing yi liao shi gu chu li fa lu zhi du ping xi*), *Jiansu Social Science* (*jiang su she hui ke xue*), 1998(6): 87-91, at 88-89.

⁸² Weihua Xiao, “Research into Several Legal Problems of Medical Compensation: Legal Analysis of 92 Cases of Compensations for Medical Harm” (*yi liao pei chang ruo gan fa lu wen ti yan jiu: dui 92 li yi liao sun hai pei chang su song an defa lu fen xi*), *Chinese Health Law* (*zhong guo wei sheng fa zhi*), 2000, 8(6): 22-26, at 22-23.

⁸³ According to Article 63 of Civil Procedure Law, the courts also have the power to examine authentication conclusions before adopting them. See Fongming Jiang and Wenping Yang, “Comment on the Application of Law in Solving Medical Disputes” (*lun yi liao jiu fen jie jue fa lu shi yong*), *Chinese Hospital Management* (*zhong guo yi yuan guan li*), 1996, 16(9): 13-15, at 13-14. Xiao, *Id.* at 24.

⁸⁴ First Civil Branch of Jiang Su High People’s Court, *supra* note 63, at 23; Zhang et al., *supra* note 59, at 222.

⁸⁵ See Oct 10, 1989 Supreme People’s Court’s reply to Sichuan High People’s Court regarding whether people’s courts should take cases of medical accident disputes (*zui gao ren min fa yuan guan yu dui yi liao shi gu zheng yi an jian ten min fa yuan ying fo shou li de fu han*). SPC expressed clearly that disputes about the conclusions of technical authentication shall not be accepted; Xiao Wei Hua, *supra* note 82, at 24; Jingzhu Liu, “Research on problems of compensating medical accidents” (*yi liao shi gu pei chang wen ti yan jiu*), *Legal Science* (*fa xue*), 1998(10): 22-24, at 23.

⁸⁶ Jiang and Yang, see *supra* note 83, at 13-14. Lingling Yang, "Urgent Need for a Uniform Legal System of Medical Accident Management" (*yi liao shi gu chu li fa qi dai tong yi gui fan*), *Medicine and Philosophy* (*yi xue yu zhe xue*), 1999, 20(5): 10-12, at 10-11.

⁸⁷ See Oct. 10, 1989 Supreme People's Court's reply to Sichuan High People's Court, *Id.* Many lay people may feel that they fall in the cleft between the administrative and the judicial systems; see Zhandong Gao and Jisheng Zhao, "Preliminary Comment on the Question of Law Application in the Management of Medical Disputes" (*qian tan yi liao jiu fen chu li zhong de fa lu shi yong wen ti*), *Modern Law Science* (*dang dai fa xue*), 1999 (5): 46-48, at 46; Yongzhang Lu, Yichen Huang, and Bin Zhang, "Exploring the Reform of Legal System of Managing Medical Accident Disputes" (*dui chu li yi liao shi gu jiu fen fa lu zhi du gai ge de tan tao*), *The Chinese Health Service Management* (*zhong guo wei sheng shi ye guan li*), 1998(6): 301-304, at 303.

⁸⁸ Basically there have been three groups of arguments. The first group, represented by health care professionals, argued *against* the application of Consumer Protection Law to medical practices because: (1) healthcare facilities are enterprises of social welfare, not managers; (2) the results of treatment could not be guaranteed; (3) patients are not general consumers since the price of health care service is still below its cost due to government control; and (4) the application will make health care workers overcautious and in the long run stifle the innovation of medicine. The second group argued *for* the application because patients (consumers) still pay for health care service and drugs (products) they receive from health care facilities (managers). The third group argued for further *differentiation* of the characteristics of health care facilities such that only welfare-oriented health care facilities should not be covered by Consumer Protection Law. See Wang Li Ming, *supra* note 72, at 9-10; Guo and Chen, see *supra* note 57, at 183.

⁸⁹ In 1999, Si Chuan Province Lu Zhou City Middle People's Court stipulated that medical disputes should be covered by Consumer Protection Law; in 2000, Zhe Jiang Province People's Congress covered medical disputes in its implementation regulation of Consumer Protection Law in 2000. See Guo Qing Wen and Chen Xin Shan, *Id.*, at 182-83. As far as we know in July, 2004, Chong King City, Guang Dong Province, Tibet, Ji Lin Province, Shan Dong Province, Jiang Su Province, Hu Nan Province, Yun Nan Province, Liao Ning Province, and Gan Su Province also have regulations covering medical practices in the implementation of Consumer Rights and Interests Protection Law. However, it is unclear to us whether and how local people's courts and local health departments apply these regulations in handling medical accidents. Further interpretation is needed with regard to what liability health care facilities should bear for medical harm caused by their service to consumers. Both the 1987 Regulation and GPCL adopt rules of negligence in determining liability for medical accidents. The plausible interpretation is that health care facilities do not bear strict or no-fault liability for medical harms caused by their health care service. See Li Yi Song, "Mistake in the Question Asked by Conventional Legal Study: Comment on the Debate Regarding Whether Consumer Rights and Interests Protection Should be Applied in Medical Disputes" (*chuan tong fa xue wen ti shi zhi wu: ping yo guan yi liao jiu fen shi fo shi yong xiao fei zhe chuan yi bao hu fa de tao lun*), *Hunan Social Science* (*hu nan she hui ke xue*), 2003(2): 160-163, at 161.

⁹⁰ Baozhen Li, "Comment on the Essential Conditions of Crime of Medical Accident" (*lun yi liao shi gu zui de go cheng yao jian*), *Legal Forum* (*fa xue lun tan*), 2000(3): 64-67, at 64. See also Article 335 of 1997 Revised Criminal Law.

⁹¹ For example, in 1998 the PRC Practicing Doctors Law was adopted; in 1994, both Regulations on the Management of Nurses and Regulations on the Management of Health Care Facilities were adopted.

⁹² Xiangang Zhou, "Exploring the Legal System of Compensation for Medical Harm" (*yi liao sun hai pei chang fa lu zhi du tan tao*), *Chinese Health Law (zhong guo wei sheng fa zhi)*, 2000, 8(5): 17-21, at 18.

⁹³ Although we do not have nation-wide statistics on the trend of medical malpractice litigation, some local statistical figures did give us a hint about this. See First Civil Branch of Jiang Su High People's Court, see *supra* note 63, at 21; Kaijun Zhang and Te Chen, "The Specificity, Difficulty and Adjudication Policy of Current Cases of Medical Disputes (I)" (*dang qian yi liao jiu fen an jian de te dian ji sheng pan dui ce (shang)*), *Judicature of China (lu shi sha long)*, 2003, 28-30, at 29; Hui Wang, "Analysis of Accepted Cases of Medical Dispute" (*liao jiu fen shou li an jian fen xi*), *The Chinese Health Service Management (zhong guo wei sheng shi ye guan li)*, 1999(6): 306-309, at 309-10.

⁹⁴ Wang, *Id.* at 309; Xiao, *supra* note 82, at 22.

⁹⁵ In its March 24, 1992 reply to Tian Jin High People's Court (*guan yu li xin rong su tian jin shi di er yi xue yuan fu shu yi yuan yi liao shi gu pei chang yi an ru he shi yong fa lu wen ti de fu han*), it confirmed that the GPCL should be applied in the calculation of compensation in civil litigation of medical malpractice. In SPC's Law Interpretation (2001) No. 7 regarding interpretations for several questions of liability for spiritual injury in tort cases (*zui gao ren min fa yuan guan yu que ding min shi qin quan jing shen sun hai pei chang ze ren ruo gan wen ti de jie shi, fa shi (2001) 7 hao*), the SPC has allowed awarding damages for pain and suffering when infringement of rights to life or health is the basis of claims. Finally, in SPC's Law Interpretation (2001) No. 33 regarding the application of Civil Procedure Law (*zui gao ren min fa yuan guan yu min shi su song zheng ju de ruo gan gui ding, fa shi (2001) 33 hao*), health care facilities have been required to bear the burden of proof in showing the lack of fault on their side as well as the lack of causal relationship between the health care services and the patient's injury.

⁹⁶ See Wenyi Zhu, "Medical Accidents: Ten Years of Law Revision" (*yi liao shi gu: shi nian xiu fa*), available at <http://cul.sina.com.cn/s/2002-04-02/11422.html>, last visit on July 2, 2004; Yu Zhu, Ten years to revise one law: the process of drafting the "Regulation of Handling Medical Accidents" (*nian xiu yi fa: yi liao shi gu chu li tiao li de qi cao guo cheng*), available at <http://health.enorth.com.cn/system/2002/04/16/000313358.shtml>, last visit on July 2, 2004.

⁹⁷ See generally, Selene Ko, "Chinese Anti-Monopoly Law: An Introduction to Chinese Legislation," *Washington University Global Studies Law Review*, 3(2) (2004): 267-275, at 270-71 (describing the procedure for developing regulations.)

⁹⁸ See Longde Wang, Ministry of Health's summary report to National People's Congress Education, Science and Culture regarding the revision of the Regulation on Dealing With Medical Incidents (*wei sheng bu jiu yi liao shi gu chu li ban fa xiu ding xiang chuan guo ren da jiao ke wen wei yuan hui suo zuo de hui bao*), 2000, available at <http://www.angelaw.com/medlaw/theory14.htm>, last visit on July 2, 2004. As Deputy Minister of Health, Wang Long De explained the directions of the revision in his 2000 brief to the NPC.

⁹⁹ See Ruilin Song, "Thoughtway on the Lawmaking of 'the Bylaw of Medical Accident Management'" (*yi liao shi gu chu li tiao li li fa si lu*), *Chinese Hospitals (zhong guo yi yuan)*, 2002, 6(6): 17-19, at 17.

¹⁰⁰ Kan Tian, "A Try to Comment on the Management of Medical Accident Disputes" (*shi lun yi liao shi gu jiu fen de chu li fang shi*), *Journal of Nanjing Medical University (Social Science) (nan jing yi ke da xue xue bao (she hui ke xue ban))*, 2002(2): 85-88, at 8; Zhu, see *supra* note 96. Cf. The legislation process was criticized for its lack of public participation and hearing; see Kun Huang and Hongying Sun, "Comment on the legislation deficits of the Regulation on Handling Medical Accidents" (*lun yi liao shi gu*

tiao li de li fa que xian), available at http://article.chinalawinfo.com/article/user/article_display.asp?ArticleID=22023, last visit on July 7, 2004.

¹⁰¹ See generally, Lo, *supra* note 23, at 126, 155-156 (regarding alternative mechanisms of dispute resolution.) According to Article 46 of the 2002 regulation, negotiation, administrative handling (*chu li*) and mediation (*tiao jie*), and civil litigation are all available procedures of dispute resolution. Moreover, requests for administrative handling and administrative mediation may be separated. Administrative handling (*chu li*) is focused primarily on the administrative management of health care staff and facilities, as indicated by Article 35 and the title of Chapter 4. According to Article 42, the results of a technical authentication can provide the basis for administrative punishment of health care providers and for mediation between the parties. Although administrative handling could be construed broadly to include administrative mediation, administrative handling under Article 37 is not necessarily the same as administrative mediation under Articles 46 and 48. See Min Shi, Tonggang Zhao and Mingjiang Wu eds., "One Hundred Questions on the Regulation on the Handling of Medical Accidents" (*yi liao shi gu chu li tiao li bai wen*), *Beijing: Fa Lu Chu Ban She*, 2002, at 75-76. Either party to the dispute may apply for administrative handling under Article 37, but an application under Article 48 for administrative mediation on the issue of compensation may only be filed if both parties agree to the application. Thus, it is possible that the two parties might agree to conduct authentication under the direction of the health department, but refuse to agree on an application for administrative mediation.

¹⁰² As referenced in Article 44, mediation may also be conducted in the people's court.

¹⁰³ Also note that Art 39 allows for a second technical authentication if requested by a party.

¹⁰⁴ This may impose incentives that are similar to the British system of attorney's fees in which the "loser pays." See, generally, T. Rowe, "Shift Happens: Pressure on Foreign Attorney-Fee Paradigms from Class Actions," *Duke Journal of Comparative & International Law* 13 (2003) 125-149, at 128 & n. 16.

¹⁰⁵ The 2002 regulation does not address the type of procedure for technical authentication that the court should adopt. Instead, it is the Law (*fa*) 2003 No. 20 Notice from the Supreme People's Court that requires courts to adopt the procedure of technical authentication as stipulated in the 2002 regulation when they deal with medical accidents. For cases other than medical accidents, the courts have discretion to use procedures in accordance with the Civil Procedure Law or Criminal Procedure Law. The wording of this notice as regards forensic examination is as follows: "In adjudication of civil cases....when it comes to forensic examination of medical accidents, the conduct of those examinations shall be handed over to medical societies as stipulated in the 2002 regulation. When it comes to non-medical-accident cases, forensic examination shall be conducted according to the Regulation on the Management of Forensic Examinations Entrusted by People's Courts to External Entities."

¹⁰⁶ According to William Sage, the system that is "usually but oddly called 'no-fault'" is really a system of strict liability. Sage, *supra* note 43, at 19. In China, the GPCL recognizes liability without fault, but only if that liability is authorized by another law. GPCL, *supra* note 47, at Art. 106. See also Wang and Mo, *supra* note 8, at 167-168.

¹⁰⁷ Art. 2. Although the regulatory definition of "medical accident" incorporates the tort law concept of negligence, plaintiffs in China apparently have the option to assert claims against hospitals for breach of contract as well. As Wang and Mo have explained, Article 106 of the GPCL "appears to have imposed a tortious liability partially by way of a contractual obligation." Wang and Mo, *supra* note 8, at 168. This appears to be distinguishable from the U.S. system, in which liability for medical malpractice is based on tort rather than contract. In U.S. jurisdictions, the establishment of a physician-patient

relationship is based on contract, and it is the creation of that relationship which imposes a duty to the patient. However, a patient's claim that the physician has breached that duty is based on negligence, which is part of the law of torts. Under common law, damages for breach of contract are limited to losses that were within the contemplation of the parties at the time of contracting, whereas damages for negligence include all losses that were proximately caused by the tortious act. In China, however, Article 112 of the GPCL apparently authorizes recovery of consequential damages for breach of contract. GPCL, *supra* note 47, at Art. 112.

¹⁰⁸ Article 131 of the GPCL provides that, if the victim also bears fault in causing the harm, the tortfeasor's liability may be decreased. With regard to medical accidents, Article 49 of the 2002 regulation provides that the amount of compensation shall be based in part on the level of responsibility (*ze ren*) of the negligent conduct in causing harm to the patient. According to Shi Min et al., the level of *ze ren* refers to the proportion of the medical harm that can be attributed to the negligent medical conduct. Shi, Zhao and Wu eds., *supra* note 101, at 77-78. In addition, according to Article 36 of the Temporary Regulation of Medical Accident Technical Authentication, there are four levels of responsibility: complete responsibility, major responsibility, minor responsibility and mild responsibility. The definitions of responsibility in the temporary regulation on technical authentication are as follow: complete responsibility (medical harm was caused completely by medical negligent behavior), major responsibility (medical harm was caused mainly by medical negligent behavior), minor responsibility (medical harm was caused mainly by factors other than medical negligent behavior), mild responsibility (almost all medical harm was caused by factors other than medical negligent behavior). Thus, the proportion of liability is determined by the proportion of medical harm that was caused by negligent medical practice. If a patient bears fault which contributed to the medical injury, then health care facilities and workers may not bear complete responsibility for the injury.

¹⁰⁹ See also Chen, *supra* note 7, at 147 and 166 (questioning whether 4 years in prison is really an administrative penalty).

¹¹⁰ Specifically, article 335 of the Criminal Law provides that "[a]ny medical worker who, grossly neglecting his duty, causes death or severe harm to the health of the person seeking medical service shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention." *Criminal Law of the P.R.C.*, Art. 335, (Law Press China, 2002).

¹¹¹ Yu Wang, "The Sameness and Difference between the Regulation of Handling Medical Accidents and the Regulation on Dealing with Medical Incidents" (*yi liao shi gu chu li tiao li yu yi liao shi gu chu li ban fa de zhu yao yi tong dian*), *Chinese Hospitals (zhong guo yi yuan)*, 2002, 6(6): 10-17, at 13. Of course, how these articles work needs empirical evidence. If these reports are accessible to the public, it is unclear whether Chinese doctors or health care facilities will report their medical errors more honestly than their U.S. counterparts.

¹¹² See The notice regarding good preparation for practicing the Regulation of Handling Medical Accidents, which was delivered jointly by Ministry of Health and National Bureau of Managing Chinese Medicine and Drugs (*wei sheng bu guo jia zhong yi yao guan li ju guan yu zuo hao shi shi yi liao shi gu chu li tiao li yo guan gong zuo de tong zhi*), available at http://news.xinhuanet.com/zhengfu/2002-08/07/content_513996.htm, last visit on July 5, 2004.

¹¹³ See generally Kenneth S. Abraham and Paul C. Weiler, "Enterprise Medical Liability and the Evolution of the American Health Care System," *Harvard Law Review*, 108 (1994): 381-436, at 393 ("hospitals under enterprise liability would be the exclusive bearers of medical liability for all malpractice claims brought by hospitalized patients"). But see William M. Sage et al., "Enterprise Liability for Medical Malpractice and

Health Care Quality Improvement,” *American Journal of Law & Medicine*, 20 (1994): 1-28. (arguing that enterprise liability in the U.S. should be imposed on health plans rather than hospitals.)

¹¹⁴ See, e.g., Abraham and Weiler, *supra* note 113, at 401-414.

¹¹⁵ See *id.*, at 411 (“Even more importantly, such a shift to EML would target the component of the health care system that possesses the greatest capacity for continuously improving the quality of care.”). See also Sage et al., *supra* note 113, at 11 (“Hospitals and other advanced facilities are usually well equipped to monitor staff physicians and to create environments that improve the total quality of care.”)

¹¹⁶ Pei et al., *supra* note 36, at 1722-1723; Hsiao, *supra* note 28, at 1051. In the U.S., some proponents of enterprise liability rely on the existing authority of hospitals to limit or terminate the clinical privileges of physicians who fail to provide quality medical care. See, e.g., Abraham and Weiler, *supra* note 113, at 414.

¹¹⁷ Liu and Chang, *supra* note 51, at 60-1. Chaojie Liu, Comment on the Defects of Medical Accident Crime Legislation and Judicial Interpretation (*Jun yi liao shi gu zui li fa ji si fa jie shi de que xian*), *Journal of Law and Medicine (fa lu yu yi xue za zhi)*, 2002, 9 (3): 154-6.

¹¹⁸ Shi, Zhao Gang, and Wu eds., *supra* note 101, at 76. Thus, administrative mediation is not a basis for judicial enforcement, but merely increases the likelihood of success in subsequent litigation.

¹¹⁹ Wang, *supra* note 111, at 14-15.

¹²⁰ See Jiang, *supra* note 2, at 53; Huang and Sun, *supra* note 100.

¹²¹ At Hai Ding District of Beijing City, within 7 months after the 2002 Regulation came into force, only one out of 40 cases was found by technical authentication groups to be a liability accident. However, in Shanghai City, 80% of more than 300 non-liability conclusions of technical authentications were later challenged by conclusions of forensic medical examinations. This may explain why most plaintiffs in Hai Ding District of Beijing City preferred forensic medical examinations for their cases. See Jun Ma, “Comment on the finalization of compensating for harm in medical disputes-challenging Article 49 of the Regulation on Handling Medical Accidents” (*Jun yi huan jiu fen sun hai pei chang de que ding- dui yi liao shi gu chu li tiao li di 49 tiao de zhi yi*), *Journal of Law and Medicine (fa lu yu yi xue za zhi)*, 2004, 11(1): 1-5, at 4.

¹²² Hu An Lin, “Preliminary Exploration of the Newly Adopted Regulation on Handling Medical Accidents” (*xin ban bu de yi liao shi gu chu li tiao li chu tan*), *Chinese Journal of Forensic Science (zhong guo si fa jian ding)*, 2002(4): 39-42, at 39.

¹²³ See Weiguo Fong, “Breakthrough and Restriction: Concise Comment on the New Regulation on Handling Medical Accidents” (*tu po yu ju xian: jian ping xin de yi liao shi gu chu li tiao li*), available at http://article.chinalawinfo.com/article/user/article_display.asp?ArticleID=21958, last visit on July 9, 2004.

¹²⁴ Yu Zhu, “Chinese Medical Association States that Technical Authentication Fee Cannot Cover its Cost” (*zhong hua yi xue hui biao shi yi liao shi gu jian ding fei yong shou zhi bu di*), available at http://news.xinhuanet.com/newscenter/2003-09/05/content_1065752.htm, last visit on July 13, 2004.

¹²⁵ These figures are available at http://www.cpirc.org.cn/tjsj/tjsj_gb_detail.asp?id=2075, last visit on July 13, 2004.

¹²⁶ According to an official of the Chinese Medical Association, even 8,500 RMB is below the actual costs of technical authentications. See Zhu, *supra* note 124.

¹²⁷ Wang, *supra* note 111, at 16. Yongtang Song, Hongbing Xiang, and Wujin Luo, “A Try to Comment on Compensation System in the Regulation on Handling Medical Accidents” (*shi lun tiao li zhong de yi liao shi gu pei chang zhi du*), *Chinese Rural Health Service Administration (zhong guo nong cun shi ye guan li)*, 2003, 23(9): 45-47, at 46.

Shi, Zhao, and Wu eds., *supra* note 101, at 78.

¹²⁸ According to Supreme People's Court Law (*fa*) (2003) No. 20 notice, the 2002 Regulation shall pre-empt GPCL as applied to the handling of all *medical accidents*. However, even though some scholars support this restricted scheme out of cost concerns, they still argue for equitable adjustment of the compensation according to the conditions of patients and their dependents. See Jianjun Zhang, "Preliminary Analysis of Several Problems with the Regulation on Handling Medical Accidents" (*yi laio shi gu chu li tiao li de ji ge wen ti qian xi*), *Journal of Law and Medicine (fa lu yu yi xue za zhi)*, 2003, 10(1): 9-13, at 12; Lixin Yang, "New Development and Adjudication Policy in the Regulation on Handling Medical Accidents (II)" (*yi liao shi gu chu li tiao li de xin jin zhan ji sheng pan dui ce (er)*), available at <http://www.civillaw.com.cn/weizhang/default.asp?id=7823>, last visit on July 9, 2004.

¹²⁹ See Supreme People's Court's notice, Law (2003) 20, regarding the application of the 2002 regulation in adjudicating civil cases of medical disputes (*zui gao ren min fa yuan guan yu can zhao yi liao shi gu chu li tiao li sheng li yi liao jiu fen min shi an jian tong zhi, fa* (2003) 20 hao), available at <http://www.jincao.com/fa/law10.s33.htm>, last visit on July 2, 2004.

¹³⁰ See Supreme People's Court's Certain Rules Regarding Evidence in Civil Procedure, *Law Interpretation* (2001) No. 33. (*zui gao ren min fa yuan guan yu min shi su song zheng ju de ruo gan gui ding, fa shi* (2001) 33 hao). Also see the explanation by First Civil Branch of the SPC on the draft of Law Interpretation (2001) No. 33 (*zui gao ren min fa yuan min shi sheng pan di yi ting guan yu min shi su song zheng ju de ruo gan gui ding de qi cao suo ming*), available at <http://mdshnx.nease.net/law/zj/zj-ms-qcsm.htm>, last visit on July 6, 2004

¹³¹ Some confusion resulted when the SPC issued a separate document entitled Law Interpretation (*fa shi*) (2003) No. 20, which is different from the Law (2003) No. 20 Notice discussed above. In its 2003 Law Interpretation, the SPC adopted a position with regard to the way in which courts should apply laws to determine compensation for personal injury. The SPC's Interpretation Regarding Questions in Applying Law in Adjudicating Personal Injury Cases (*zui gao ren min fa yuan guan yu sheng li ten sheng sun hai pei chang an jian shi yong fa lu ruo gan wen ti de jie shi*), *Law Interpretation* (2003) No.20. It is important to note that *Law Interpretation* (2003) No.20 is different from Law (2003) No. 20. The 2003 Law Interpretation by the SPC aroused suspicion about whether it preempts the 2002 regulation on medical accidents. On the basis of that 2003 Law Interpretation from the SPC, patients and their families might be awarded higher amounts of damages than they could receive under the 2002 regulation. Eventually, this issue was clarified by means of a newsletter on the SPC's website, which re-emphasized the message of the Law (2003) No. 20 Notice. Basically, this newsletter is a collection of answers given to reporters' questions by the chief official of the First Civil Court of the SPC (*zui gao ren min fa yuan min yi ting fu ze ren jiu sheng li yi liao jiu fen an jian de fa lu shi yong wen ti da ji zhe wen*), available at <http://www.court.gov.cn/news/bulletin/activity/200404120015.htm>, last visit on July 6, 2004.

The newsletter on the SPC's website basically directs the courts to apply the Law (2003) No.20 Notice in dealing with cases of medical accidents, instead of applying the 2003 Law Interpretation which addresses interpretation and implementation of laws in cases of personal injury. Thus, for cases of medical accidents, the 2002 regulation shall be applied; for other cases the 2003 Law Interpretation shall be applied.

¹³² Song, *supra* note 99, at 17.

¹³³ See Article 4 of Supreme People's Court Law Announcement (1997) No. 15 that sets forth certain rules regarding the work of legal interpretation (*zui gao ren min fa yuan guan yu si fa jie shi de ruo gan gui ding*), available at

<http://www.court.gov.cn/lawdata/explain/main/200304040012.htm>, last visit on July 13, 2004.

¹³⁴ For example, Article 385 of the Revised Criminal Law stipulates that the act of officials receiving others' property to benefit others through their duties comprises the crime of bribery; no severe outcome is needed. However, in Article 53 and 57 of the 2002 regulation, severe outcomes are stipulated as the conditions that comprise the crimes. In addition, Article 53 and 57 of the 2002 Regulation add 'receiving interests' as one of the conditions that comprise the crime of bribery. However, this is beyond the projection of 'receiving property' in Article 385 of the revised Criminal Law. See Xiaofang Shi and Daomin Xu, "The Conflict between the Regulation on Handling Medical Accident and Criminal Law" (*yi liao shi gu chu li tiao li yu xing fa gui ding de chong tu*), *People's Procuratorial Monthly (ren min jian cha)*, 2002(6): 54-55, at 55. Also see Huang and Sun, *supra* note 100; Fong Wei Guo, *supra* note 123.

¹³⁵ This 2001 law interpretation took effect on April 1, 2002.

¹³⁶ Zhihua Chen, "Several problems regarding the Regulation on Handling Medical Accidents" (*guan yu yi liao shu gu chu li tiao li cun zai de ji ge wen ti*), *Journal of Law and Medicine (fa lu yu yi xue za zhi)*, 2002, 9(2): 72-76, at 72-73; Lei Yu, "Analysis of Legal Problems in the Regulation on Handling Medical Accidents" (*yi liao shi gu chu li tiao li ruo gan wen ti fen xi*), *Journal of Law and Medicine (fa lu yu yi xue za zhi)*, 2003, 10(1): 6-9, at 6; Fong Wei Guo, *supra* note 123.

¹³⁷ Further research and analysis are also needed with regard to informed consent and confidentiality of peer review materials, both of which are important issues beyond the scope of the present article.

¹³⁸ See D.M. Studdert, et al, "Medical Malpractice," *New England Journal of Medicine*, 350(3) (2004):283-292. See also D. A. Hyman, "Medical Malpractice and the Tort System: What Do We Know And What (If Anything) Should We Do About It?" *Texas Law Review*, 80(7) (2002):1639-1655.

¹³⁹ Pei et al., *supra* note 36, at 1717, 1724.

¹⁴⁰ M. Mello and T. Brennan, "Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform," *Texas Law Review*, 80 (2002): 1595-1637.

¹⁴¹ *Id.*

¹⁴² Mohr, *supra* note 26, at 1732.

¹⁴³ Jost, *supra* note 40.

¹⁴⁴ M.K. Lim, et al, "Public Perceptions of Private Health Care in Socialist China," *Health Affairs* 23(6) (2004): 222-234, at 231-233.

¹⁴⁵ As Catherine Struve has written, "juries do better than their critics charge, and specialized courts would generate problems of their own." C. Struve, "Improving the Medical Malpractice Litigation Process," *Health Affairs* 23(4) (2004):33-41, at 37.

¹⁴⁶ B. Liang, "The Adverse Event of Unaddressed Medical Error: Identifying and Filling the Holes in the Health-Care and Legal Systems, *Journal of Law, Medicine & Ethics*, 29 (2001): 346-368, at 357 (footnote omitted).