Product Stewardship Regulatory Affairs Compliance/Litigation April 27, 2021



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Objectives / Issues

- Objectives
 - Appreciate how compliance or non-compliance with a product stewardship program can prevent, or give rise to, litigation.
 - Understand the legal theories underlying product liability claims.
 - Anticipate the product steward's role in taking actions that will prevent litigation.
- Issues
 - Product liability claims and defenses
 - Product stewardship role in minimizing product liability
 - Litigation and the product steward



What Is Product Stewardship?

- A process for:
 - identifying and managing health, safety, and environmental risks
 - throughout all stages of a product's life,
 - while maximizing a company's economic value*
 - And correspondingly reducing liability risks
 - * Product Stewardship Society, Core Competencies for the Product Stewardship Professional (2014) at 4.



Overview

- A robust product stewardship program can avoid products liability and toxics litigation, and provide a defense should such litigation arise.
- Failure to implement a product stewardship program can provide evidence of a company's negligence and even provide a basis for punitive damages.



Product Liability Overview

- Toxic tort and product liability litigation involve allegations that a purportedly toxic substance or defective product caused injury to the plaintiffs' bodies or damaged their property (real or personal).
- Toxic tort and product liability claims arise from exposure to a variety of substances and products, including consumer products, pharmaceuticals, raw materials used in manufacturing, chemicals, waste products, and radioactive materials.
 - Exposures can occur anywhere, including in the environment, in the home, or in occupational settings.



Product Liability: Asbestos

- The Magic Mineral
- Full regulatory compliance
- Developing knowledge of risks
- 40 years of litigation
- 100 corporate bankruptcies
- Current peripheral defendants
- Total costs: \$250,000,000,000



Product Stewardship: Asbestos

Johns-Manville Executive: In retrospect, if the company had responded to the risks of asbestos with

- "extensive medical research,
- assiduous communications,
- insistent warnings,
- and a rigorous dust reduction program,

it could have saved lives and would probably have saved the stockholders, the industry, and, for that matter, the product."



Product Stewardship: Asbestos

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Product Liability & Product Stewardship

- Key issues at the intersection of product stewardship and product liability:
 - Liability life cycle analysis identifying liability risks throughout the product lifecycle
 - Defective design claims, product development, and the duty to test
 - Minimizing risk through raw material substitution
 - Quality and preventing manufacturing defects
 - Proper labeling and hazard communication to avoid failure to warn claims
 - Liability assessment in new business or product line acquisition
 - The liability impact of regulatory non-compliance and the limited benefits of compliance
 - Appropriate parent and subsidiary corporation product stewardship roles
 - Use of documented hazard and risk assessments in defense of tort liability claims



Global Product Liability

- United States
- Europe
- Australia / New Zealand
- China
- Japan
- Mexico



Product Liability Law

- Regardless of the source of the alleged injury, the legal bases for toxic tort and products liability lawsuits we discuss are generally similar, although there are variations by jurisdiction.
- State common law (judge-made law) generally applies, although some states have passed statutes that govern products liability claims.



Product Liability Case: Defendants

- All within the chain of product distribution may be liable in products cases:
 - The manufacturer of a defective product
 - The seller of the product
 - A company that places its trademark on a product it neither manufacturers nor sells
 - Courts may pierce the corporate veil to impose liability on a parent corporation for the actions of its wholly-owned subsidiary.



Product Liability 101

- Elements:
 - Defective product, causation, injury, damages
- Negligence
 - Duty of care and breach of duty
- Strict Liability
 - Defective product
 - E.g. Risk/utility analysis



• See Professional Practices of Product Stewardship chapter 14, Product Liability (2018)



Product Liability: Negligent Design and Manufacturing

- Defendant fails to act as a "reasonable person" under the circumstances
 - Duty of care owed
 - + Foreseeability?
 - Breach of that duty
 - + Standard of care and the state-of-the-art (knowledge of the product's potential health hazards) at time of the product sale
 - Breach was the "but for" and proximate cause of injury
 - Plaintiff suffered actual an quantifiable injury



Product Liability: Negligence

• Negligence *per se*

- The violation of a statute may constitute negligence per se.
- In such case, the statute creates a duty of care and the violation establishes a breach of that duty.
- For example, in a recent fracking-related case brought by landowners against an oil and gas exploration company for alleged releases of hazardous substances into their water supply, the plaintiffs brought negligence per se claims, alleging violations of the Pennsylvania Clean Streams Law, the Pennsylvania Solid Waste Management Act, the Pennsylvania Oil and Gas Act, and the Pennsylvania's Hazardous Sites Cleanup Act.
 - + Roth v. Cabot Oil & Gas Corp., 919 F. Supp. 2d 476, 488-89 (M.D. Pa. 2013).



Product Liability: Negligence Defenses

- Insufficient proof of elements of claim
- Contributory and Comparative Negligence
 - Contributory negligence or comparative negligence defenses consider plaintiff's conduct in causing the alleged harm.
 - "Pure contributory negligence" is an absolute bar to liability.
 - Most states have adopted the doctrine of comparative negligence, which reduces the plaintiff's damages in an amount commensurate with his degree of fault.



Product Liability: Strict Liability

- From negligence to strict liability
 - Unlike negligence, strict liability imposes liability on the manufacturer of a product regardless of the level of care taken by the manufacturer.
 - Thus, all the plaintiff needs to show is that the product was defective.
 - A product can be defective in three ways: its design, its manufacture, or its warnings or instructions
 - Focus is on the product in its use environment; no longer on the defendant's conduct



Product Liability: Strict Liability

- Three types of product defect:
 - Design defect:
 - + Whether the product met the reasonable consumer's expectations as to its safety ("consumer expectations test") and/or whether the product's risks outweighed its utility ("risk-utility test").
 - Manufacturing defect
 - + Product departed from its intended design or specifications
 - Failure to warn (marketing defect)
 - + Inadequate warnings or instructions render the product not reasonably safe
 - + Inadequate warnings cause injury



Product Liability

- Strict liability failure to warn
 - Warning inadequacy: Courts have required expert testimony to establish the inadequacy of the warning where the warning issues exceed common knowledge, including, for example, in cases involving prescription drugs, tires, gasoline, and insecticides.
 - Causation: plaintiff must show that the defendant's failure to warn or provision of an inadequate warning proximately caused her injuries. E.g., one with a duty to warn is not liable for failing to warn a party of facts that the party already knew.



Product Liability Claims: Breach of Warranty

- Breach of the implied warranty of merchantability and breach of the implied warranty of fitness for a particular purpose
 - These began as contract claims in many states, strict liability theories have essentially replaced implied warranty claims, and the theories.
- Breach of Express Warranty
 - An express warranty claim for goods sold requires at least proof that: (1) defendant made an express warranty as to a fact or promise relating to the goods, and (2) defendant's breach of the express warranty and the breach was the proximate cause of the injury.



Product Liability Defenses

- Assumption of risk
 - Plaintiff knew / appreciated risk created by alleged product defect
 - Plaintiff voluntarily assumed risk
- Product misuse
 - Used in way for which it was not designed
 - Misuse was not reasonably foreseeable to defendant
- Commonly-known danger
 - Danger so commonly known by general public that defendant had no duty to warn user
- Superceding cause
 - Learned intermediary, sophisticated user, bulk supplier
 - Danger is or should be known by product users so seller not liable
- State of the art
 - May be limited to reasonableness of alternative design in strict liability cases



Product Misuse (Men & Ladders)





Product Liability Defenses: Statutory

- Federal preemption
 - Compliance with federal regulations may avoid liability under state liability law
- Statute of limitations
 - Action brought within specified period after users action occurred or user discovered or should have discovered injuries
- Statute of repose
 - State specific absolute outer limits on time within which action must be brought



Product Liability Claims

- Fraud/Consumer Protection Statutes
 - Every state has consumer protection/unfair trade practices acts that prohibit unfair or deceptive acts and practices and unfair competition in the marketplace.
 - These can be used in product liability cases.
 - Many of these statutes permit damages multipliers and allow consumers to recover costs and attorney's fees.



Product Liability Damages

- Compensatory
 - medical expenses past / future
 - Lost wages
 - pain and suffering
- Punitive defendant acted with malice...
 - punish defendant
 - deter repetition
- Joint and several liability
 - plaintiff can recover full amount of judgment from any defendant ("deep pockets")



Lots of Torts

- Strict liability has resulted in a significant number of lawsuits

 in turn, this can effect
 market sector decisions by companies
 new product development
 economic viability of company
- Active and coordinated plaintiffs bar



Types of Lawsuits

- Individual Claims
- Multi-District Litigation
 - Consolidated for discovery and other pre-trial purposes
- Class Action Lawsuits
 - Common issues / causation
 - Damages
- Criminal cases



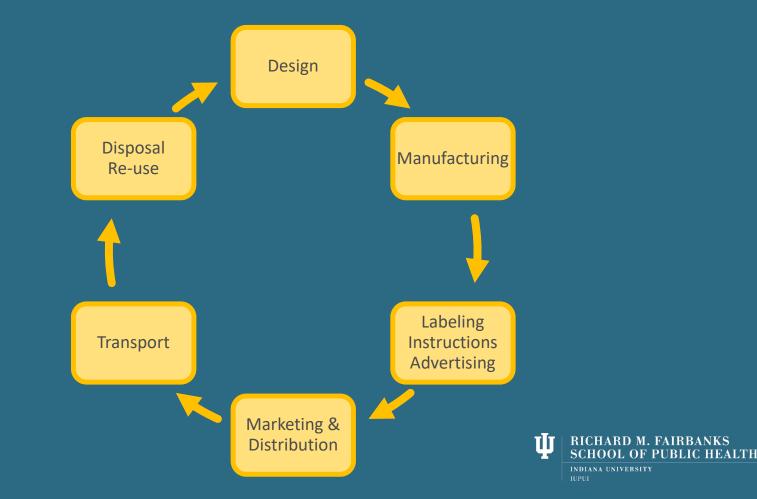
"The Ninth Circle of Corporate Irresponsibility"

- William Nordhaus "These firms know about their dangerous products, withhold that knowledge, subvert science to advance their commercial interests and put their guests to death."
 - Philip Morris (cigarettes)
 - Exxon Mobil (climate change)
 - Johns Manville (asbestos)
 - Purdue Pharma (oxycontin)
 - Facebook (personal information)
- Plaintiffs' attorney playbook put every corporate defendant on this list



Product Liability Life Cycle Analysis

Limiting product liability risk at each stage of product life:



Product Design

- Product poses an unreasonable risk of harm
- Toxicological hazard
 - Hazardous material
 - Contaminated material
 - Exposure Risk
- Mechanical hazard
 - Fails during normal use
 - Fails during an unexpected but foreseeable circumstance (accident)





Avoiding Design Defects

• Design Process

- Critical to understand that the recognized engineering principles related to product design are in a hierarchical form which requires all hazards to be identified at the development stage
- With respect to each hazard, the design engineer must
 - + determine whether the hazard can be designed out
 - + If the hazard cannot be designed out, determine whether the hazard can be guarded against
 - + If the hazard cannot be guarded against, the hazard must be warned about
 - + Or the product shouldn't be marketed



Defensible design process

- A manufacturer will have a strong defense against the allegation that its product is defective if it rigorously complies with and documents the following design and testing process:
 - Assess health risks of raw materials & final products
 - Adequately test raw materials & final products (including test all likely failure modes)
 - Consider material substitutes
 - Determine that there is no reasonable safer alternative
 - Evaluate the probability of injury/damage and severity of harm
 - Constantly evaluate and examine the design of the product and correct design defects when you acquire knowledge
 - Make certain that the product's safety devices are "state of the art," and be prepared to improve those safety devices as technology advances
 - Monitor the product in the field
 - Consider a periodic "safety audit" of the product, performed either by the company's own engineers or by outside consultants



Product Design Stewardship

- A defensible design process starts with a strong product stewardship structure:
 - Employ experienced and knowledgeable design personnel
 - Document the design process and improvement efforts
 - Manage supply chain: codes of conduct, certifications, audits
 - Conform with customer requirements
 - Monitor and meet or exceed government/Industry standards
 - Closely monitor competing products
 - Keep active in industry organizations



Design Defect Cases

- Messer v. Amway Corp., 106 Fed. App'x. 678 (10th Cir. 2004)
 - Floor stripper used without dilution caused chemical burns
 - Failure to test allegation
 - Court granted summary judgment to supplier finding:
 - + Supplier had conducted toxicological tests of product
 - + Plaintiff failed to identify any other tests that would be more appropriate or effective in preventing injury
- Zeigler v. CloWhite Co., 507 S.E.2d 182, 184 (Ga. App. 1999)
 - Lemon-scented bleach cleaning solution caused throat, respiratory, and skin injuries
 - Court denied SJ where evidence that:
 - + Lemon-scented additive used in the product was incompatible with strong oxidizing agents, like the bleach
 - + Thus product's formulation was defective



Manufacturing Defect

- Product does not meet its manufacturing standards, specifications, or other quality criteria
 - Contaminated by chemicals used at a factory
 - Assembly line machine malfunction results in a product that differs in composition or physical properties than intended



Avoiding Manufacturing Defects

- Supplier codes of conduct
- Manufacturing standards
- Quality control
 - purchase/inspection
 - of materials / components
 - manufacturing process
 - inspect completed products
- Health & safety compliance
- Post-sale monitoring

THINK QUALITY!

Our Aim Is ZERO Defects



Warnings/Information Defects

- Failure to provide information that will allow safe use of product
 - Incomplete safety data sheets
 - Inadequate labeling fails to identify hazards
 - Lack of instructions for safe use
 - Advertising fails to convey warning
 - Information
 - Customer-specific communications
 - Overpromotion





Warning Adequacy

- If a product can cause injury or property damage under circumstances during its intended or foreseeable use, and the risk of injury cannot be eliminated, then the product must be accompanied by appropriate warnings.
- Adequate warning
 - Warning "explains the risk which allegedly caused the plaintiff's injury"
 - Duty to give a reasonable warning, not the best possible one
 - Manufacturer "need not warn of every mishap or source of injury that the mind can imagine flowing from the product"
 - Do benefits of more detailed warning outweigh costs of requiring change?
 - Consider whether additional details will undermine the effectiveness of warnings: "Well-meaning attempts to warn of every possible accident lead over time to voluminous yet impenetrable labels – too prolix to read and too technical to understand."
 - ✓ Stanley v. Cent. Garden & Pet Corp., 891 F. Supp. 2d 757, (D. Md. 2012)



Preventing Communication/Warnings Defects

- Perform testing to determine risks of use and provide warnings of such risks
- Warnings and product literature should identify and warn of the precise risks involved and how to avoid
- Warnings and product literature should comply with all applicable regulations and standards
 - + Ensure information delivered in manner calculated to reach intended and foreseeable users
 - ✓ Beware the unintended but foreseeable user ("Industrial Use Only")
- Warning recipients (sophisticated user)
- Continuing duty to warn



MSDS

Negligent Marketing/Distribution

- Moning v. Alfano, 254 N.W.2d 759 (Mich. 1977)
 - "The issue in the instant case is not whether slingshots should be manufactured, but the narrower question of whether marketing slingshots directly to children creates an unreasonable risk of harm."
- Soto v. Bushmaster Firearms (Conn. 2019)
 - Gun makers and sellers negligently marketed AR-15s to civilians with knowledge that doing so posed unreasonable risk of injury
 - Protection of Lawful Commerce in Arms Act (2005) federal statute provides Immunity, except negligent entrustment or negligence per se
 - Trial court bar held not jurisdictional, allowed discovery, but then dismissed case as barred by the statute (Oct. 14, 2016)
 - Conn. Supreme Court: plaintiffs allowed to proceed on limited theory of wrongful marketing of AR-15 for illegal/offensive purposes under Conn Unfair Trade Practices Act



Marketing: "Greenwashing"

- FTC Green Guides "Environmentally Friendly"
- "Natural" products
 - Vermont Act 120 (effective July 2016) prohibits calling GMO-containing products "natural"
 - Kane v. Chobani (9th Cir. Mar. 24, 2016) deferring to FDA re "natural" on primary jurisdiction grounds
 - In re General Mills Kix Cereal (D.N.J. 2012) argument that company has a First Amendment right to describe product as "natural"
- "Crunchberries" and "Skinny Girl cocktails"



Hazardous Materials Transport

- DOT regulations and industry standards
- Product steward role in advising company shipping departments
 - Nature of the materials and their potential hazards
 - Incompatibility, container, and storage requirements
 - Characteristics that give rise to appropriate labeling
 - International import, export,
 - disclosure, and warning requirements



Post-Sale Product Stewardship

Claims

- Failure to warn about emerging safety issues
- Failure to conduct a recall & negligent recalls
- Failure to report defects to regulatory agencies
- Product stewardship post-sale monitoring and response
 - Written standards and policies with management support
 - Frequent communication with partners in the supply chain
 - Toll-free complaint numbers for consumers
 - Robust complaint handling, recording, processing, and reporting process
 - Documentation of the process
- Product disposal
 - Extended Producer Responsibility
 - PaintCare



Regulatory Compliance

- Failure to comply claim
 - Private right of action
 - Negligence per se
 - Evidence of negligence
- Compliance as a defense
 - Statutory presumption of no defect
 - Defense to punitive damages



Industry Standard Compliance

- Failure to comply as evidence of negligence
 - Elledge v. Richland/Lexington School District 5, 573
 S.E.2d 789 (S.C. 2002): Evidence of industry standards for playground equipment relevant to appropriate standard of care.
- Compliance as evidence of due care
 - Howard v. Omni Hotels Management Corp., 136
 Cal. Rptr. 3d 739 (Cal. App. 2012): hotel bathtub
 fall evidence that the tub met ASME and ASTM
 standards for slip resistance relevant.



Product Stewardship as a Standard of Care

- American Chemistry Council Responsible Care
- Commitment to RC principles of safe, secure and environmentally sound practices
- Adoption of Responsible Care Management System (RCMS) -- an integrated health, safety, security and environmental management

system



Liability Based on Lack of Product Stewardship



- Restaurant worker burned by caustic floor cleaning liquid
- Claimed manufacturer (Ecolab) failed in its duty to adequately train and warn restaurant's workers
- Plaintiff's expert: "[p]roduct stewardship has been a well recognized and practiced safety tool" of the CMA for decades – Responsible Care[®] requires supplier to train customers on safe use of chemicals
- Ecolab: RC did not apply; no duty to train customer's employees
- Expert allowed: "Since the concept of 'product stewardship' appears to be an accepted industry standard in the area of chemical safety," expert's testimony was relevant

Westley v. Ecolab, Inc., 2004 WL 1068805 (E.D. Pa. 2004)



Liability Based on Lack of Product Stewardship



- Pyrotechnics ignited soundproofing foam
- Plaintiffs sued foam manufacturer:
 - Defendants had, and breached, a duty of product stewardship; that is, because of the extremely hazardous nature of the foam, Defendants had a duty to anticipate possible applications and misapplications of its use, and to take some precautions to ensure that the product was put to a safe use, even after it left Defendants' hands.
- Defendant argued it was a "bulk supplier" not product manufacturer
- Court held that plaintiffs had sufficiently alleged that the foam was dangerous as sold, its use was foreseeable, and the manufacturers failed to warn about dangerous applications of the foam.
- Court also found sufficient design defect that claim foam "was extraordinarily flammable, yet was not treated with any flame-retardant chemicals. Moreover, it ignited too easily, burned too quickly and released highly toxic smoke and gases when burning."

Gray v. Derderian, 365 F. Supp. 2d 218, 222-23 (D.R.I. 2005)



Alleged Lack of Product Stewardship Irrelevant



- Chemical release to river, contaminating city's water supply
- Plaintiffs' expert: Supplier failed to properly assess, disclose and mitigate risks in chemical's sale, citing Responsible Care[®]
- Eastman moved for summary judgment on Responsible Care issue, arguing that Responsible Care "is a voluntary program rather than a codified set of standards against which its conduct can be measured."
- Court agreed, holding that "[w]ithout some foundation to conclude that the broad principles of Responsible Care translated into specific practices or actions of companies that were well known and commonly accepted within the industry," Responsible Care did not represent the industry standard
- And "did not independently create a duty on Eastman owed to Plaintiffs."

Good v. American Water Works, 2016 WL 6024426 (S.D.W. Va. 2016)



Alleged Lack of Product Stewardship Irrelevant



- Plant owner sued chemical supplier to recover clean up costs for spills occurring during off-loading
- Plaintiff: Industry standards imposed an obligation on supplier to off-load the product in a safe manner, citing supplier's adoption of Responsible Care[®] Program
- Court: "None of the evidence submitted by Robbins contained in the CMA material imposes a duty on Eastman to ensure that a particular method or technique is used to off-load Eastman product at a customer's facility."
- Court: Eastman not responsible for the spills

E.S. Robbins Corp. v. Eastman Chemical Co., 912 F. Supp. 1476 (N.D. Ala. 1995)



Alleged Lack of Product Stewardship Irrelevant

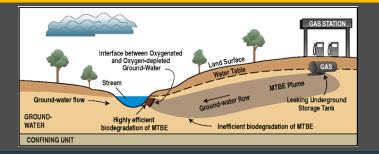


- Plaintiff alleging lung injury following exposure to chlorine gas brought negligence and strict liability claims against company (JCI) that supplied chlorine cylinders to his employer. Complaint alleged:
 - "JCI assumed the duty of '<u>Responsible Care</u>' regarding the use of chlorine it sells to its customers and distributors."
 - "The duty of <u>Responsible Care</u> include [sic] the duty to audit and prescreen customers and distributors for competence in the safe *handling* of chlorine gas, offering and providing education and training to customers and distributors who are not prepared to reliably *handle* chlorine in a safe manner, and enforcing safety standards with customers and distributors who do not become competent in safe *handling* of chlorine by refusing to sell chlorine to them."
- Court held that plaintiff's claims were expressly preempted by federal law (Hazardous Materials Transportation Act and the Hazardous Materials Regulations)

Parrish v. JCI Jones Chemicals, Inc., 2019 WL 1410880 (D. Hawaii Mar. 28, 2019)



Product Stewardship – Relevant in Part



- Duty to warn water providers, gas station operators, and public about special dangers of MTBE-containing gasoline
- NYC Expert: Defendant failed in its duty of product stewardship, because it knew of MTBE's health risks, resisted regulation, delayed additional toxicology studies, and promulgated misleading communications
- Court excluded testimony: All expert did is gather public corporate statements and she "applied neither scientific technique nor technical expertise in presenting them"
- Court, however, allowed testimony re availability of risk information and applicable regulations

MTBE Prods. Liab. Litig. 643 F. Supp. 482 (S.D.N.Y. 2009)



Product Stewardship – as a Defense



- Refinery workers sued defendant who made benzenecontaining product, alleging it caused injuries and defendant supplier failed to warn them
- Defendant relied on the "learned intermediary defense" arguing that it had provided sufficient information about the products' hazards to the refinery operator, and thus had no duty to directly warn plaintiff workers
- Court granted SJ
 - Defendant "wrote that it would be providing product stewardship" before providing the product and attached a summary of the OSHA benzene standard and instructions on safe handling, and met with the operator.

Curtis v. M&S Petroleum, Inc., 174 F.3d 661 (5th Cir. 1999)



- Manufacturer should follow and document a rigorous product development and testing process.
 - Demonstrating the reasons for the design decisions and the hazard analysis process will be critical to the defense of the product
 - Manufacturer must take care that documents are not created casually and without thought or, more importantly, leaving critical issues unanswered.



• General guidelines:

- Write accurately and factually; avoid opinions, speculation, and exaggeration; communicate only what needs to be said (*e.g.*, humor can be misinterpreted particularly by lawyers).
- If a document creates an open issue, particularly one re safety (*e.g.*, notice of a safer alternative), that "loop" must be closed and the closure should be carefully documented.
- Internal memos and correspondence are inappropriate forums to wage turf battles;
 employees should avoid blaming others for mistakes or failings through internal memos.
- To the extent possible, sensitive documents should be reviewed by counsel before dissemination and/or should be directed to counsel (corporate or outside) to attempt to protect the privileged and confidential nature of the communication.
- All advertising literature, brochures, operating manuals and instructions should be carefully reviewed by all appropriate persons (*e.g.*, marketing, engineering and legal departments).
- The company should establish a document control and retention policy -- Documentation demonstrating design and manufacturing process should be kept in an orderly manner and for an appropriate period of time.



Corporate structure

 – liability assessment in new business or product line acquisition or divestiture

 appropriate parent and subsidiary corporation product stewardship roles



- Relationships with suppliers and distributors
 - For any supplies or materials that a manufacturer purchases for its products and for other products and parts supplied by third parties, the manufacturer should attempt to contractually shift the liability to such suppliers
 - Typically done through defense and indemnification clauses with upstream distributors and manufacturers



Product Stewardship – Attorney Role

- Structure product stewardship programs to reduce litigation risks
 - Achieve statutory/regulatory compliance
 - Avoid incidents that could give rise to litigation
 - Properly allocate responsibility among suppliers/customers
 - Protect confidentiality
 - Demonstrate the exercise of due care
- Outside counsel
 - Program design
 - Emerging issue review
 - Product/corporate changes
 - Training
 - Program compliance
 - Audits



Preparing for Litigation: Documents

- Preservation and production of documents
 - litigation / legal "hold"
 - discovery
 - need for records retention policy / procedures
- Careful communication/creation of documents
 - "smoking guns"
 - + email
 - + memos admitting liability
 - + deleted design documents
 - + Documents that make company ... look bad
 - Approaches
 - + prevention
 - + training
 - + culture



Preparing for Litigation: Working with Attorneys

• Preserving privileges:

attorney client privilege / attorney work product

- protect from disclosure the substance of confidential communications between client and attorney
 - \checkmark communication
 - ✓ made between privileged persons
 - \checkmark in confidence
 - ✓ for purpose of seeking, obtaining, or providing legal assistance to client
- + does not protect
 - ✓ disclosure of underlying facts
 - ✓ factual circumstances of the communications (e.g., when, documents reviewed, etc.)



Preparing for Litigation: Working with Attorneys

- Preparing defense
 - Fact development
 - Identify relevant documents and document custodians
- Testifying
 - Deposition or trial
 - Fact witness
 - + Personal knowledge: What you know / observed
 - Corporate designee witness
 - + Discuss specific programs and procedures in given time period
 - Expert witness
 - + Specialized knowledge in field
 - + others may rely upon their knowledge / opinion about evidence / facts



Preparing for Litigation: Expert Witnesses

- Important for Product Defect, Causation, and Liability Issues
 - Normally, courts prohibit witnesses from testifying based on their own opinions or analysis. Courts allow such testimony for qualified expert witnesses testifying about matters within their field of expertise.
 - An expert witness is a witness, who by virtue of education, training, skill, or experience, is believed to have expertise and specialized knowledge in a particular subject beyond that of the average person, sufficient that others may officially and legally rely upon the witness's specialized (scientific, technical or other) opinion about an evidence or fact issue within the scope of his expertise, referred to as the expert opinion, as an assistance to the fact-finder.



Preparing for Litigation: Expert Witnesses

The Supreme Court's landmark ruling in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), as adopted in the Federal Rules of Civil Procedure, sets forth the test for admissibility of expert testimony in federal court.

- The Court held that scientific expert testimony must satisfy the dual requirements of scientific reliability and relevance to be admissible, and that trial judges must serve as gatekeepers to keep scientifically unreliable and irrelevant expert testimony out of the courtroom. *Id.* at 589.
- While acknowledging that "many factors will bear on the inquiry," id. at 593, the Court suggested four factors potentially helpful in determining the scientific reliability of a theory or technique: (1) testing; (2) peer review and publication; (3) error rate and standards; and (4) general acceptance, *id.* at 593-94.



Preparing for Litigation: Too Careful Communication

- Law360, New York (March 15, 2016):
- "As GM refrained from urgently investigating reports of failing ignition switches, engineers deep within the organization were effectively prevented from sounding alarms by a policy that forbade terms like "problem," "bad" and "rolling sarcophagus," a former automotive industry engineer testified in a bellwether trial."
- Terms engineers were directed to avoid included "safety," "big time," "good," "defect," "ghastly," "Challenger," "powder keg," "deathtrap," "widow-maker" and "Cobain."
- Plaintiffs' expert: "You're limiting [engineers] from being as precise and accurate as they could be"



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