Best's Insurance Law Podcast

Foreseeable Use - From a Risk Management and Safety Perspective - Episode #230

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John Czuba: Welcome to Best's Insurance Law Podcast, the broadcast about timely and important legal issues affecting the insurance industry. I'm John Czuba, managing editor of *Best's Insurance Professional Resources*.

Very pleased to have with us today expert service provider Dr. Janine McCartney of HHC Safety Engineering Services and HHC Safety Consulting Services, Corporation of Wilmington, Delaware and Houston, Texas.

The companies provide safety consulting, safety engineering consulting, and expert witness services to law firms and the insurance industry. Dr. McCartney is a senior safety engineer and expert witness.

She has a certified safety professional and a construction health and safety technician designation with 32 years' experience in safety, as well as possessing a PhD and MBA. Dr. McCartney has two CSHO credentials. Her professional career has spanned over 45 years in private and government service with OSHA consultation.

Dr. McCartney has worked in the oil and gas industry and the pipeline and construction industry as a regulatory expert. In safety, she worked her way up from safety representative to safety manager of 300-plus facilities, then to safety officer II for the state of Texas, then to consultant senior safety engineer, and then to an expert.

She has extensive OSHA policies knowledge and has technical and historical knowledge in construction, telecommunication, utilities, manufacturing, food processing, distribution, oil and gas exploration and production, and property management.

Dr. McCartney served as an editor of ScienceDirect "Heliyon" and "Data in Brief," and as an editor and reviewer of "Science of The Total Environment" from the years 2005 to 2024. She also works as an expert and consultant on a day-to-day basis. Dr. McCartney, we're very pleased to have you with us again today.

Today's discussion is foreseeable use from a risk management and safety perspective. Dr. McCartney, for our first question, what is expected of a manufacturer in identifying hazards of the product that they are manufacturing?

Dr. Janine McCartney: That's a great question, John. Before a manufacturer identifies the hazard of a product, they must first choose the standard to which they will manufacture the product. A manufacturer is expected to manufacture a product to a specific standard and then have a third party certify that the product is manufactured to that standard.

A manufacturer can then place the product for sale commercially, provided that they actually manufacture the product to that standard. The manufacturer cannot make material changes to the product to cut costs and then state that the product is manufactured to a certified standard when in fact it's not.

This type of manufacturing behavior was seen in the 1990s when a certain company that manufactured oriented strand board sent a compliant sample to the American plywood standard testing lab, obtained the certification, but then decided to manufacture that strand board to a lesser quality.

They did so by using more epoxy and less wood. This decreased the strength of the oriented strand board and the cost. The manufacturer then sold the oriented strand board to HUD, and the US Air Force. The oriented strand board failed and there were consequences for the manufacturer.

After manufacturing the product to a specific standard, the manufacturer can identify the hazards of the product based on that specific standard. The standard that they manufacture the product to, has hazards and control measures identified in their selected standard. A manufacturer is expected to manufacture a product and control the hazards identified in that standard.

In addition to this, the manufacturer is expected to provide warnings in their product literature. The manufacturer is expected to also identify proper use and improper use of their product.

The manufacturer is expected to communicate to its distributors the product warnings, proper operating conditions and application of the product, and the conditions to which the product is to be used. The manufacturer's warning in their product literature must specify the responsibilities of the end user to select the correct product for their use through their expertise.

The end user must also agree that all performance, safety and warning requirements must be met by the end users as required by the manufacturer. The manufacturer must provide safety warnings, instructions, and a list of improper uses.

The manufacturer must warn that improper use can result in property damage, personal injury, and possibly death. The manufacturer must also include markings on their products.

The standards organization to which a product can be manufactured, can include the military MIL specs, the ANSI standards, the ASTM standards, the IEC standards, and the API standards. There are many, many more standard organizations to which a product can be manufactured, and those standard organizations are found in the United States and internationally.

If the manufacturer's product is manufactured in a country other than the US, the manufacturer must also perform due diligence to ensure their product is not being manufactured counterfeitly and sold under another manufacturer's name or under their name.

Manufacturers may also complete their due diligence review of other competitor manufacturers' products and hazard warnings and their product literature. Manufacturers should also review recall data of other competitors' manufacturers of their same product.

John: Dr. McCartney, what methods may a manufacturer use in determining hazards of the product that they are manufacturing based upon the standards?

Dr. McCartney: That's another great question, John. One of the most common methods to determine the hazards of a product is for the manufacturer to conduct a foreseeable use analysis.

The Consumer Product Safety Commission published a handbook for manufacturers, entitled: "Foreseeable Use Analysis, Handbook for Manufacturing Safety Consumer Products, July 2006.

The Consumer Product Safety Commission also states that:

Manufacturers may consider an examination of "*materials, configuration, packaging and labeling for purposes of identifying potential product hazards*" (U.S. Consumer Product Safety Commission Foreseeable Use Analysis The Consumer Product Safety Commission, Handbook for Manufacturing Safer Consumer Products, July 2006, p. 9).

A design review may consist of including a Foreseeable Use Analysis as a method to determine product use hazards that are measured against accepted product standards such as industrial standards and/or regulatory standards (U.S. Consumer Product Safety Commission Foreseeable Use Analysis The Consumer Product Safety Commission, Handbook for Manufacturing Safer Consumer Products, July 2006, p. 9).

Other traditional hazards analysis that manufacturers may perform to discover hazards in a product, can include: a Fault Tree Analysis (FTA), a Failures Mode and Effects Criticality Analysis, (FMECA), a Functional Hazard Analysis (FHA) and a Hazard Operability study (HAZOP) or What if Study.

John: Dr. McCartney, what is a foreseeable use analysis?

Dr. McCartney: That's a great question, John, and very, very helpful for the manufacturing industry as well as for expert witnesses. A foreseeable use analysis is and considers the potential ways that a consumer will interact with and/or operate the product. It is a critical step in designing a safe consumer product.

Foreseeable use includes the use as intended by the manufacturer and also use in ways that were not intended but couldn't reasonably be expected to occur. This information is found in the US Consumer Product Safety Commission Foreseeable Use Handbook for manufacturers.

The Consumer Product Safety Commission states that the effectiveness of a safe product design may be evaluated in various ways. For example, a proposed design may be measured against accepted product standards, such as a set of industrial voluntary standards or regulatory standards.

Additionally, it may be measured against a set of objectives for the product and even comparable products. The product evaluator must define product use environments and contexts as precisely as possible, as well as the kinds of people who will operate or interact with the product.

The evaluator should define the age levels, physical and cognitive limitations of users, and contingencies that might occur, including uses not intended by the manufacturer.

A design review may consist of including a foreseeable use analysis as a method to determine product use hazards measured against an accepted product standard such as an industrial standard or regulatory standard.

Manufacturers may consider an examination of materials, configuration, packaging and labeling for purposes of identifying potential product hazards.

John: Dr. McCartney, what is the definition of consumer foreseeable use and the definition of consumer foreseeable misuse of a product?

Dr. McCartney: That's another great question, John. The manufacturer and the expert can go to the ANSI standard B11-2008, section 3.31, Safety of Machinery.

The ANSI Standard B11-2008, Section 3.31, Safety of Machinery, defines "intended use" (of a machine) as follows:

a. "***3.31 intended use (of a machine):*** *The use for which a machine is suited according to the information provided by the supplier or which is deemed usual according to its design, construction and function. Informative Note: Intended use also involves compliance with suppliers instructions, which should take into account reasonably foreseeable misuse. The intended use may be determined by the user*" (ANSI B11-2008, Section 3.31, Safety of Machinery, August 4, 2008).

The ANSI Standard B11-2008, Section 3.58, Safety of Machinery, defines reasonably foreseeable misuse as follows:

a. "***3.58 reasonably foreseeable misuse:*** *The use of a machine in a way not intended by the supplier or user, but which may result from readily predictable human behavior*" (ANSI B11-2008, Section 3.58, Safety of Machinery, August 4, 2008).

The ANSI Standard B11-2020, Section 3.71, Safety of Machinery, defines "reasonably foreseeable misuse" as follows:

a. ***"3.71 reasonably foreseeable misuse:*** *The use of a machine in a way not intended by the supplier or user, but which may result from readily predictable human behavior.* ***Informative Note:*** *For example, a risk assessment should address the following human factors (this is not intended as an all-inclusive list):*

- *Inappropriate actions as a result of mistakes, errors, and poor judgment, excluding deliberate abuse of the machine;*
- *Inappropriate actions or reactions taken in response to unusual circumstances such as equipment malfunction;*
- *The tendency to take the "path of least resistance" in carrying out a task; and*
- *Misreading, misinterpreting or forgetting information*" (emphasis supplied, ANSI B11-2020, Section 3.71, Safety of Machinery, December 16, 2019).

John: Dr. McCartney, one final question today. How far does a manufacturer have to go to identify all consumer foreseeable misuses of a product based upon the standards?

Dr. McCartney: That's a great question, John, and really the whole purpose of this podcast, and that is the manufacturer should determine whether the end use of the product is a commercial application by a sophisticated user or the end use is a consumer market application by an unsophisticated consumer user.

Based upon the standards we just went through, the question will become, will the manufacturer be required to caution the general public and the end users against all unintended uses for which the product was never intended, and then capture all the warnings in endless, all-encompassing what-if scenarios in a foreseeable use analysis?

Here's what I found. The term "Workplace hazard" can be defined as follows:

> "*There are many definitions for hazard but the most common definition when talking about workplace health and safety is: A hazard is any source of potential damage, harm or adverse health effects on something or someone*" (https://www.ccohs.ca/oshanswers/hsprograms/hazard/hazard_risk.html).

When we talk about risk and we talk about workplace hazards, we talk about whether there is a chance or probability that a person will be harmed with this product or experience an adverse health effect if exposed to a hazard. It may also apply to a situation with property or equipment loss or harmful effects on the environment.

If you use the example, the risk of developing cancer from smoking cigarettes can be expressed as cigarette smokers are 12 times more likely to die of lung cancer than non-smokers. The number of 100,000 smokers who will develop lung cancer will depend on their age, how many years they've been smoking, etc.

All of these risks are expressed as probability or the likelihood of developing disease. What a manufacturer also has to determine are the methods and risky behavior that the person will use the product in an unintended use. It's common to see the process of identifying hazards and assessing the corresponding risk to be described by a risk assessment for some reasonable unintended uses of the product. However, what about the farfetched misuses of a product?

The literature and standards suggest that if a manufacturer of a product performs a risk assessment and hazard analysis, manufacturers the product to a specific standard which is certified, and provides hazard warnings, hazards warning literature and marks the product according to the standard marking requirements, then the manufacturer would not be required to determine every possible "what if scenario" in an endless foreseeable consumer misuse analysis. The manufacturer may consider performing their "due diligence" as mentioned above, in reviewing recalls of their competitors, reviewing warning product literature and product markings of their competitors.

This question contemplates when is enough, enough? Can a manufacturer limit its "Foreseeable Misuse Analysis" with identification of warnings identified in the manufacturing standard and hazards found in the workplace, as well as warnings found by their competitors and hazards that resulted in recalls to the same type of product, hazards of their products found in literature and from actual accident investigations, with warnings found in their own foreseeable misuse analysis, and hazards found in the standard to which the product is manufactured?

Does the manufacturer have to continue performing a Foreseeable misuse analysis for a consumer that misuses the product in the most outrageous and absurd condition? Each state has case law describing how much is enough. Product Liability laws and federal case law describes how much is enough.

From a safety and risk management perspective, and for the Expert writing an Expert Report, the standards determine the hazard warnings, product markings, and identifies workplace hazards of use of the product. It is commonplace in manufacturing that a manufacturer preform a "Foreseeable Misuse Analysis" with identification of warnings found in the workplace, warnings found by their competitors and analysis of hazards that resulted in recalls to the same type of product, identification of workplace hazards of their products found in literature and from actual accident investigations, and hazards discovered in their own foreseeable misuse analysis.

The bottom line to all this is that in litigation, with respect to foreseeable misuse of a product, each state has its own laws. The federal laws are also to be considered.

John: Dr. McCartney, thanks so much for joining us again today.

Dr. McCartney: Thank you, John, for the opportunity.

John: You just listened to Dr. Janine McCartney of HHC Safety Engineering Services and HHC Safety Consulting Services Corporation, with offices in Wilmington, Delaware, and Houston, Texas. Special thanks to today's producer, Frank Vowinkel.

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I'm John Czuba, and now this message.

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