Using Rules of the Road in a Machine Design Case

By
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Rick Freeman and Patrick Malone have authored books and videos where they teach their "Rules of the Road ™" technique for trying cases. Jurors want clear boundaries that delineate right from wrong, and they will rely on bright-line rules, even when they are irrelevant. That is why evidence of objective standards, such as Occupational Safety and Health Administration (OSHA) regulations are so powerful and probative in proving fault. The Rules of the Road approach helps attorneys define relevant, clear rule violations, thereby increasing jurors' certainty of fault. Rules can come from industry standards, product labeling, statutes, contracts, jury instructions, expert testimony, procedures manuals, professional literature, ethical codes, common sense, etc. (Rules at p32.) The Rules approach gives jurors a sense of certainty, whereas many legal standards are fuzzy.

The Rules of the Road approach is not actually a new or novel approach if you think about it. In a medical malpractice case or a legal malpractice case, the plaintiff has the burden to prove the applicable standard of care and that the defendant violated that standard. e.g. *Cosgrove v. Grimes*, 774 S.W.2d 662, 665 (Tex. 1989) (Legal Malpractice). In a product liability case, the case law may say that the Plaintiff does not have to prove negligence to prove liability, and that may be true to avoid a directed verdict, but to motivate the jury to find for the plaintiff, you need to prove that the defendant made a conscious decision to violate a basic standard of conduct. This is true for a product liability case, a bad faith insurance case, a consumer case or any case.

In essence, a product liability case is an engineering malpractice case, and to motivate a jury to find in your favor, you need to show that the defendant violated basic engineering standards. So what is the "standard of care" in a product liability case? I believe the standards of care are the basic principles of machine design. In every product liability case I have handled, the defendant corporation has violated one of these basic engineering standards.

You might ask yourself "So why do I need to know the standards? My expert will cover that." Well, first of all, your expert may get lost in the minutia of the case and assume the jury knows the basic rules and never tell the jury about them. More importantly, these standards should govern how you prepare the case from the start. I believe that you cannot effectively cross examine the defendant's witnesses or experts unless you have first mastered and identified the design standard of care and identified how and why the defendant failed to follow those standards. That is also, by the way, what Freeman and Malone teach.

So what are the rules of the road for a machine design case? Well, actually, these are the same rules of the road for almost any product liability case,

and these "rules" can be used even in a premises liability case at a factory or a refinery where the premises was designed by a process control engineer.

The difference between ad hoc design and engineering design is the process. Engineering design is the systematic and analytic application of the scientific method to the design of a product. In other words, there is a universally accepted step –by - step procedure for an engineer to properly design a product. The first step in the design of a product is to conduct a "Design Hazard Analysis." This is not a legal rule. It is the most fundamental principle of engineering design. It is taught in every basic machine design book, and I have never had an engineer deny it.

Rule No. 1: A design engineer has a duty to identify all hazards associated with the use or foreseeable misuse of the product. This is also known as "Hazard Identification." A "hazard" is a condition that has the potential of causing or contributing to an injury. On conducting a hazard analysis, the designer must consider all foreseeable uses or misuses of the product and all foreseeable environments of use.

Rule No. 2: In conducting a hazard analysis, the design engineer has a duty to consider the human element. To put it another way, the design engineer has a duty to consider how the machine could be redesigned to reduce the chance of human error.

Rule No 3: Once a hazard has been identified, the design engineer must collect all available evidence to determine the probability and severity of potential injury. The more frequent the injury, the more severe the risk. The more severe the injury, the greater the risk. A hazard that has a remote possibility, but a catastrophic consequence is a serious risk that must be properly controlled. This process is called a "risk assessment."

Rules 1-3 are collectively known as a "hazard analysis." There are three or four different ways that an engineer can use to conduct such an analysis. Each has advantages and disadvantages. The two most common hazard analysis procedures are a Fault Tree Analysis and a Failure Modes and Effects Analysis (FMEA). Lately, in cases I have been seeing the FMEA.

You will find that engineers many times do not conduct a formal design hazard analysis. They will often claim that it was done informally, or that the hazards were intuitive, so a formal design hazard analysis was unnecessary. If they did not identify the risk or properly evaluate it, you can argue that they did not identify the hazard or appreciate the risk because they did not do what they were taught to do in engineering school. Juries want to know why the manufacturer designed a dangerous product. If they claim they did not identify the hazard, well you may have proven WHY they designed a defective product. Why? Because they broke the rules. On the other hand, if they claim that they did

recognize the hazard and the risk, that's ok too, because if they knew about the hazard, you are halfway to proving that they designed a defective product.

Once the design engineer has identified the hazards and evaluated the risks, the design engineer has duty to control the risk. In controlling a risk the design engineer must follow a risk management hierarchy of strategies. The strategies are a hierarchy because the goal is to, if possible, eliminate the hazard. The hierarchy is as follows:

1. Eliminate the hazard.
2. Avoid the hazard.
3. Reduce the hazard.
4. Accept the hazard.

A product designer controls risk by following the "Design Hierarchy." It is a hierarchy because one step is more important than the next, which brings us to Rule No.4.

Rule No. 4: If it is economically and technologically feasible without affecting the utility of the product, a design engineer has a duty to design the product so that it will eliminate the hazard. This is the principal of the "inherently safe design."

The most effective way to control a hazard is to eliminate it, and the most effective way to eliminate a hazard is to design the hazard out of the product. Often the fight will be whether the design was economically or technologically feasible. If you follow the rules, you have cornered the rat and hopefully eliminated the ambiguity and confusion the defense will try to introduce by saying they warned the plaintiff or by otherwise arguing that someone else's error caused the accident, that a safer design would affect the usefulness or the product, or introduce a new risk. A lot of times, you can show the jury that the manufacturer could have eliminated the hazard for a small amount of money. If so, you have proven that the defendant violated a rule of design and knowingly manufactured a dangerous product so they could save a little money. That is profit over safety, and profit over safety is one of the most powerful case themes a plaintiff can use to motivate the jury.

Rule No. 5: If it is not feasible to design the hazard out of the product, the design engineer has a duty to guard or isolate the hazard from the user if that is economically and technologically feasible. Rule No 5 applies only if Rule No. 4 cannot be followed. Some hazards cannot be eliminated. For example, the hazard of a pinch point between a belt and pulley cannot be eliminated; however, in most cases, a guard will not affect the usefulness of the product. When I first started practicing law, machine guarding cases were a plaintiff's lawyers bread and butter. Fortunately, we have all but cured this cancer. Machine guarding cases are rare today.

Rule No. 6: If it is not feasible to design the hazard out of the product or provide a guard, the product designer has a duty to warn the user of the hazard and instruct the user on the steps he or she can use to avoid the hazard. Warnings and instructions are a last resort. That is because humans are the least reliable method to control a hazard. The procedure for constructing and locating a warning is beyond the scope of this article; however, I will say that if your case is a warnings case, you need to retain a human factors expert.

Often, the defense will be that they warned the plaintiff or the plaintiff otherwise "screwed up." You need to emphasize that it is not acceptable to ignore an inherently safe design and just expect the user to not make an error.

Rule No. 7: Once the design engineer has conducted a hazard-risk analysis followed the design hierarchy, the design engineer must start the process all over again and repeat the process until all hazards have been controlled.

Rule No. 8: Once the design engineer has decided on a potential design, the engineer has a duty to validate the design. "Design validation" is testing to ensure that the product will perform as intended under foreseeable operating conditions. If the design cannot be validated, the design engineer has the duty to start over.

This is where you see problems in drug and medical device cases. A clinical study is the attempt to validate a design. The manufacturer has spent millions of dollars on a design so there is a strong bias that the drug or device will work without side effects. Sometimes they make a mistake in the study design. Sometimes they ignore negative data in the validation testing.

Rule 9: A manufacturer has a duty to test and inspect its products to ensure that the product actually manufactured meets the specifications of the product designed. This is known as "Manufacturing Quality Assurance." If a product is defectively manufactured, more likely than not, the manufacturing defect was caused by a flaw in the quality assurance protocol. Quality assurance is often a separate department in a facility, and there are degree programs in Quality Engineering. All of the principles and procedures of quality assurance are beyond the scope of this paper, but if you have a manufacturing defect case, you will want do more in-depth research of quality assurance principles before you begin working up your case.