

Special Feature

Should medical accidents be judged in criminal court?—Establishing a new patient safety system in Japan

The Case of Tokyo Women's Medical University From the standpoint of the defense counsel

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Today I would like to talk about the case of Tokyo Women's Medical University (TWMU) from the standpoint of a defense counsel and, more in general, the meaning of bringing to the court a criminal case of professional negligence resulting in death by physicians.

The Criminal Justice Is Not an Appropriate Forum for Investigating the Cause of an Accident

First, I would like to point out that the purpose of criminal justice is not to investigate facts or the cause of an accident. Of course, one of the functions of criminal justice is to bring out the facts. However, seeking facts—in case of this TWMU case, why the patient died—is not the ultimate purpose of criminal justice per se. Many people are inclined to presume that everything will be revealed in a court of law once a case is indicted, and such assumption may cause various misunderstandings or expectations among many including patients and their families. But, I would like to explain why that is not necessarily the case in court proceedings.

As to where the cause of the accident lay in the TWMU case, the prosecution and we, the defense counsel, confronted each other head-on.

Points Claimed by the Prosecution and by the Defense Counsel

The prosecution claimed Dr. Satoh, who was operating the heart-lung machine, made two mistakes. One was that he raised the rotation

speed of the suction pump too much. Normally it runs at 40 or 50 revolutions per minute, but in this operation it was raised to over 100 and was kept at that speed for a long time. This made the internal pressure of the reservoir positive whereas it was supposed to stay negative. Since the air inside the reservoir is being vacuumed by negative pressure, the positive pressure caused the vacuum to fail. Another mistake alleged by the prosecution concerned the filter: condensation made the filter wet and obstructed the filter. Naturally this stopped the depressurization, and therefore, the allegation went, the vacuum failed. The inside of the reservoir even became positively pressured, and caused the flow of blood to reverse. The prosecution stated that it led to blood congestion of the brain of the patient.

Against these claims, we, the defense counsel, argued that the operation of the heart-lung machine was not the cause of death. Rather, we claimed that the problem lay in other factors, such as the operation site, direction, and/or angle at which the blood withdrawing cannula on the superior vena cava was attached. And because the impropriety with respect to the blood withdrawing cannula had been unnoticed for a long time, ultimately the patient suffered blood congestion of the brain.

So, the prosecution claimed that the problem was the heart-lung machine, and we claimed that it was the operation site.

Both the Tokyo District Court and the Tokyo High Court found Dr. Satoh, the defendant, not guilty.

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The Main Point Addressed in the Tokyo District Court Was the (Non-) Existence of “Negligence”

Although the outcome of two judgments were the same, the content of them were completely different. The district court first decided whether the negligence on the part of the physician who operated the heart-lung machine could be sustained, which depended upon whether the obstruction of the filter was foreseeable. The court acknowledged that the pressure of inside reservoir would not have become positive unless the filter had become obstructed, and the filter obstructed by condensation reversed the flow. The court further stated that since no one had considered that the filter positioned at a specific point in the circuit might be obstructed, it was not possible for the defendant to foresee the dangerousness of the filter. The court, therefore, concluded that the defendant did not have the obligation to foresee the obstruction of the filter and avoid the outcome caused thereby. Accordingly, the court rendered the judgment of not guilty.

But this judgment by the district court did not clarify why the patient died. Indeed, the district court did not deal with this point. Since the claim of the prosecution was that the defendant had the obligation to foresee the obstruction of the filter and cope with it, and the district court found that the defendant had no such obligation, the court did not find it necessary to ascertain the cause of death of the patient.

For those of us who deal with the law, this line of logic and the result thereof were very familiar and natural. But, questions that ordinary people would expect a court to answer—such as “Why did the patient die?” or “What went wrong in this operation?”—remained unanswered.

The High Court Clarified the Patient's Cause of Death

Against this judgment by the district court, the prosecution appealed to a high court. In the high court, the question of why the patient died was addressed squarely. The Tokyo High Court determined that, the poor positioning of a blood withdrawing cannula caused insufficient blood removal of the superior vena cava. The court further found that because this condition continued over time while blood transmission continued,

the poor blood removal from the superior vena cava plus the new blood transmitted from the heart-lung machine to artery caused the blood to build up in the brain and led to blood congestion of the head, which in turn caused the death of the patient.

The defendant, Dr. Satoh, was in charge of the heart-lung machine. Naturally, he was not involved with the positioning of a blood withdrawing cannula of the superior vena cava. That means there was no causal relationship between the defendant's acts and the death of the patient. Accordingly, he was found not guilty. The point is that the high court did, by reaching this conclusion, clarify why the patient died.

When we compare the judgment of the district court with that of the high court, it is true that they both found the defendant not guilty. However, as to why the patient died, the district court did not address this matter, and it only became evident in the high court. Let me explain where this difference came from.

Criminal Justice Is Only to Determine the Indictment by the Prosecution Is Proved

In case of professional negligence resulting in patient's death, the purpose of a criminal justice is not to compare the claims that the prosecution and the defense each make and determine which is sustainable. All the court does is to determine whether the indicted charge is proven beyond a reasonable doubt. The district court considered whether the defendant had the obligation to foresee the obstruction of the filter and addressed the issue accordingly. Once the court found that the defendant had no such obligation, that was the end of quest for the facts by the court. Why the accident happened is not for the court to ascertain.

In the high court, we insisted that the court determine why the patient died. As a result, the court ultimately acknowledged that a blood withdrawing cannula was poorly positioned and reconfirmed that the defendant did not have the obligation to foresee the obstruction of the filter. Therefore, the defendant was found to be completely innocent. However, as I have explained here, the purpose of the court is not necessarily to investigate the cause of the accident or the facts about the surgery itself. I very much hope

that the system and the role of the court is well understood.

The Defense Strategy Was to Establish the Facts Based on Medical Standards

It may sound somewhat contradictory to what I said before, but our defense strategy was to establish the facts based on medical standards.

Let me explain more in detail. There were many witnesses during the Tokyo District Court proceedings; 8 physicians, 4 lab technicians, 1 nurse, the hospital director who was in charge of the internal report of TWMU and 3 others (including the family members of the deceased). Additionally there was documentary evidence—in this case the medical literature and papers; the prosecution submitted 6, and we submitted 113 of them. We were trying to clarify based on medical standards all relevant facts, i.e., whether the obstruction of a filter had become conceivable before this accident, whether the possibility of the pressure turning positive was conceivable, or the poor positioning of a blood withdrawing cannula at the operation site could lead to death. We also examined 3 physicians and the documentary evidence of 9 medical papers for the high court, and the prosecution provided 1 piece of documentary evidence. By doing so, we were trying to help the judges understand what was medically possible and what was not.

Very few judges are medical school graduates, and most of them come from law schools or liberal arts departments—I, too, have the same background. So, as I was studying this case, my plan was to have the court understand what happened during the operation and review all the facts.

Why did we have such a defense strategy? Because the way the prosecution constructed the case was against common medical sense or even elementary knowledge in the natural sciences.

Defense That Established the Irrationality of the Prosecution's Claim

The prosecution, for example, claimed that increasing the suction pump speed too much turned the pressure of inside the reservoir positive. As mentioned earlier, they said that the positive pressure was brought about by 100 revolutions as opposed to normal 40, but that claim could not stand. Even if the speed of the suction pump was raised,

unless the filter was obstructed, the flow did run toward the negatively pressured suction apparatus. According to the manufacture's materials and the review by TWMU as they were considering adoption of the negative pressure suction method, their data showed that even a speed of 200 revolutions would not cause any problem. So scientifically speaking, the claim that 100 revolutions caused positive pressure did not make any sense at all. But at the early stage of trial, we did not know this, and the judges probably didn't know it either. Thus, we needed to accurately establish that it was impossible.

Also, regarding the prosecution's claim that the obstruction of the filter by vapor could have easily been foreseen, we pointed out that if that was the case, no one would have placed a filter at a specific point in issue. Perhaps it might be a mistake that a filter was attached there, but no one thought it was dangerous. Actually, according to a survey conducted by medical societies, about 30% of medical facilities in Japan still used the filters even several years after this accident. Therefore, it was impossible that someone should have been aware of the risk caused by using a filter.

Thus, these two claims were clearly mistakes.

The prosecution said that “the negative pressure caused the poor blood withdrawal and/or reverse flow, which led to blood congestion in the head, and that was the cause of death.”

But common sense tells us that, if the blood flow was reversed and ran from the heart-lung machine to the patient, and if the blood congestion in the head led to patient's death, then, the patient's lower body would have shown a similar symptom. But the biochemical data and palpation examination showed no problem with the patient's lower body. Therefore, it is only natural to think that the factor that had such a selective effect on the body was the cause of death. But the prosecution did not consider such aspect.

As I have shown here, the prosecution's claims in this case were far from common sense from the perspective of medical or natural science. Therefore, we, the defense counsel, believed that the fact-finding should be based on medical standards, and we proceeded accordingly.

I have been practicing law for about 34 years, and during that time I dealt with two cases of professional negligence by physicians resulting in death. One was this TWMU case, and the other was

the AIDS case of Dr. Abe of Teikyo University.

Dr. Abe was indicted for using unheated blood products in the treatment of hemophiliacs from May to June of 1985, when there was only 1 case or 2 of death in Japan by AIDS, whereas the number amounted to hundreds in the U.S. Even in the U.S., the use of unheated blood products was never banned, and they were fairly used. The U.S. was an “advanced” nation when it came to dealing with AIDS, but even in the U.S. where the spread of AIDS was a serious social concern, the use of unheated blood products was not prohibited. Yet, in a county like Japan where no such case had been reported, the prosecution claimed that the use of unheated blood products constituted professional negligence resulting in death. This was just irrational and absurd.

So, we argued in court accordingly, and Dr. Abe was found not guilty by the court of first instance. In the second instance of the court, the lawsuit was suspended due to his illness. But the fact still remains that Dr. Abe was found not guilty by the court of first instance.

I am afraid to say that when prosecutors indict medical accidents, in many cases they go against medical common sense and ignore the medical standards at the time when the accident occurred. I am ready to admit that my experience is limited to the two cases, the AIDS and TWUMU cases, but in both cases the prosecution's indictment was just too unreasonable. I don't know if it was because of their ignorance, or they had to indict for some unknown reasons. But in order to cope with such absurd indictment, it is important above all to accurately establish meaningful medical facts in court and have the judges understand them.

Why the Medically-Amateur Prosecutors Made a Reckless Indictment

As I have been explaining, the prosecution made a reckless indictment in these cases. But, prosecutors are amateurs in the medical field. So, what motivated such amateurs to make a reckless indictment? The internal report prepared by TWUMU stated that the main cause was the raising of the suction pump speed. But the review committee that prepared this internal report consisted of 3 members of TWUMU only, and none of them was specialized in cardiac surgery. In fact, most of them had neither seen nor touched the

heart-lung machine.

In addition, those committee members, who were not specialized in cardiac surgery, did not receive advice from a cardiac surgery specialist when they prepared the report. They conducted what they called an experiment, noticed certain conditions that seemed to make the internal pressure of the reservoir positive, and believed that it was the cause. I say for sure that their conclusion was truly unscientific based on unscientific deduction.

Their conclusion was patently wrong, of course. But the university's responsibility itself was overlooked, and the one physician who was in charge of the heart-lung machine was held responsible by the prosecution who hastily believed in the internal report. By doing so, I do believe that the university was trying to evade its responsibility.

Indictments of Medical Accidents Bring about Irreparable Damages to the Lives of the Physicians Involved

In January of 2011, about 10 years after the accident, the civil lawsuit filed by Dr. Satoh against TWUMU and its director in charge of preparing the internal report reached settlement at the Tokyo High Court. Both TWUMU and its director admitted that the internal report contained an incorrect description suggesting that the operation of the heart-lung machine by Dr. Satoh was the cause of death, and sincerely apologized from the bottom of their hearts to Dr. Satoh for placing him in the position of the defendant in a criminal trial that lasted for 7 years and causing serious suffering including damaging his career as a cardiac surgeon. It took 7 long years to reach this point. And now, there is nothing anyone can do to gain back those lost years in Dr. Satoh's career. So this consequence is also a part of the entire result of the wrongful indictment.

The judgment of not guilty is one thing, but it cannot return things to the way they were before the accident of March 2001. Being accused in a court of law has caused irreparable harm, and I hope everyone can fully understand that.

Consult a Lawyer to Avoid Unfair Punishment When a Medical Accident Happens

Needless to say, I hope cases like this one do not

happen too often—but as the saying “accident waiting to happen” goes, you never know when a medical accident will happen and accusations of negligence arise. So lastly, I would like to talk briefly about what a physician should do in such an event.

In our case, we have been offering consultation to Dr. Satoh since January of 2002. He was arrested in June of that year, so we had about 6 months to give him advice. Of course, we did not imagine that he would be arrested, but having this period of time allowed us to prepare for the case and build trust between Dr. Satoh and us. So when he was arrested, we gave 3 pieces of advice to Dr. Satoh about what he should and should not do during interrogation.

Dr. Satoh was in charge of the heart-lung machine. So, we instructed Dr. Satoh to make a statement as to what he actually saw. On the other hand, he was not alongside the operation table and could not see the operation site. So, we instructed him not to make any statements with regard to the operation site or things he did not know and also told him never to include any conjecture in his statement. Lastly, in this particular case, the issue was whether the charge of professional negligence resulting in death could be established, and, therefore, questions regarding negligence would be surely raised in interrogation. But the judgment regarding existence

of negligence could not be determined unless and until full knowledge of the operation became available. As I mentioned earlier, whether the problem lay in the heart-lung machine or the operation site would have entirely changed the understanding of negligence. As Dr. Satoh could not tell the prosecution about the operation site, he could not determine where negligence lay or what constituted negligence. Thus, we advised him not to make any statements regarding this point. However, in order to make sure that silence on this point would not be misunderstood as simply refusing to make any statements, we informed the prosecutor as to why Dr. Satoh was not making a statement as to negligence.

The end result was that, the interrogation statement prepared by the prosecution was basically what we anticipated although there were a few minor points we were not satisfied with. I cannot stress enough how important this result is. I hear things have changed a lot recently, but what is included in the interrogation statement greatly influences the outcome of trial. So, if you think something might happen, I strongly advise you to consult a lawyer as early as possible. You will need to teach your lawyer so that he or she can understand what the problem is and have him or her decide how you should behave in the field of the Penal Code. I beg you all to follow the advice of your lawyer.