

## **Product Liability**

# **Limiting Product Liability Risks with Nanotechnology**

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## Product Liability Claims Involving Consumer Products

- **Strict Liability, Negligence, Breach of Warranty**
  - Design defect
    - Risk/utility test
    - Consumer expectations
  - Manufacturing defect
  - Failure to warn (pre- and post- sale)
    - Reasonably foreseeable risks
    - Breach of express warranty
    - Fraudulent misrepresentation
- **Damages Claims**
  - Personal injury
  - Medical Monitoring
  - Fear of future injury
  - Deceptive Trade Practices violations (treble damages)
  - Punitive damages
- **Proximate cause**

## Hindsight Assessments of Company Conduct: Problematic Scenarios

- **Inadequate research and testing**
- **Inadequate disclosure of known or reasonably knowable risks in warning labels or marketing materials**
- **Withholding information from the FDA or other regulators**
- **Noncompliance with industry or regulatory standards**
- **Failure to modify design in light of newly revealed risks**
- **“Bad” documents and email**

## Nanotechnology: A Unique Risk Profile

- **Evolving scientific and medical knowledge**
  - Exposure possible via skin, inhalation, ingestion
  - Nanoscale materials may cross the blood-brain barrier
  - Some nanoscale materials appear to aggregate in the body similar to asbestos
- **Evolving industry standards and practices**
- **Evolving regulatory standards**
- **Evolving practices of disclosure of nanoparticle content and potential risks**

## Despite lack of evidence to date of personal injuries from nanotechnology-based products . . .

- **Lack of industry and regulatory standards for nanotechnology creates potential for hindsight judgments**
- **Evolving knowledge creates greater opportunities for “junk science” based claims**
- **Greater potential for design defect claims**
- **Potential for latent, undetected exposure in absence of studies**
- **Complex causation scenarios could lead to highly individualized, case-by-case litigation**

## Limiting Product Liability Risks with Nanotechnology

- **Keep abreast of evolving scientific/medical knowledge in the field**
- **Track and comply with evolving industry standards and practices concerning product development and risk assessment, as appropriate (e.g., 2/26/07 Dupont-Environmental Defense Draft Framework)**
- **Develop and ensure compliance with internal policies and procedures**
- **Closely monitor post-sale product complaints and adverse event reports and respond appropriately**
- **Remember that compliance alone will not eliminate potential liability; conduct must be reasonable in light of all the circumstances**

## Limiting Product Liability Risks with Nanotechnology (continued)

- **Properly document issues**
  - Write clearly and convey context
  - Assume that email and other documents may become public
  - Always be professional
  - Close the loop
  - Understand privilege