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## A U.S. View of the Product Liability Aspects of Innovation

*George S. Frazza\**

**A**s Mr. Nomura was talking about the different cultural characteristics of the Japanese and Americans you may have been wondering whether the American product liability monster is deeply embedded in our culture. What makes the U.S. tort system unique? Our product liability system did not come over on the Mayflower; but rather it was born about twenty-five years ago.

When I first came to Johnson & Johnson, the lowest lawyer on the totem pole had two duties: to get beer for the lawyers' picnic and to handle all the product liability cases. Somebody would come to you with a small folder. You would look through it and there would be a couple of "who beat whom to the intersection" cases. I remember one case involving a man who filled a bathtub with baby powder, tried to drown himself in it, and then sued us for failure to warn how dangerous our product was. That was about it, product liability was a legal backwater — and the corporation was, even then, probably the largest health care company in the world.

The product liability phenomenon is less than twenty-five years old, and it is, incidentally, a distinctly American phenomenon. For those of you who are interested in how this genie got out of the bottle, I recommend Peter Uber's book, *Liability: The Legal Revolution and Its Consequences*. It is a highly readable account of how we got where we are. I will not dwell on the reasons for the explosive growth of product liability, a growth that has come about in an unprincipled and uncoordinated fashion. It is always fun to bash the lawyers and blame it on them. I think a part of the problem is that we turn out more lawyers than the Japanese do engineers.

Let's take a brief look at the U.S. product liability system and what makes it unique. First, there is the number and size of claims that are involved. The U.S. tort liability system encompasses all non-contractual claims for personal and financial injury. It is a very broad spectrum of claims arising from medical malpractice to football injuries to skiing in public parks. Automobile claims represent about half of the total, and they have remained remarkably steady over the last ten to fifteen years. This is due, in part, to the no-fault laws and the mechanisms that have been fashioned to resolve these cases. The automobile cases do not pose a tremendous burden on either the court system or on society in general.

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\* Vice-President and General Counsel, Johnson & Johnson.

They are generally settled for amounts within predictable ranges, and they are not included in my remarks today.

Apart from the auto cases, there has been a dramatic increase in liability claims relating to products, professionals, municipalities and non-profit entities. Excluding the asbestos claims, the number of product liability claims has increased fivefold between 1975 and 1985. The greatest growth, of course, is in the mass toxic tort area, for example, Agent Orange and Dalkon Shield.

There are now 325,000 claims involving the Dalkon Shield. There were 15,000 claims when Robins filed for bankruptcy hoping they could clean up everything. Robins was ordered to advertise in the newspapers to notify potential claimants and 325,000 claims miraculously appeared out of nowhere. That was far beyond anybody's expectations.

In the last decade there has been a dramatic increase in negligence claims. There has been a threefold increase in malpractice claims, especially against obstetricians and pediatricians. There has also been a substantial increase in claims against municipalities. New York City reported almost a 400% increase in claims between 1979 and 1983.

In 1966, Johnson & Johnson had three or four tort claims other than auto cases, now we have close to a thousand. Half of our profits and half of our sales are outside the United States, but I doubt whether we have more than two dozen claims outside the United States. At last count, we had settled all but five of the non-U.S. lawsuits, and those are not a significant concern to us. In the United States, however, we have seven lawyers and paralegals in our law department managing the U.S. cases, along with hundreds of outside lawyers around the country. These people manage and coordinate the claims, formulate settlement policies and try to settle the claims before they go to court. I doubt whether all of our product liability problems outside the United States take up the time of a single lawyer.

Aside from the number of claims, the size of the awards in the United States has increased also. The average jury verdict in malpractice suits has gone from \$200,000 to \$1 million during the past ten years. In the decade between 1975 and 1985 the average product liability verdict went from about \$392,000 to \$1.85 million, according to Rand Institute statistics. It is very difficult to get accurate figures, but no one can deny that there has been a dramatic increase.

There were three malpractice verdicts in 1975 of \$1 million or more. There were seventy-four in 1985. Most of these awards come at the high end of the scale. Many cases settle, with inflation taken into consideration, for just about what they settled for ten or fifteen years ago, but one \$15 million or \$20 million verdict can skew all the figures. Remember that most cases are not tried. Most cases are settled, and the settlement amounts reflect the jury verdicts in the cases that are tried. When you are about to go to trial on a case in the same jurisdiction two weeks after

a multimillion dollar verdict has been returned in a similar case, it is like negotiating a settlement in the shadow of the gallows. You either have to pay the demand or buckle up and go at it again.

The cost of the system is far greater than anywhere else in the world. Estimates range between \$30 billion and \$80 billion. At any rate, the United States spends more on the tort liability system than on fire and police departments or state social welfare programs. Whatever the direct cost, there is an enormous expenditure of public and private resources independent of the costs incurred in the courts. The great bulk of these funds are not going to injured plaintiffs, they are going to transaction costs. The Rand study indicates that sixty-two cents of every dollar in asbestos cases goes to transaction costs, including attorneys' fees. The percentages are similar in other mass tort cases. These costs are outlandish by any measure. They make Jim and Tammy Bakker look like frugal administrators, when you look at the rake-off that the system takes before anything goes to the plaintiff. Of course, these costs are paid by the consumer in the form of higher prices or in the form of products that never get to the market.

We have moved from a fault-based system to a strict liability system. That means you pay as if you are at fault whether you are actually at fault or not; you pay if you caused an injury, negligent or not; and often you pay, absent proof of causation, simply because you have the money. In many cases, the outcome can be explained only by an unprincipled search for a deep pocket.

The New York courts last week expanded on the *Sindell doctrine*, which subjected a manufacturer to liability in a DES case absent proof that the plaintiff used its drug. Manufacturers are held liable for damages based on their market share. In other words, if the total recovery was \$100,000, each of five manufacturers paid \$20,000 or one fifth of the total. The New York courts expanded this idea, saying that a claimant does not even have to prove the product was sold in New York. All that must be proven is that in the 1960s the product was sold somewhere. If a manufacturer sold it anywhere in the United States, a New York plaintiff can recover against the manufacturer. We have come light miles from a fault-based system.

All of you are familiar with the *Bashoda* case. *Bashoda* was the asbestos case where the court held that even if the dangers of asbestos were scientifically undiscoverable at the time that the products were produced, the defendant manufacturers were still liable for the failure to warn of a risk they didn't know about. That was overturned by the New Jersey legislature about three years later, but it may have been the high water mark in product liability.

Also responsible for the expansion of product liability is the erosion of causation as a prerequisite of liability. In pharmaceutical cases, for instance, the claimant ostensibly has to prove that the drug caused the injury, and that the manufacturer negligently failed to warn of the injury,

knowing the state of the art. Those were the two issues. Today the search for cause has become much more elusive. We can now detect innumerable substances that may be linked to cancer, inject high doses into animals and extrapolate the results of those studies to humans. This complex, scientific data is brought into the courtroom before a lay jury, not on the basis of impartial scientific testimony, but on the basis of paid experts for each side. By impartial, I do not mean scientifically impartial, I mean impartial from the standpoint of not having a stake in the outcome of the case. Independent scientific testimony which is undistilled is rigorously excluded from U.S. courts — your advocate and my advocate get up there and we have it out. Plaintiffs and defendants play the same game. When you look at a scientist, you look at his apparent credentials and then you videotape him to see how well he does before the jury. That is not the way you would pick your family doctor. If someone had a very serious disease, you would not ask for the best-looking pathologist you can find.

That is our system and it has many other characteristics that do not exist anywhere in the world, such as open-ended damages for pain and suffering and mental anguish. Consider punitive damages. Punitive damages originated in England because the sheriff simply could not jail everyone who got in a Saturday night barroom brawl. Individuals were given the right to bring a civil action, and the court had the right to award punitive damages. It was a way of helping the sheriff keep up with the mayhem. Today, punitive damages are given for the most outlandish reasons. One particular case against Ortho, the *Wooderson* case, involved a rare kidney disease. Someone in an obscure medical journal linked oral contraceptives to the disease. The pharmaceutical companies asked the FDA to put a warning about the linkage in the physician instructions and the FDA said, "Get out of here, you're crazy. It's unsubstantiated, the data's flawed." To make a long story short, somebody sued, claimed they had the disease, and that it had been caused by the oral contraceptive. Punitive damages were awarded. The jury said, "You should have tried harder to get the FDA to put the warning on the drug."

There is another feature of the system that is part of the problem — joint and several liability. If you are 1% liable, you are responsible for 100% of the damages. That means, if the anesthesiologist is drunk and he is judgment-proof, if he has no money, and the hospital has no money, you sue the drug company claiming that the labeling on the anesthetic was not in big block letters. The lawyer says to the jury, "You should find these guys 1% liable. Send them a message." The jury does not know that the 1% means that the person who is not judgment-proof is responsible for the entire judgment. So the system is inefficient, unprincipled and unpredictable. How can you be deterred from something if you don't know where lightning is going to strike?

We are here to talk about the effect of product liability on innova-

tion. Hard data is very difficult to find, but you can use informed judgment, some common sense, some deductive reasoning and some anecdotes to show that product liability suits have a direct and debilitating effect on innovation. Defending product liability suits costs an awful lot, and those funds have to come from somewhere. So if you link productivity or allocation of resources with innovation, that means that those funds spent on lawyers are not being spent on scientists. That money probably is going to flow somewhere else.

We also know it changes behavior patterns. Oral contraceptives are a classic example. There is a warning on oral contraceptives that goes to the doctor. It is just a little shorter than *War and Peace*. The lawyers write it, but the doctor never reads it. It is not a medical document, it is a legal document. The FDA is absolutely enraged, but they go along with the labeling because lawyers say, "You have to protect the manufacturer." I say that the system is not honest with itself and that drug warnings that are scientifically invalid debase the whole health care system.

If a child gets a bump on his head, he is given a CAT scan, not for medical reasons, but to protect against liability. The American Medical Association has figures on the number of unnecessary procedures. They say an incredible percentage of procedures costing millions are done to protect doctors, not to help patients.

We know that products are priced higher. We know that 30% of the price of a stepladder or 95% of the price of children's vaccines goes towards liability protection. We know consumers are paying for it.

There is only one manufacturer of football helmets left in the country. Recently in New Jersey there was a suit brought against a junior high school football coach because he told his players to hit harder. Of course, the suit was thrown out of court, but the New Jersey legislature had to pass a law protecting little league coaches because the coaches were just walking out. About a year and a half later Governor Kean signed a law limiting the liability of high school coaches.

We know the effect of lack of insurance. In the drug industry there has not been any insurance for years. The American insurance companies used to write policies and then reinsure them with Lloyds, but Lloyds has left the table.

As a result, all the large pharmaceutical companies are self-insured. That is a tremendous burden, but more important for innovation, it benefits the entrenched, because the small biotech company developing and selling new products on risky and unfamiliar frontiers cannot compete without insurance.

Contraceptives are a good example of lack of innovation. Johnson & Johnson is the biggest oral contraceptive manufacturer in the world. The patents have been out for years and the product has not changed much. There has been no real research done on different products because any new product dealing with the reproductive system, despite ap-

proval by the FDA, has a high element of product liability risk. No one knows whether a new product would be better than the current product because no new products have appeared. As a large established company, we benefit from the status quo. We do very well by this system.

The Dalkon Shield, which deserved to go off the market, also resulted in removal of our IUD from the market. We had fifty or sixty lawsuits and sales of about \$3 million or \$4 million. IUDs are not very profitable, the doctors make most of the money on intrauterine devices. So the gain was not worth the gamble.

The classic example is *Bendectin*, a Merrill-Dow drug. There is not a responsible scientist in the world who believes that there is any hard data linking *Bendectin* to birth defects, but a large number of cases were brought on the basis of some poorly-crafted animal studies. Merrill-Dow won most of them, but got hit with \$75 million in damages, which is on appeal. The fact is that most pharmaceuticals have a finite amount of sales potential; you cannot increase morning sickness medication sales, there are only so many customers. On the other hand, you have an infinite exposure to liability.

Seventy percent of the price which Cessna and Beech charge for their airplanes goes for insurance. Aerodynamic research used to come from small plane manufacturers in this country, but this is no longer the case. Burt Rutan, who flew a sailplane around the world, had begun to sell kits. He went out of business because he couldn't get any insurance.

Vaccines, of course, are another prominent example. There are only one or two vaccine manufacturers left in the United States. The Japanese are taking the research lead away from us. It is appalling that there is so little interest in research on mass inoculation vaccines in the United States right now.

I could go on but I don't want to end on a dark note. As Mark Twain said, "Wagner's music is not as bad as it sounds." Well, product liability is not as bad as it sounds, because a lot of the problems are finally being corrected.

Reading the court decisions or criticisms of the system in the lay press gives us hope that the winds of change are blowing. A recent *New Republic* article written by Henry Farley talks about the United States' morbid fear of risk. We have always prided ourselves on being a country of diversity, with people from all different backgrounds, races and countries, but the one thing we had in common was that our ancestors were all risk-takers. The risks of coming to the United States were enormous, but our ancestors were all people who took risks. Today, if Columbus had trouble, I wonder whether he would turn around and go back to sue the sail manufacturer.

I think the climate is changing, but whether or not there is a competitive difference, there is simply no comparison between the U.S. and

Canadian product liability systems. This is one area where we should look north and emulate our good friend and neighbor.

