

# Warning Information Development Process

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Benchmark  
Research  Safety, Inc.

# Benchmark Research & Safety, Inc.

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- Founded in 2000
  
- Services & products we provide:
  - Product & occupational safety
    - Warning information design, development, & evaluation
    - Product liability litigation support
    - Research design, development & analysis
  
  - Usability
  
  - Web application design & development
  
  - Program administration & contract monitoring
  
  - Training & education

# What is a Warning?

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- Warnings provide information about risks
  - Notification (facts)
    - Nature of the hazard
    - Instructions on how to avoid the hazard
    - Consequences for failing to do so
  - Advice (judgments)
    - What people ought to do
    - Recommended course of action

# Warnings & Product Safety

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- Safety hierarchy
  - Design
  - Guard
  - Warn
  - Train
  
- Warnings are intended to contribute to product safety
  - Decreasing residual risk
  - Increasing tolerable risk
  
- Reasonably safe = residual risk  $\leq$  tolerable risk

# Warning Considerations

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- Why does it seem so easy to write a warning, but in actuality it's quite difficult?
- Developing warnings is a balancing act
  - Trying to achieve many objectives
  - Working with limited resources
  - Choosing and implementing warning features
- So what is the solution?

# Warning Information Development Process

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**Phase 1: Project Planning**

**Phase 2: Hazard Identification & Analysis**

**Phase 3: Warning Development**

**Phase 4: Warning Evaluation**

**Phase 5: Final Approval & Documentation**

# Benefits

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- Structured v. ad hoc process
  - Minimize time & money waste
  - Increased confidence in the warning information quality
  - Greater repeatability
  - Reduce likelihood of product recalls
  
- Legal concerns
  - Consistency across product lines
  - Maintain record of decisions
  - Deal with legal issues more efficiently and effectively

# Project Planning

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- Defining the scope
- Identify team members
- Resource allotment



# Project Planning, cont.

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- Defining the scope
  - Saves times and money
  - Identify affected products (including accessories)
  - “System of Information”
    - On-product labels/markings
    - Hang tags
    - Instruction & service manuals
    - Packaging
    - MSDSs
    - Signs
    - Point-of-purchase materials
    - Advertising & promotional materials

# Project Planning, cont.

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- Identify team members
  - Goal: identify & respond to hazards
  
  - Consider including:
    - Design engineers (mechanical, electrical, chemical, etc.)
    - Human factors engineers/psychologists
    - Packaging engineers
    - Technical writers
    - Marketing
    - Customer service
    - Regulatory affairs
    - Trade association representatives
    - Legal counsel

# Project Planning, cont.

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- Resource allotment
  - Provide sufficient time & money
  - Engage early in the design process
  - Warnings are often an afterthought
  - Avoids costly redesigns

# Hazard Identification & Analysis

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- “Know what was not previously known”
- Two general ways – formal techniques & external sources
- Formal tools:
  - Hazard Checklists
  - Preliminary Hazard Analysis
  - Fault Tree Analysis
  - Failure Modes and Effects Analysis
  - Event Tree Analysis
  - Root Cause Analysis
  - Job Safety Analysis
  - Critical Incident Technique
  - Risk Assessment Matrices
  - Hierarchical Task Analysis

# Hazard Identification & Analysis, cont.

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- External sources of information
  - Codes, regulations, and standards
  - Competitor's warnings information
  - Technical literature
  - Trade or industry groups & publications
  - Safety organizations & associations
  - Incident/accident data & reports
  - Medical literature
  - Warranty returns
  - Customer service complaints
  - Litigation claims
  - Subject matter experts
  - Product users

# Hazard Identification & Analysis, cont.

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- Unlikely any single method will address all needs
- Consider using multiple methods
- Formal techniques may not be necessary
  - Established products w/known histories
- Ultimately, decision lies with design team

# Warning Development

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- Three parts:
  - Identify potential topics
  - Determine delivery method
  - Prototype creation
  
- Two key questions
  - What do you want people to know?
  - How do you expect them to know it?

# Warning Development, cont.

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- Identify potential topics
  - Transform knowledge about hazards into possible topics
    - Some hazards generate multiple topics
    - Some topics address multiple hazards
    - Not every hazard will lead to a warning topic
  - Why not provide a message about every topic?
    - Space limitations
    - Overwarning issues



# Warning Development, cont.

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- Identify potential topics, cont.
  - Characteristics of the target audience
    - Age
    - Gender
    - Literacy (e.g., reading level, non-native language users, etc.)
    - Personality traits (e.g., self-efficacy, locus of control, risk taking, etc.)
    - Product familiarity
    - Hazard perception
  - Hazard likelihood & severity
  - “Open and obvious” hazards
  - Regulations & standards
  - Space limitations
  - Cost of compliance
  - Spatial & temporal placement

# Warning Development, cont.

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- Determine delivery method
  - Content
    - Warning components
    - Message length
    - Message explicitness
    - Space limitations
    - Multilingual presentation
  - Location
    - Temporal (user should see before hazard exposure)
    - Spatial (locate where product user will see it)
    - Durability
  - Format
    - Signal word
    - Text v. symbols
    - Color v. black & white
    - List v. prose
    - Font type & size
    - Layout

# Warning Development, cont.

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- Determine delivery method, cont.
  - Presentation methods
    - On-product labels/markings
    - Hang tags
    - Instruction & service manuals
    - Packaging
    - MSDSs
    - Signs
    - Point-of-purchase materials
    - Advertising & promotional materials

# Warning Development, cont.

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- Prototype creation
  - Consult relevant regulations & standards
  
  - ANSI Z535 series:
    - Z535.1 – Safety Color Code
    - Z535.2 – Environmental and Facility Safety Signs
    - Z535.3 – Criteria for Safety Symbols
    - Z535.4 – Product Safety Signs and Labels
    - Z535.5 – Safety Tags and Barricade Tapes (for Temporary Hazards)
    - Z535.6 – Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials
  
  - Focuses on format w/ some content & location guidance

# Warning Development, cont.

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- Prototype creation, cont.
  - Reference documents
    - CPSC (2003, October) – “Manufacturer’s guide to developing consumer product instructions”
    - FMC Corporation (1993) – “Product safety signs and label system”
    - Lehto (1992) – “Designing warnings signs and labels”
    - Wogalter (2006) – “Handbook of warnings”
  - Consider using outside subject matter experts

# Warning Evaluation

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- Prototypes should receive some type of evaluation
- Two general types
  - Internal reviews
    - Can help identify potential errors or problems
  - Empirical testing
    - Some believe it's a requirement
    - No easy answer re: when empirical testing is needed

# Warning Evaluation, cont.

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- Internal reviews
  - Compliance - regulations, standards, & guideline compliance?
  - Comprehension - is it understandable?
  - Consistency – across products & industry?
  - Content - hazard, how to avoid it, & consequences
  - Durability
  - Legibility – can users see & read information?
  - Readability – can users understand & process info?

# Warning Evaluation, cont.

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- Empirical testing
  - When might a design team consider it:
    - Marketed & sold to special populations
    - Substantially different from other products on the market
    - Symbols/pictorials used without text
    - Warning information included in a standard
  - Provides no guarantee that user will notice, read, & comply



# Research Findings

**Table 1:** Rates of noticing, reading and complying with warnings reported in the literature

Study	% Noticed	% Read	% Complied
Frantz & Rhoades (1993)	57	42	28
Frantz, et al. (2000)	98	--	17
Friedmann (1998)	88	46	27
Gomer (1986)	100	--	21
Hatem (1993)	87	--	2
Otsubo (1988)	74	52	38
Shaver, et al. (2006)	90	47	10
Smith-Jackson & Durak (2000)	0	0	0
Strawbridge (1986)	91	77	37

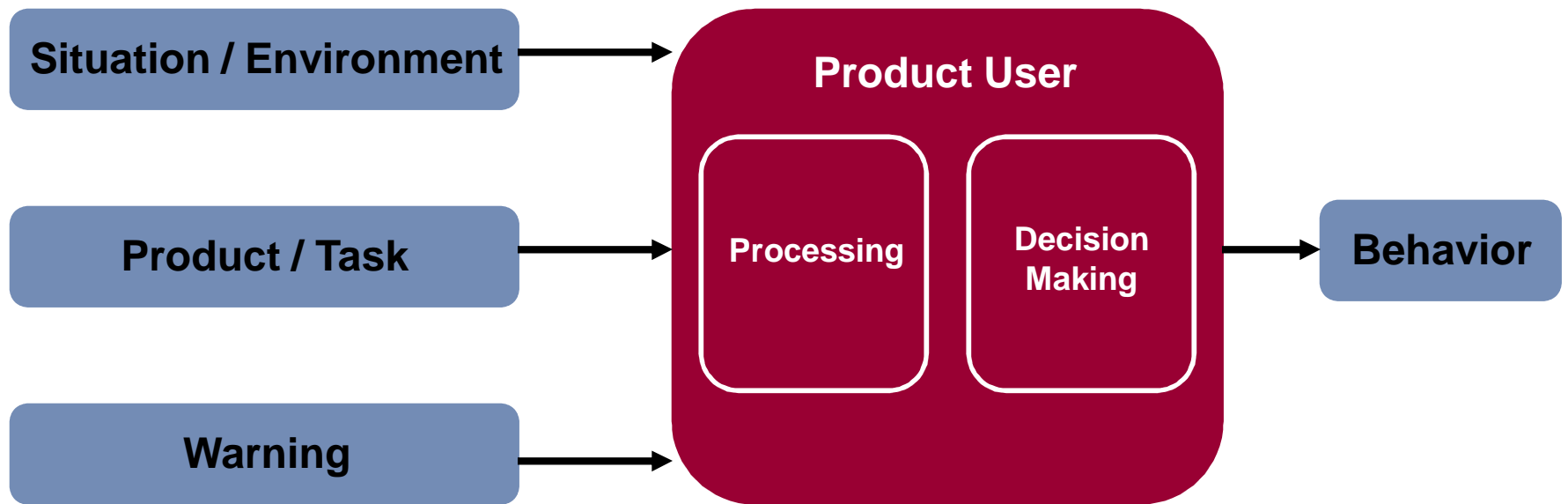
# Why is behavioral compliance so low?

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- Several steps involved:
  - See it
  - Read it
  - Understand it
  - Accept it
  - Follow it
- The warning is only part of the puzzle

# FAB Model

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# Warning Evaluation, cont.

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- Empirical testing, cont.
  - Several considerations when
    - What type of test(s) will be used?
    - What research methods will be employed?
    - Will intended product users be tested?
    - How will the company recruit participants?
    - Will the warning be tested as a whole or certain components?
    - What acceptance criteria will be used?
  - Enlisting an outside consultant
    - Decrease wasted time and money
    - Guide process completion
    - Determine if empirical testing is necessary
    - Perform the empirical testing

# Final Approval & Documentation

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- Final approval
  - Company personnel
  - Regulatory agencies (if necessary)
  
- Documentation
  - Easier to replicate in the future
  - Demonstrates reasonable care
  
- May want to implement a monitoring program
  - Changes in regulations & standards
  - New scientific findings re: warning information
  - Warranty returns
  - Customer service complaints
  - Litigation claims