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Confidustria Udine

Prospettive, tendenze e opportunità di
business nel continente americano

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Primary Goal?

1. Keep costs down
2. Keep costs down
3. Keep costs down

Easiest Way To Achieve That Goal?

AVOID LITIGATION

The Team:



How Is The Goal Achieved?

AWARENESS

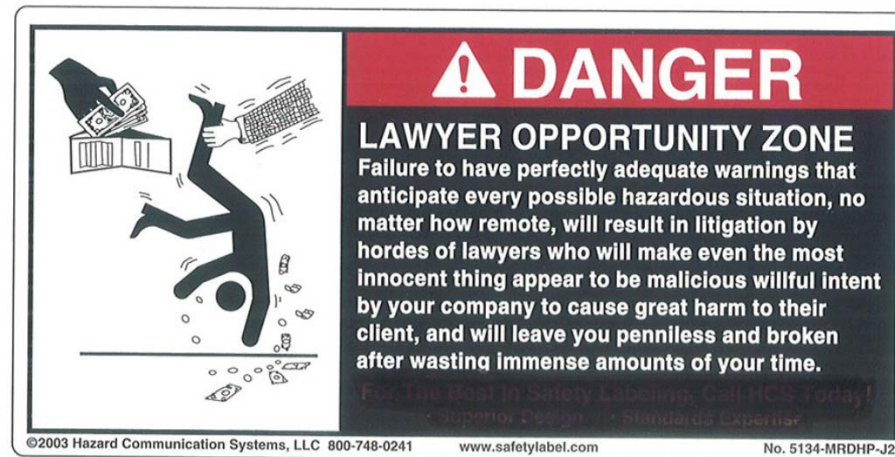
1. Risks
2. Services Available to Avoid These Risks

Primary Risks In The U.S.

1. Products Liability
2. Warranty
3. Standard Compliance
4. Market Surveillance
 - a. Accident Investigation
5. Recalls
6. Contracts
7. Patent / Trademark / Intellectual Property
 - a. Offensive
 - b. Defensive
8. Immigration
9. Advertising
10. Website
11. Document Retention Systems
12. Insurance

Risk 1

Product Liability Claims



Risk 1

Product Liability Claims

1. Strict Liability In Tort
 - a. Defect in design
 - b. Defect in manufacture
 - c. Failure to Warn

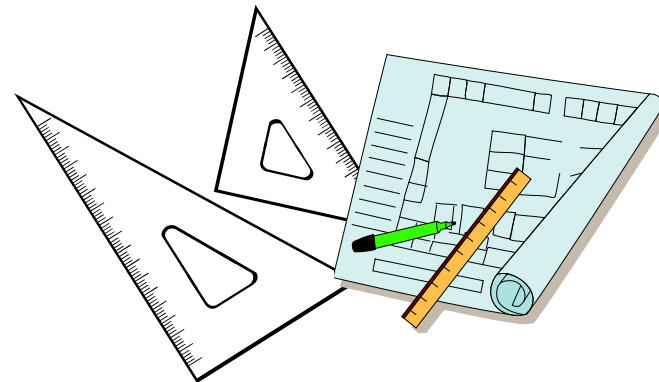
Liability “without regard to fault”

Risk 1

Product Liability Claims

Design Defect

- There is no variance from the product's specifications, but the design causes or fails to prevent injuries to users.



Risk 1

Product Liability Claims

Manufacturing Defect

- Error in the manufacturing process.

Risk 1

Product Liability Claims

Failure to Warn

- A manufacturer is required to provide adequate warnings and instructions for the safe and effective use of its products and against any dangers not within the knowledge of, or obvious to, the ordinary users

Risk 1

Product Liability Claims

Locations of Warnings

- Owners Manual
- On-Product Labels
- Website

Risk 1

Product Liability Claims

- The warnings must be sufficient to alert the user to foreseeable risks associated with using the product, but there cannot be too many warnings.
- The warnings must be sufficient to convey the nature of the risk(s), but easily understandable.
- The warnings must be sufficient to convey the nature of the risk(s), but succinctly (briefly) worded.
- The warnings must be clear and not ambiguous, but cannot be too narrow in scope.
- The warnings must be clear and not ambiguous, but cannot be too broad in scope.

The meaning of the different signal words as defined by the ANSI Z535.6 and ANSI Z535.4 standards may be provided in collateral materials. The following artwork may be used for this purpose.



DANGER indicates a hazardous situation which, if not avoided, will result in death or serious injury.



WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.



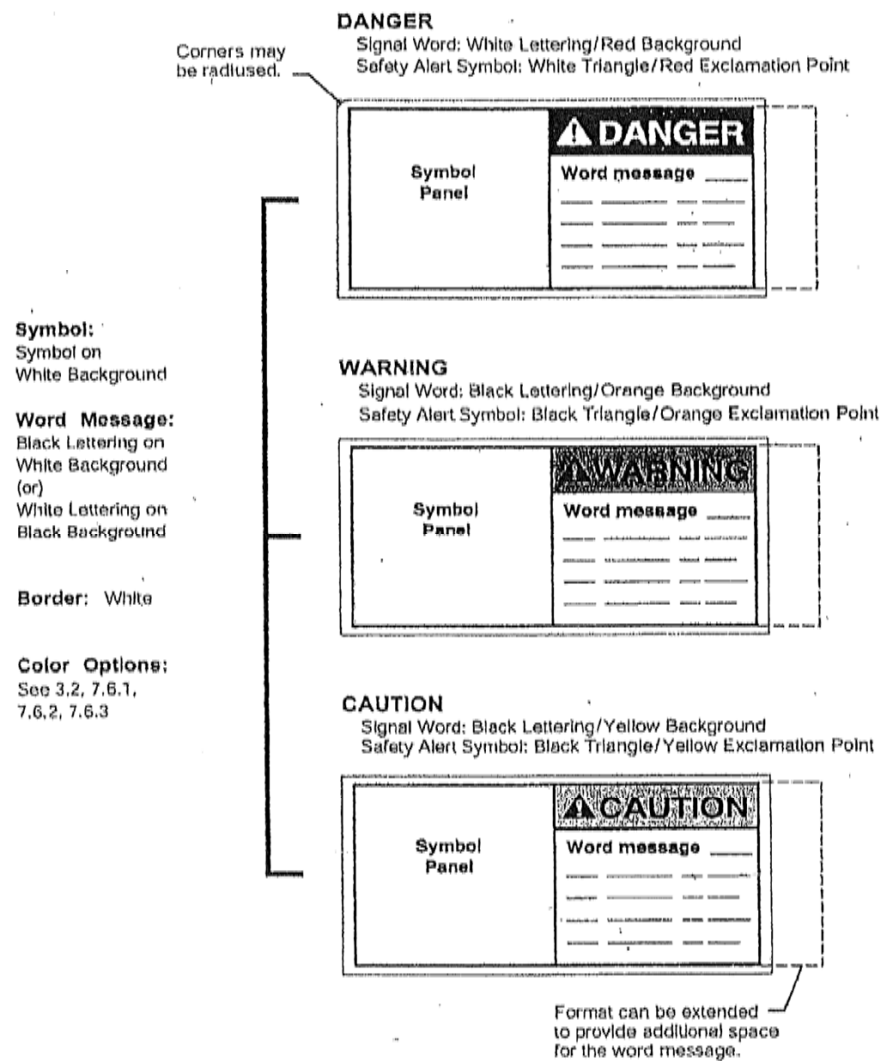
CAUTION, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.



NOTICE is used to address practices not related to personal injury.



CAUTION, used without the safety alert symbol, is used to address practices not related to personal injury.



Does your owners manual
and on-product warnings
comply with the standards?

Risk 2

Warranty

Contract/Breach of Warranty

- Breach of express or implied warranties, misrepresentation or fraud.



Risk 2

Warranty

Magnuson Moss Warranty Act

- Define Scope of Coverage
- Warranty Claim Procedure
- Confirm Express Warranties
- Confirm Implied Warranties
 - Merchantability
 - Fitness for a particular purpose
- Limit incidental and consequential damages
- Transferable?
- Applicable Law



Risk 2

Warranty

Warranty

- a. Disclaimer of express and implied warranties must be done properly
- b. European and U.S. warranty forms **are not interchangeable**
 - i. A U.S. warranty form *creates* liability in Europe

Is your warranty correct?

It is easy to check!

Risk 3

Standards

Do your product comply with relevant standards?

- American National Standards Institute (ANSI)
- American Society of Testing and Materials (ASTM)
- Underwriters Laboratories (UL)
- National Highway Traffic and Safety Administration (NHTSA)
- Consumer Products Safety Commission (CPSC)
- Food and Drug Administration (FDA)
- Federal Trade Commission (FTC)
- United States Coast Guard (USCG)
- Federal Aviation Administration (FAA)
- Snell Memorial Foundation (Helmets)

Risk 3

Standards

Two types of standards:

- Mandatory
- Voluntary

Risk 3

Standards

From a litigation perspective, *all* Standards are mandatory.

- Sets a minimum level of acceptable behavior

Risk 4

Market Surveillance

Develop product
surveillance procedures



Risk 4

Market Surveillance

- You have a system to be kept informed of loss trends, warranty claims, product incidents, claims and litigation?
- Were your operating and maintenance manuals reviewed to insure conformity with actual uses of product?
 - Does the manual warn about known misuse of the product?



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Inspection/Investigation

Early Notice Of An Accident and Immediate Investigation Are Critical

- Preserve physical evidence
- Assess the actual conditions in which the incident occurred
- Avoid “group recollection”
- Eliminate circumstantial evidence



Develop “affirmative defenses”

Investigation

The damages allegedly sustained by plaintiff was caused or contributed to by plaintiff's own negligence or culpable conduct.



The damages allegedly sustained by plaintiff was caused by the negligence or intentional conduct of other parties.



Plaintiff's damages were caused and brought about by an intervening and superseding cause.



Plaintiff assumed the risk of his alleged damages.





The product in question, when sold as new property, was merchantable and reasonably suited to its intended use.



The product was substantially misused, abused, modified and/or altered subsequent to its placement into the stream of commerce.

The alleged damages were the result of the product having been used in a manner not intended or in a manner not in accordance with the instructions and labels provided with it or with known safety practices.





If the product was dangerous or defective, then such condition was open and obvious.



Defendant had no duty to warn.



Plaintiff destroyed, lost or spoliated evidence crucial to the defense of the claims.



Risk 5 Recalls

Have A Recall Plan



Risk 5

Recalls

Section 15 Reports

A company must notify CPSC **immediately** if it obtains information which reasonably supports the conclusion that a product distributed in commerce:

1. Fails to meet a consumer product safety standard
2. Contains a defect which **could** create a substantial product hazard to consumers
3. Creates an unreasonable risk of serious injury or death.
4. Fails to comply with a voluntary standard issued by the CPSC

Risk 5

Recalls

Federal Agencies with Similar Responsibilities:

- Food and Drug Administration (FDA)
- National Highway Traffic and Safety Administration (NHTSA)
- United States Coast Guard (USCG)
- Environmental Protection Agency (EPA)
(similar idea)

Risk 5 Recalls

No Admission of Defect

Reporting a product to the CPSC does not automatically mean that a recall will be ordered.

The CPSC staff “works with” the reporting firm to determine if corrective action is appropriate.

Risk 5

Recalls

When to Report

Section 15 requires firms to report “immediately” of obtaining information of a potential hazard.

If the company is uncertain whether information is reportable, the firm may spend “reasonable” time investigating this matter. That investigation should not exceed **ten working days** unless the firm can demonstrate that a longer time is reasonable in the circumstances.

Risk 5

Recalls

Identifying a Defect

A single defective product could be the basis for a substantial product hazard determination if an injury is likely or could be serious.

- An accident does not need to occur in order to conduct a recall

Risk 5 Recalls

Products for children, the elderly, or the disabled require an extremely high level of vigilance.

Risk 5

Recalls

Fast Track Product Recall Program

If a company reports a potential product defect and, within 20 working days of the filing of the report, implements with CPSC a consumer-level voluntary recall that is satisfactory to the CPSC, the staff will **not** make a preliminary determination that the product contains a defect which creates a substantial product hazard.

Risk 5

Recalls

Fast Track Program

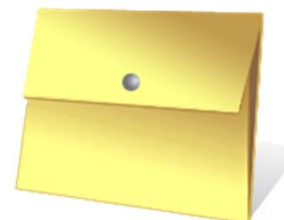
To participate in this program, companies must:

- Provide all of the information required for a full report.
 - Request to participate in the program.
 - Submit a proposed corrective action plan which is to occur within **twenty (20) working days** of the report.
-
- Substantial Cost Savings
 - It is critical to have a recall policy in place.

Risk 5 Recalls

Records Maintenance

The CPSC believes that maintaining accurate records about the design, production, distribution, and marketing of each product for the duration of its expected life is essential for a company to conduct an effective, economical product recall.



Risk 5

Recalls

Penalties

SEC.20 [15 U.S.C. 2069]

Civil penalty not to exceed **\$100,000** for each such unsafe product, but the maximum civil penalty shall not exceed **\$15,000,000** for any related series of violations.

Covered?



Risk 5 Recalls



Penalties SEC.21 [15 U.S.C. 2070]

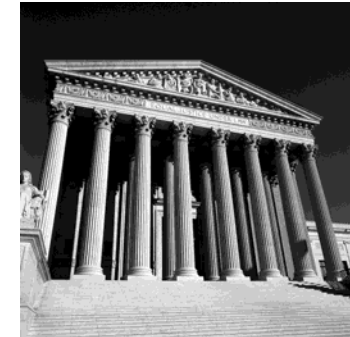
- Any **person** who knowingly and willfully violates section 19 of this Act after having received notice of noncompliance from the Commission shall be fined not more than **\$250,000** or be **imprisoned** not more than **five (5) years**, or both.

Is a defense against criminal claims covered?

Risk 5 Recalls

Penalties

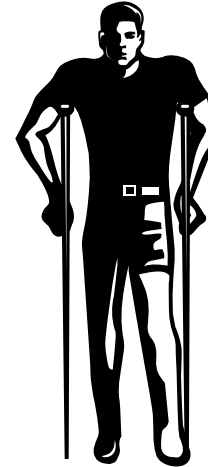
SEC.22 [15 U.S.C. 2071]



The United States district courts shall have jurisdiction to take the following action:

- Restrain any violation of section 19.
- Restrain any person from manufacturing for sale, offering for sale, distributing in commerce, or importing into the United States a product in violation of an order in effect under section 15(d).
- Restrain any person from distributing in commerce a product which does not comply with a consumer product safety rule.
- Business interruption insurance?
- Third party claims of distributors?

Risk 5 Recalls



Penalties

SEC.23 [15 U.S.C. 2072]

Any person who shall sustain injury by reason of any knowing (including willful) violation of a consumer product safety rule, may sue any person who knowingly (including willfully) violated any such rule or order in any district court of the United States shall recover damages sustained, and may, recover the costs of suit, including reasonable attorneys' fees and reasonable expert witnesses' fees.

Risk 6

Contracts

Do you have effective agreements?

- Distribution Agreements
- Dealer Agreements
- Terms and Conditions of Sale
- Purchase Order Forms
- Licenses
- Joint Venture Agreements
- Confidentiality Agreements
- Sharing Agreements
- Non Compete Agreements



Risk 6

Contracts

Cover Issues Such As:

- Apportionment of Liability
- Recalls
- Insurance
- Jurisdiction
- Choice of Law
- Intellectual Property Rights

Risk 6

Contracts

Indemnity Agreement

- Suppliers and
 - Clearly specify design/performance parameters of components
- Customers
 - Include specific reference to owners manual

Risk 7

Patent/Trademark/Intellectual Property Violations

Do your products violate the
intellectual property rights of
other companies?

Risk 7

Patent/Trademark/Intellectual Property Violations

Protect your own intellectual property

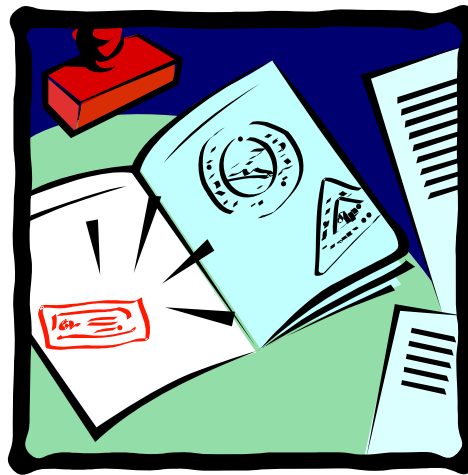
- Patents
- Trademarks
- Trade secrets
- Business plans
- Methods of doing business
- Customer lists



Risk 8

Immigration

Before expanding into the U.S., did you confirm that your key employees can work in the U.S.?



Risk 9

Advertising

Did you confirm that advertising literature and other product labeling complies with applicable statutes controlling product representations

- “Consumer protection” or “commercial fraud” statutes



Step 9

Advertising

Proposition 65

CALIFORNIA PROPOSITION 65 WARNING:

WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

Risk 10

Website

Do you use your website wisely?

- Standard Contracts
 - Purchase Agreements
 - Sales Agreements
- Warranty
- Safety Information
 - Point of Contact
 - Report of Hazards for Market Surveillance
 - Owners Manuals
 - Warning Stickers
 - Recalls



Risk 11

Do You Have A Document Retention System

Request for Production of Documents

- “Documents” is broadly defined to include records, correspondence, video and audio tapes, files, drawings, graphs, charts, photographs, computerized information, e-mail, electronic documents, etc.

Does your storage room look like this:



Risk 11

Develop Document Retention Systems

Can you find these categories of documents:

- R&D
- Design drawings
- Manufacturing records
- Quality control records
- Test reports
- Sales documents
- Malfunction and deficiency reports
- Warranty claims
- Intra-company correspondence
- Documents supplied to governmental agencies
- Post-accident test reports
- Expert reports
- Advertising Records
- Accident/Failure/Complaints/Claims History
- Market Research and Advertising



Risk 11

Do You Have A Document Retention System

The following is a list of guidelines for determining whether a document retention policy is "reasonable:"

- Length of the retention period;
- Frequency in magnitude of claims involving the type of documents at issue; and
- Reasons why the policy was adopted.

Must supplement with a litigation hold policy.

Risk 11

Document Retention Systems

Electronic Discovery Management Programs

Companies have a duty to:

- Know exactly how electronic documents are managed
- Know how to prevent the computer system from destroying relevant electronic documents
- Implement “Legal Holds” to prevent the destruction of relevant electronic documents when litigation is initiated, eminent or expected
- Meet with key players to determine existence of electronic documents and stress preservation and enforce Legal Holds

Risk 12

Insurance

Procure the appropriate insurance



You Cannot Protect Yourself Against Risks That You Do Not Know About

It Is Your Attorney's and Broker's Responsibility To Educate You About The Risks

Marsh and Goldberg Segalla Can Pro-Actively Address and Avoid These Risks

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