



PRESENTERS



Welcome and Background on Product Liability Law

Allen C. Schlinsog, Jr.

Shareholder and chair, Litigation Practice Area; chair, Product Liability and Safety group



Your Product Failed in the Field... Now What?

Jennifer L. Naeger

Attorney, Litigation Practice Area, member of Product Liability and Safety group



Reporting and Recall Requirements/Issues

Patrick J. Hodan

Shareholder, Litigation Practice Area, member of Product Liability and Safety group



Prepare for a Crisis Before It Happens

Colleen E. Fielkow

Shareholder, Litigation Practice Area, manages Product Liability and Safety group

AGENDA

2:30 p.m.

Registration and Networking

3:00 p.m.

Presentations

Welcome and Background on Product Liability Law ~ Allen C. Schlinsog, Jr.
Your Product Failed in the Field... Now What? ~ Jennifer L. Naeger
Reporting and Recall Requirements/Issues ~ Patrick J. Hodan
Prepare for a Crisis Before It Happens ~ Colleen E. Fielkow
Summary and Q & A with Panel ~ All Presenters

5:00 p.m.

Networking Reception

2

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The Legal Framework For Product Liability Risks



3

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Fundamental Public Policy:

It is unfair to subject people to products that are "**unreasonably dangerous**."

If a product is "unreasonably dangerous," it may be considered **defective**.

If we manufactured or sold a **defective** product, we can be held liable for injuries stemming from that defect.

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What Does It Mean to Be "Defective" or "Unreasonably Dangerous?"

- Risk/Utility Test: Essentially, after balancing several factors, does the risk of using the product outweigh its benefits?
or/and
- Consumer Expectation Test: Is the product more dangerous than an ordinary consumer would have contemplated?

5

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These tests have led to additional guiding principles:

- A hazard cannot be "unreasonably dangerous" if it is open and obvious
- The hazard needs to be "latent" -- unknown or unappreciated by the user



6

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- Similarly, a sophisticated user may more fully appreciate hazards than a novice



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These tests have led to additional guiding principles:

- Statutes of Repose
- Assumption of Risk



- Warnings/Labeling/Instructions/Training
 - can make a hazard known; thereby making the product not "unreasonably" dangerous (and therefore not defective)

8

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Product Liability Concerns (that you can control)

1. Defective Design



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Product Liability Concerns (that you can control) (cont.)

2. Defective Manufacturing



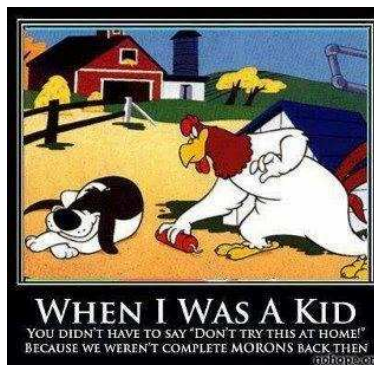
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Product Liability Concerns (that you can control) (cont.)

3. Failure to Warn



11

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Typical Product Liability Claims

- Strict liability (focuses on the product itself)
 - Defendant is a manufacturer or commercial seller
 - The product was defective
 - Defect proximately caused the plaintiff's injury



12

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Typical Product Liability Claims (cont.)

- Negligence (focuses on defendant's behavior)
 - Duty of care to plaintiff
 - Breach of duty ("knew or should have known")
 - Breach proximately caused plaintiff's injury
 - Plaintiff was injured

13

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Typical Product Liability Claims (cont.)

- Failure to warn
 - Defendant made or sold the product
 - Defendant knew or should have known about hazards at the time of sale
 - The product was substantially dangerous when used in foreseeable way
 - Ordinary consumers would not recognize the risks
 - Defendant failed to "adequately" warn of the risks
 - Plaintiff was injured
 - Lack of sufficient warning caused the injury

14

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What Is An "Adequate Warning"?

Need to prominently and clearly inform the user of the nature of the hazard **and** the potential consequence of not heeding the warning.



15

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Strict Liability

- Fault is not at issue
- Rather, if you are a seller in the stream of commerce, and the product was defective when it left your possession, you can be liable for injuries proximately caused by the defect

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Negligence

- Fault is an issue
- In addition to finding a defect, causation and damages, a jury must determine that we were negligent in the design, manufacture or failure to warn
- That is, did we fail to act as a reasonably prudent manufacturer or seller?

17

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Failure to Warn

- Even if designed and manufactured properly, did we fail to warn of a known hazard that the user would not appreciate?
- Was the hazard latent?
- Was our warning sufficient?
 - Legible, prominent, understandable?
 - Advise of the hazard and the consequence of failing to heed the warning?

18

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How Far Can Product Liability Extend?

Standard Defenses:

- Statute of repose – nothing lasts forever
 - Open and obvious hazard
 - Assumption of risk
 - Sophisticated user
 - Learned intermediary
- } Product not "unreasonably" dangerous because Plaintiff knew of the hazard

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Standard Defenses (cont.):

- Fault of user or third party
 - Compliance with standards/
regulations/agencies
 - State of the art
- } No better design existed

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Standard Defenses (cont.):

- Preemption
Federal law requires our product to be made a certain way; you cannot sue us for following instructions.
- Misuse
We did not intend or expect our product to be used that way.
- Failure to maintain properly
It was not dangerous when it left our control. The plaintiff made it dangerous by not taking care of it.

21

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But Wait; There's More...

Post-Sale Duty To Warn

- Did you learn of a defect after you sold the product?
- Is it reasonable and feasible to warn prior purchasers of the hazard?

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Post-Sale Duty To Warn Example

- Product sold two years ago; claim occurs today
- Question in that traditional product liability case?
 - Could you have designed or manufactured a non-defective product two years ago?
 - Bottom line -- Whether you knew or should have known of that problem at the time of sale

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Post-Sale Duty To Warn Example (cont.):

- But then an identical failure occurs five years later
- Questions now?
 - As before, what did you know; why did you fail to warn (-seven years) at the time of sale?
 - But also -- why didn't you warn me five years ago when this happened the first time?

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How would you defend that second claim?
What evidence will prove that you did everything right
five years ago?

- Thoroughly evaluate the credibility of each incident when it occurs
- If credible:
 - Is a warning appropriate? Is it feasible?
- Document decision to warn (or to not warn)
 - Include reasoning; identify key persons involved
- If you warn, describe steps taken; monitor and record effectiveness
- Send document only to legal counsel
- Modify document retention policies

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Key Take-Aways Regarding Post-Sale Duty to Warn:

- Can arise at any time – "knowledge" relevant to a duty to warn is not limited to the time of sale. Evaluate all accident and claims of defect.
- Establish a protocol for evaluating complaints and information regarding product failures.

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Key Take-Aways (cont.):

- The actual protocol you employ can be highly variable, depending on your business and your product
- We can help sort through the complexities if you would like

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How Can You Manage Your Risk?

- Evaluate product liability risk
 - Product safety review
 - Audit product claims/exposure
 - Evaluate vendor contracts
 - Evaluate customer contracts
 - Evaluate insurance coverage
 - SIR/deductible (Is this what you want?)
 - Recall (highly variable)
- Defend claims should they occur

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How Can We Help?

- Seminars to in-house legal or engineering teams:
 - Tort reform (Wisconsin & elsewhere)
 - Recall strategy/preparation/risk allocation
 - Literature, warnings, manual review
 - ADR Strategy
 - Post-sale duty to warn protocol
 - FDA regulatory issues/compliance
 - CPSC regulatory issues/compliance
 - Contract review
 - Assist with risk management and defend claims



29

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Questions?



THANK YOU!

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31

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Your Product Failed in the Field... Now What?

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Time is of the Essence

- Every company must take action within **72 hours** of discovery of a product failure
- Time is of the essence! Delay is likely to exacerbate costs and liabilities.



Overview

- Implement crisis management plan
- Assemble crisis response team
- Communicate with outside counsel
- Notify insurer
- Begin investigation of product failure
- Consider notifying relevant regulatory authorities and/or recalling product

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Initial Action Items

1. Put the company's planned (and tested) crisis management plan into effect
 - Implement the plan before a crisis ever occurs
 - Goal of the plan:
 - To manage immediate risks
 - To end the crisis quickly
 - To restore the company's credibility and reputation in the market
 - Anticipate the types of crises your company could face

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Initial Action Items (cont.)

- To be effective, the response plan should include the following:
 - Identification of core crisis response team
 - Identification of outside counsel
 - Identification of company spokesperson
 - Development of the key messages to be delivered by the company spokesperson
 - Development of a plan to retain all relevant evidence

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Initial Action Items (cont.)

- Conduct live drills on an annual basis
 - Tests strengths and weaknesses of the plan
 - Enables team to develop and maintain capabilities
- Review plan annually in strategy sessions
 - Examine crises affecting other companies so team can discuss how your company would have responded to a similar event



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Initial Action Items (cont.)

2. Assemble the crisis response team

- Form team when crisis management plan is initially implemented
- Include representatives from key areas of the business, such as:
 - Management
 - R&D/Engineering
 - Manufacturing
 - Distribution
 - Quality Assurance



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Initial Action Items (cont.)

- Marketing
- Legal – In-house and outside counsel
- Additional members can be added based on the particular crisis
- Choose team leader in advance
 - Responsible for evaluating crisis, assembling the team, filling slots with specialists and ongoing coordination throughout the crisis

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Initial Action Items (cont.)

3. Involve outside counsel early in the crisis to minimize risk to the company
 - **WARNING:** Communications with in-house counsel may not be privileged
 - Advice solicited must be predominately legal as opposed to business
 - Do not transmit information via e-mail; if possible, stick to telephone and in-person communications
 - Cautionary tales

40

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Initial Action Items (cont.)

- With outside counsel, more likely that investigative work and analysis will be covered by attorney client privilege
 - Scope of the privilege
 - Allows company personnel to safely and fully disclose sensitive information to legal counsel in most instances
- Tips for maintaining privilege

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Initial Action Items (cont.)

4. Notify insurer of circumstances that could give rise to a claim
 - Obtain copies of all relevant policies
 - **WARNING:** Communications with insurer may not be privileged
 - Depending on the jurisdiction, communications between insurer and insured for the purpose of establishing a defense may be privileged

42

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Initial Action Items (cont.)

- However, Wisconsin courts refuse to extend any privilege to these communications
- Company has a contractual obligation to report
- Best to assume insurer is adverse to the company, especially if there are unresolved coverage issues



43

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Initial Action Items (cont.)

5. Investigate product failure to determine root cause and develop plan to fix it
 - Involve product designer
 - Schedule visit of accident scene/site inspection
 - Secure product at issue and/or request it be preserved
 - Research product line (general)
 - Determine number of products affected
 - Local, regional or national

Initial Action Items (cont.)

- Research product (specific)
 - Evaluate failure in conjunction with complaint files and product history
- Identify witnesses
- Identify local dealer/distributor information
- Identify suppliers
- Gather media accounts of accident and any photos, raw video, audio, etc.
- Obtain a copy of the police/accident report
- Obtain a weather report for the day of the accident

Initial Action Items (cont.)

6. Consider notifying relevant regulatory authorities and/or conducting a product recall
 - This will depend on what the investigation reveals
 - May have legal duty to report to government agency that regulates industry
 - If company does report, this doesn't mean that it has to launch a full-blown recall

46

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Questions?



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47

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Reporting and Recall Requirements/Issues

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CPSC

- Is my product covered by the CPSC?

Report an Unsafe Product | Contact CPSC | Website Design Feedback | Consumers: Español | Businesses: Español | 中文 | Tiếng Việt

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION

Home | Recalls | Safety Education | Regulations, Laws & Standards | Research & Statistics | Business & Manufacturing | Newsroom | About CPSC

Report an Unsafe Product
Are you aware of a potentially hazardous product?
Consumers | Businesses

Search Product Safety Reports on SaferProducts.gov
Business Portal on SaferProducts.gov

Connect with Us
On these networks: [Social Media Icons]
Join the Neighborhood Safety Network
Put CPSC Recalls on Your Website

IKEA Recalls 2.9M Kids' Wall-Mounted Lamps; Child Died
Two children, a 16-month-old and a 15-month-old, got tangled in the lamp's cord while the children were in their cribs. Take down these lamps until you get and install the free repair kit from IKEA.
Learn More



CPSC's Reach is Long

- The CPSC asserts jurisdiction over 15,000 types of "Consumer Products"
 - The definition of "Consumer Products" is intentionally broad and rarely challenged in court
 - It has been interpreted to include any product or component **used by or having an effect on consumers**
 - Commercial products, drugs and motor vehicles are examples of products not covered

50

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My Product is Covered; Do I Need to Report?

Under Section 15:

- A manufacturer, distributor or retailer of consumer products, or any other product over which CPSC has jurisdiction, distributed in commerce must notify CPSC immediately upon receipt of information that reasonably supports the conclusion that:
 1. The product fails to comply with a consumer product safety rule or voluntary standard;
 2. Contains a defect that could **create a substantial product hazard**;
 3. Creates an **unreasonable risk of serious injury or death**; or
 4. Fails to comply with any other rule, regulation, standard or ban under the Consumer Product Safety act or any other act enforced by CPSC

51

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Reporting Obligation Construed Very Liberally...

- The only reported decision interpreting the reporting requirements, United States v. Mirama, 185 F. Supp. 2d 1148 (S.D. Ca. 2002), is extremely problematic for manufacturers
- Mirama sets a very low threshold for requiring manufacturers to report problems with their products

- Not what company believes
- Not what experts believe
- It is what "reasonable person believes"



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- Mirama involved 23 reported incidents of exploding juicers
- 22 people were injured in the reported incidents
- 7 people required medical treatment (5 people required stitches and 1 required surgery)
- The court concluded that this was "overwhelming" evidence that the product was defective or unreasonably dangerous and that the manufacturer's failure to report the incidents violated the CPSCA

What Happens If You Do Not Report?



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Civil Penalties

- May be imposed for "knowing" violations of the CPSA:
 - \$100,000/violation
 - \$15 million max



- Following Mirama, courts will not consider a failure to report a single violation, but rather will count the number of potentially defective or unreasonably dangerous products in the stream of commerce as individual violations
 - Court concluded that manufacturer had not committed 23 violations for failure to report each incident, but 30,000 to 40,000 violations based on the number of potentially affected products in the stream of commerce
- This combination makes it relatively easy to maximize civil penalties

56

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Criminal Penalties

- May be imposed for a "knowing and willful" violation of the CPSA
 - \$250,000 fine
 - Up to 5 years in prison



57

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Prohibited Acts

- Among the prohibited and potentially criminal acts are the following:
 - Knowing and willful manufacturer, sale or distribution of a product that does not conform to the requirements contained in the CPSA; and
 - Knowing and willful **failure to comply with mandatory reporting requirements**



58

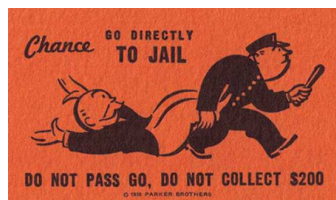
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Criminal Conduct

A first-time knowing and willful violation of the Act is a criminal offense

- Places increased pressure on corporate actors to determine whether certain conduct violates the new law in the first instance



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What Does It Mean?

- No case law or federal regulations interpreting the new law
- Very little useful legislative history
- Statutes containing similar language provide little assistance

**Left with plain language and stated intent
to provide expansive protection**

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Who Could Be Affected?

- Reasonably likely to apply to:
 - CEO
 - President
 - Officers
 - Directors
 - Managers
 - In-house counsel
 - Outside counsel(?)



**Essentially, anyone with decision-making
authority**

61

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So what do you do when faced with knowledge of incident and Section 15(b) reporting obligation?

- Product Safety Group
- Report problem and recall?
- Report problem but do not recall?



62

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What Happens in Canada Does Not Stay in Canada

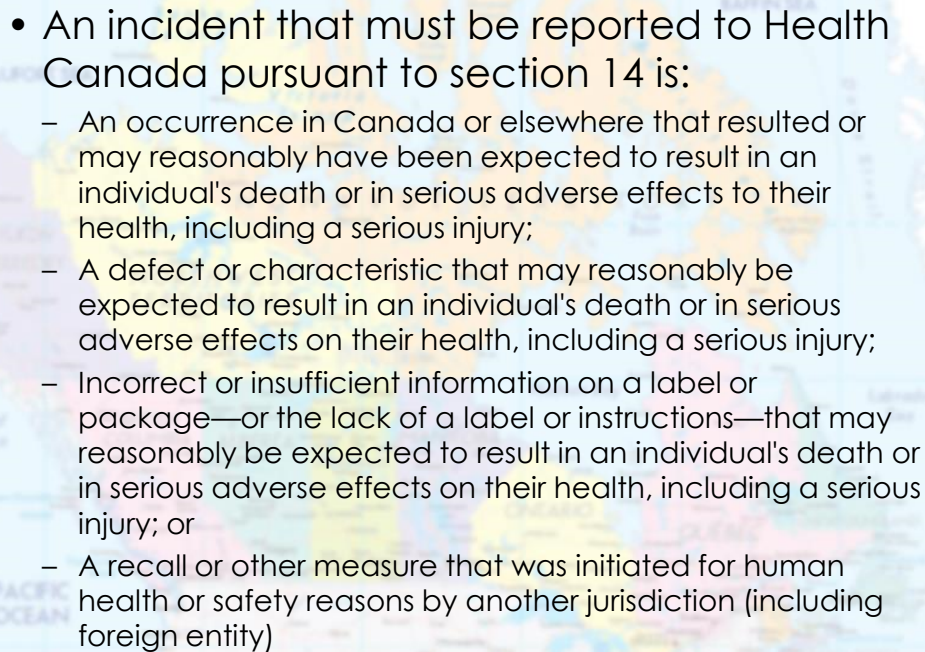
- Canada Consumer Product Safety Act
- In effect June 2011
- Mandatory incident reporting



63

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- 
- An incident that must be reported to Health Canada pursuant to section 14 is:
 - An occurrence in Canada or elsewhere that resulted or may reasonably have been expected to result in an individual's death or in serious adverse effects to their health, including a serious injury;
 - A defect or characteristic that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury;
 - Incorrect or insufficient information on a label or package—or the lack of a label or instructions—that may reasonably be expected to result in an individual's death or in serious adverse effects on their health, including a serious injury; or
 - A recall or other measure that was initiated for human health or safety reasons by another jurisdiction (including foreign entity)

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Conflicting Guidance from Canada

- Very similar to U.S. reporting obligations (Health Canada Information Session (July 3, 2013))
- But risk assessment guidance is difficult

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Product Liability Risk

- A second incident occurs resulting in a serious injury
- Now you face potential punitive damages for not recalling the product



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Questions?



THANK YOU!

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How To Prepare For A Crisis Before It Happens:

Risk Management for Today's Modern Warrior

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The Truth About Your Risk

- Even the safest, most well-made products can hurt someone or damage property
- Good companies making or selling good-quality products will get sued
- Let's talk Army

Meet Your Army Guide:



70

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Strategic Thinking and Planning

- Win without going to battle (best)
- Win in battle
- Win the War
- Manage your risk:
 - *Build your fortresses*
 - *Stockpile shields and swords*



71

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Overview of Risk Management

1. Your Product
 - Design, build, test
2. Your chain
 - Protect up- and downstream
3. Your customers
 - What you say and what you hear
4. Your partners



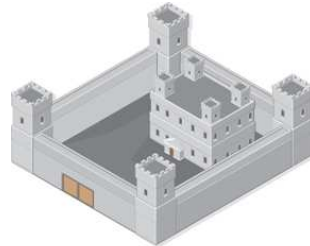
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Build Your Fortresses and Survey Your Tools and Weapons

- Each product needs its own defendable core
- Protect your product's core—but one fort or wall is enough
- Invest in shields and swords (when the bad creeps in)



73

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Battle Plan From 50,000 Feet

The Product

- Design
- Manufacturing
- Testing
- Warnings

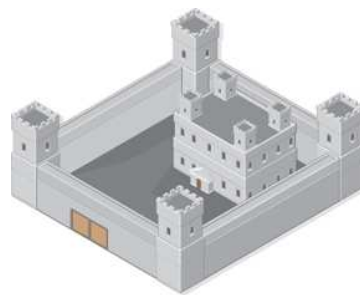
The "Paperwork"

- Contracts
 - Chain: Vendors, suppliers, customers
 - Insurance policies
- External
 - manuals
 - brochures, ads, websites
 - Regulators
- Internal
 - Systems, databases

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The Product Fortresses

- Design
 - Research and development
 - Testing
- Manufacturing
 - Quality manual
 - GMPs; ISO standards
- Warnings
 - On-product (ANSI and ISO)



The Paperwork: Shields and Swords

- Purchase order contracts
 - Buyer or seller?
 - "Form" contracts
 - Battle of the forms
 - Review them up and down your supply chains



76

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Armor and Weapons: POs

- Implied and express warranties
 - Buyer: Maximize
 - Seller: Minimize
- Indemnification & Damage Limitations
 - Buyer: Minimize
 - Seller: Maximize
- Other terms that also matter
 - Choice of law/venue
 - Recall responsibilities
 - ADR



77

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Another Shield: Insurance

- General commercial liability
- Recall
- Umbrella
- Covered under another's policy?
 - Get certificate of liability coverage
- "Notice" trigger



78

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External Communications (going out and coming in)

Communications about your product is not a
one-way street



79

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Your External Communications

TECHNICAL and REGULATORY

- Manuals
- Regulators
- Education efforts
- Safety bulletins

SALES and MARKETING

- Website
- Advertising
- Brochures
- Trade shows
- Social Media

80

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Technical Product Communications

- **Manual and on-product warnings**
 - Development and testing
 - ANSI/ISO standards
- **Regulators**
- **Training, education efforts and safety bulletins**
 - **Save training records of users—
could include the next plaintiff!**

81

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Sales and Marketing

- Claims about product's uses and features can be exaggerated here
- Warnings must carry through
- Also watch discussions among trade groups about knowledge of category product risks

82

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Unify External Messages

- Identify internal sources
- Where is message going?
- Purpose?
- Develop protocols/systems
- Include data received into company from outside sources

83

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Communications: Right Back At 'Ya

- Customers/end users do talk
 - Collect and retain feedback, reports of injuries, failure, misuses
 - Protocol for injuries
- Blogs, social media about product (but not directed to you)
 - Do you really want to know? (Yes)

84

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Develop Systems to Collect and Disseminate Information



85

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Internal Communications

The Product

- Design/manufacturing
- Testing
- Improvements/updates
- Regulatory issues
- Product feedback

Reports of Failure/Misuse

- Reports/feedback from end-users
- Seek legal advice
- Recall
- Post-sale duty to warn

86

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Blueprint Your Crisis Plan

TO-DO CHECKLIST

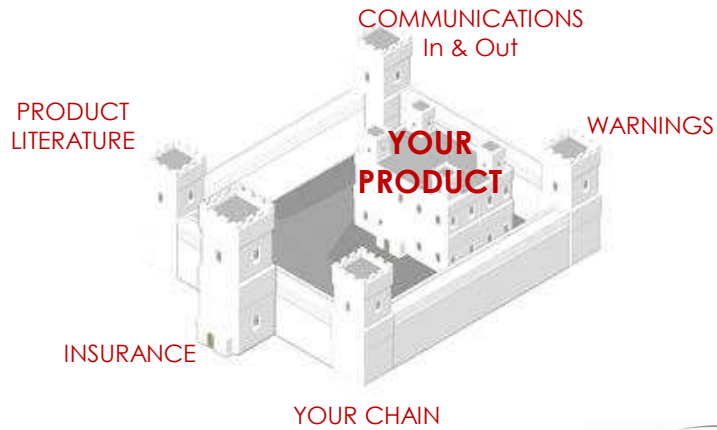
- What to do in first 72 hours
- Create it now

RESPONSE TEAM

- Counsel—legal advice
- Product designer
- Management/exec
- Safety
- Local contact
- Regulatory
- P.R.

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Defenses are Ready



88

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Questions?



THANK YOU!

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89

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Questions?

Thank you for attending our presentation. If you have questions, please contact your Reinhart attorney or one of our presenters.

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THANK YOU!