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Product Liability: strategies for avoidance and management

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Hogan Lovells in partnership with the Association of Corporate Counsel Europe

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Challenge for global manufacturers – The convergence of transatlantic risks

- Old assumptions no longer apply
  - Risk management and defence strategies need to be adjusted
- Same factors that have led to the globalisation of markets eventually lead to a globalisation of risks
- Rise of US-influenced litigation risks in Europe
  - e.g. "collective redress", national developments
- Rise of European-influenced regulations in the US
  - e.g. CPSA
- ...and BOTH factors influential around the world (Asia, Middle East, Africa etc)

Understanding the changing nature of product liability risks

- For most product manufacturers, especially major brand names, their most valuable asset is the good reputation of their products in the marketplace
- Whenever the quality or safety of a product is challenged, it threatens that reputation
- The greatest challenge is in establishing, and maintaining, control of the risks globally

Preventing and managing these risks

- Regulatory policy, especially in Europe, is being driven by a "no risk" mentality
- Society is being trained to be intolerant to risk
- Developments in product safety regulation are having a direct impact on liability risks for product manufacturers

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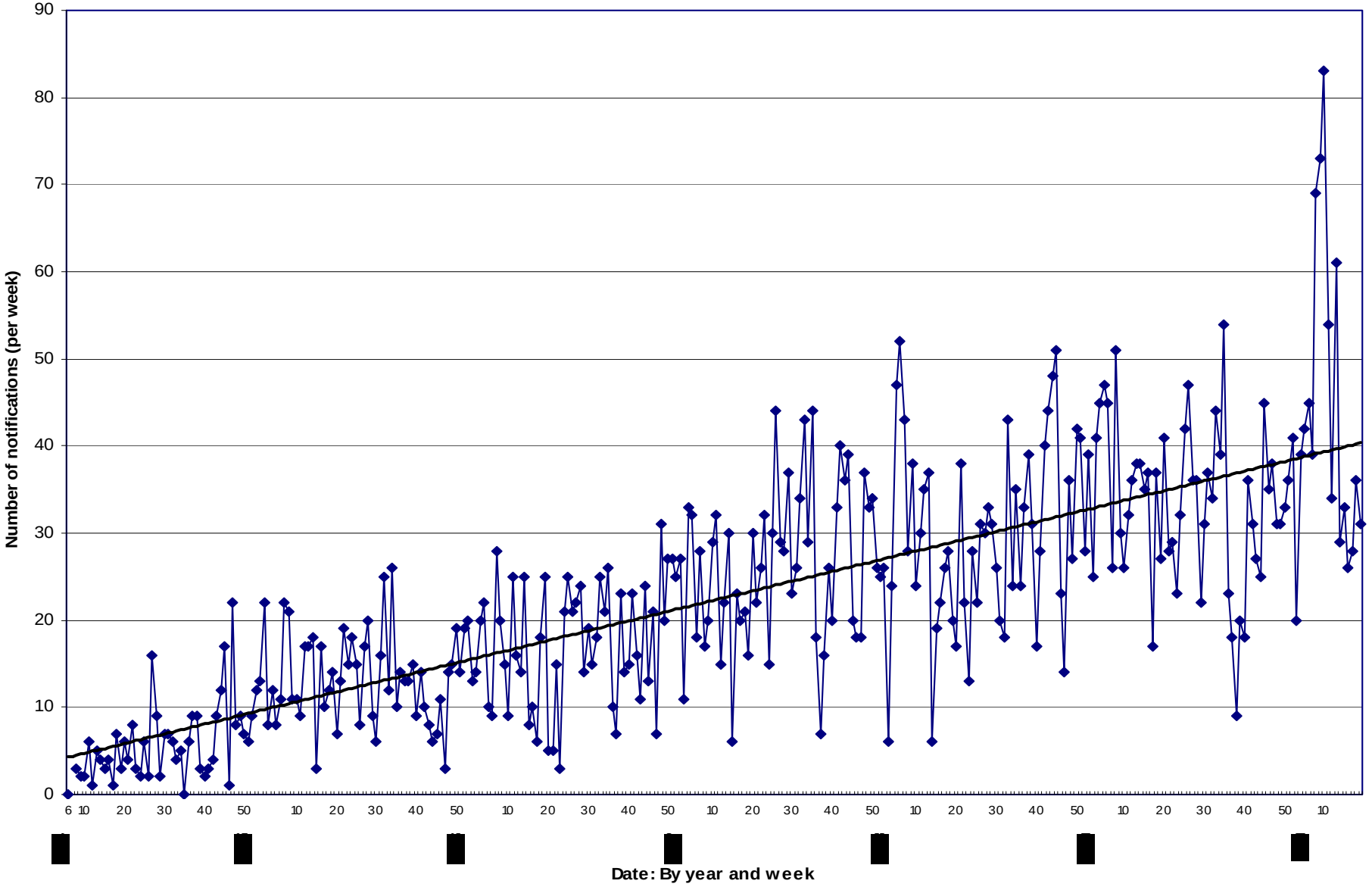
RAPEX Notifications from January 2004 to 30 April 2010
Consumer Products (excluding food and pharmaceuticals)



The intersection of product safety regulation and product liability litigation

- In Europe, and increasingly around the world, regulatory risks that accompany product liability issues may be more damaging to the business than risks of civil litigation
  - e. g. recent issues affecting the toys and automotive industry

- The world has changed – for international companies product liability issues have become more complex
  - New thinking needs to be applied
  - New strategies need to be adopted
  - Don't have a "Maclarens issue"

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Part 1:
Preventing Product Liability Risks

Warnings and disclaimers as first step

- **Warnings**
  - Risk of failure to warn claims may be reduced if proper warnings accompany a product
  - Warning language can be used to support multiple defences

- **Disclaimers**
  - National and state laws vary regarding whether liability can be disclaimed

The intersection of product safety regulation and product liability: Preemption defence

- Purpose: To prevent defendants from being subject to conflicting state and federal standards
- In products liability lawsuits, a preemption defence arises when:
  - Governmental or regulatory body has developed rules and regulations regarding the safety of a product; and
  - Plaintiff brings state tort law claims that would impose additional duties on defendant than those required by the governmental or regulatory rules
- Some courts have found state tort products liability claims are preempted by the governmental or regulatory rules

The preemption defence applied

- **Medical Devices**: Certain claims are preempted by Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act (*Riegel v. Medtronic,* 128 S. Ct. 999 (2008))
- **Automobiles**: Claim that automobile manufacturer was negligent in failing to equip the car with an airbag was preempted by the 1984 Federal Motor Vehicle Safety Standards (*Geier v. American Honda Motors Co. Inc.*, 120 S. Ct. 1913 (2000))
- **No preemption for**:
  - Prescription Drugs (*Wyeth v. Levine*, 129 S. Ct. 1187 (2009))
  - Tobacco (*Altria Group, Inc. v. Good*, 129 S. Ct. 538 (2008))

The European side of preemption – Regulatory compliance defence

- In Europe, regulatory compliance does not exclude product liability per se

- Demonstrating regulatory compliance can serve as argument that there was no breach of duties and/or defect (failure to warn etc.)
  - Most valid in highly regulated industries where products are thoroughly scrutinized by authorities before marketing

Establishing regulatory compliance defence – Document management

- First step: Raise awareness throughout company that regulatory compliance is defence in litigation
- Documents have to be organized properly
  - Pre-defined structure
  - Searchable electronic data bases
- Wording of regulatory documents should be in line with subsequent litigation needs
- Customer complaints have to be structured
  - Reaction hereto documented with underlying reasoning (product safety group meetings)

Establishing regulatory compliance defence – Internal communication

- Internal documentation relevant as litigation may call for disclosure
  - In common law countries (e.g. US, UK) broad disclosure of documents through discovery
  - In civil law countries (e.g. Continental Europe) recently improved access to information (FOIA, new regulatory rules with disclosure requirements (e. g. REACH))

- Internal documentation should bear in mind possible future litigation
  - Emails
  - Transcripts of internal product safety group sessions

Developing awareness within legal team

- If possible, members of the team should specialise in litigation management
- Being aware of national specificities: e.g. discovery, criminal exposure, notification obligations
- Mastering cross-border cases: through experience or training
- Knowing the group's structure and setting up a network
- Training the rest of the legal team

Developing awareness in management and staff

- Key role of legal team: training, monitoring

- Prevention
  - Avoidance and detection of risks
  - Day-to-day basics

- Reaction
  - Immediate reporting
  - Legal team as primary contact

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Part 2:
Document Management as Key Defence Factor

Document management is key in US litigation

- Broad Discovery Allowed
  - Federal Rules of Civil Procedure allow parties to obtain relevant, non-privileged information from adverse parties

- Parties may obtain information relevant to case by
  - Taking depositions of factual and expert witnesses
  - Propounding written interrogatories
  - Requests for production of documents
  - Requests for admissions
  - Physical and mental examination of a party

Document management in US litigation

- Discovery obligation extends to electronically-stored information
  - Computers
  - Servers
  - PDAs
  - Voicemails
  - Video surveillance





- Companies face potential sanctions for failure to produce electronically-stored information
- No privacy exception to disclosure of relevant information

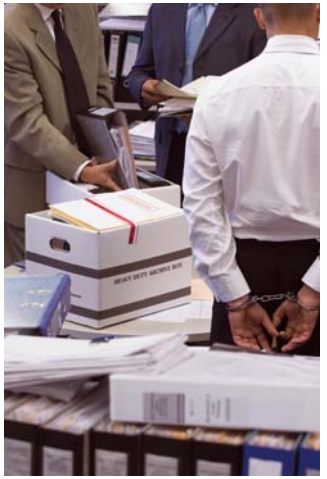
Document disclosure in international litigation

- E-Discovery enables disclosure of documents worldwide

- E-Discovery in US can collide with strict EU Data Privacy rules
  - Discovery requires vast disclosure
  - EU Data Privacy allows disclosure of personal circumstances only where strict requirements are met

Document disclosure in international litigation

- Non-compliance may have significant consequences
  - Reversal of burden of proof if documents are not disclosed in US
  - EU authorities have fined companies up to 76 million Euros in individual case



- Conflict will have to be handled case by case
  - US courts have to be educated
  - EU Data Privacy authorities have to be involved

- Various instruments
  - Safe-Harbor
  - Protective orders
  - Pseudonymising of personal information before disclosing

Document disclosure in criminal proceedings

- Traditional in France and Italy
  - Investigative powers
  - Media exposure
  - More and more frequent

- In the UK: more recent, esp. Corporate Manslaughter and Corporate Homicide Act 2007

- Other countries: e.g. Poland

⇒ Broad disclosure of information and documents
Adverse publicity
Internal crisis and individual pressure
Sanctions (fines, imprisonment, publication...)

Management of documents in light of criminal exposure

- Setting up document retention policy
- Making sure of the location and content of the files
- Retaining internal knowledge on files
- Getting prepared for searches
- During searches: monitoring scope and... making copies!

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Part 3:
Product Liability Litigation – the Initial Phase

What to do during the initial days of litigation

- Activate core team (management, legal, public relations, people with knowledge on product)
- Notify insurer
- Select and retain counsel
- Manage and monitor tests and studies
- Don't forget internal communication

How to communicate during the initial days of litigation

- Consider retaining crisis PR agency
- Set up basics of communication – Q&A
- Appoint and train spokespersons
- Adapt reaction to adverse parties: esp. consumer associations
- Anticipate possible next steps

Complication of regulatory issues during the initial days of litigation

- Product liability claims invariably raise questions about the safety or quality of the product
  - Inevitably, this will draw in issues involving the regulation of the product
- It needs to be part of the fundamental strategy to analyse the regulatory position at the earliest point
  - It is surprising how often this is not given sufficient attention
- Failure to be on top of the regulatory issues can easily lead to an "issue" becoming a "crisis"
  - Get the right advice from the right people – internally and externally

Initial days of US litigation – Steps to take to preserve documents

- Document hold orders should be issued when the company receives notice of litigation or reasonably expects litigation to arise
- Hold Order should
  - be issued to the key players involved in the particular issue
  - instruct key players not to destroy, discard, modify, remove, transfer, or make inaccessible any documents and data relating to litigation
  - define the various types of “documents and data,” including recorded, graphic, or electronic material, including hard copy documents, audio recordings, voicemail, videotapes, e-mail, instant messages, word processing documents, spreadsheets, databases, calendars, telephone logs, contact manager information, internet files, and all other hard-copy or electronic information maintained, created, or received

Initial days of US litigation – Litigation strategies to consider

- Regulatory Report
  - Determine whether report has to be made to relevant regulatory authority
- Removal to Federal Court
  - The statute permits removal only when the federal court would have had original jurisdiction of the action had the plaintiff brought it in federal rather than state court
  - In product liability context, cases may be removed when there is diversity of citizenship
  - Must remove within 30 days of service of initial pleading
- Bifurcation
  - Consider bifurcating case on a key issue (e.g., causation)

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Part 4:
Multi-jurisdictional litigation

Handling multi-jurisdictional litigation

- Immediate establishing of facts is vital
  - No "late" changes to messages

- Consistency is key in multi jurisdictional litigation
  - Consistent factual statements
  - Consistent strategy while identifying local legal issues at early stage
  - Litigation PR
  - Criminal proceedings

Handling multi-jurisdictional litigation

- Special in-house litigation teams
  - Members of legal teams in various, possibly affected countries
  - Members from other departments (e.g., PR, regulatory) to ensure consistency throughout the company

- Special outside counsel teams
  - Integrated teams ensure consistency and reduce costs through sharing of work product
  - Local actions have to be coordinated in line with global strategy and statements (review of pleadings, talking points for hearings)
  - Local "hubs" for strategy, science and regulatory aspects reduce costs further

Handling multi-jurisdictional litigation

- Special tools
  - Searchable and secure litigation data bases
  - Expert teams (in-house and outside scientists)
  - Standardized regulatory and scientific histories
  - Issue and fact sheets

Multi-jurisdictional litigation – Drawbacks to litigating in the US

- Juries
  - In both federal and state courts, either party may demand trial by jury
    - Unpredictable jury awards
    - Untrained in technical matters
    - Sympathetic to plaintiffs

- Punitive Damages
  - In general, to recover punitive damages, a plaintiff must show "actual malice," meaning defendant's conduct was characterized by evil motive, intent to injure, ill will, or fraud
  - In products liability cases, plaintiff may have to establish actual malice by proving: (1) defendant's actual knowledge of the defect; and (2) defendant's conscious or deliberate disregard of the foreseeable harm resulting from the defect

Potential to remove cases from courts in the US

- Personal Jurisdiction defence
  - Plaintiff bears the burden of establishing the Court's personal jurisdiction over the defendant
  - Plaintiff must allege specific facts upon which personal jurisdiction is based
  - Plaintiff must also establish that exercising jurisdiction over the defendant comports with due process
    - Defendant must have minimum contacts with the forum so that the exercise of jurisdiction does not offend traditional notions of fair play and substantial justice

Potential to remove cases from courts in the US

- *Forum Non Conveniens*
  - Permits federal courts to dismiss case when:
    - A different forum has jurisdiction to hear the case; and
    - On balance, trial in the chosen forum would be more oppressive and/or vexatious to defendant than convenient to plaintiff
  - Factors courts typically consider:
    - Location of witnesses and evidence;
    - Ability to obtain compulsory process over witnesses;
    - Ability to inspect accident site;
    - Cost of obtaining access to willing witnesses;
    - Interest of sovereigns;
    - Administrative burdens associated with trying the case;
    - Need to apply foreign law

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Part 5:
Recent and Future Trends

US Consumer Product Safety Improvement Act of 2008

- Most comprehensive overhaul of the consumer protection safety laws since the CPSC was created in 1972
- New law will impact virtually all manufacturers, importers, distributors and retailers of consumer products
- Product Testing and Certification Requirements for all products:
  - Manufacturers must certify that products are in compliance with all applicable rules, bans, standard, and regulations under the act or otherwise enforced by CPSC
- Public Consumer Product Safety Database:
  - CPSC has created and maintains a public searchable database containing all reports and complaints related to consumer products received by CSPS
- Increased civil and criminal penalties for violations of the Act
  - Civil violations punishable by up to $15 million fine
  - Criminal violations punishable by up to five years in prison and forfeiture of assets associated with violation

The European product safety regime

- General trends
  - Increasing focus on enforcement – with added national complexity
  - Increasing focus on greater accountability of economic operators
  - Greater level of information-sharing between authorities
  - Growing use of precautionary principle (both formally, and informally)
  - Merging of environmental regulation with safety and health regulation

The European product safety regime

- Some specific developments to be aware of:
  - Introduction of new mandatory risk assessment methodology (Regulation 2010/15/EU)
  - Future impact of the "New Legislative Framework" for product regulations
  - Safety concept to include "foreseeable misuse" of product (see new Machinery Directive)
  - Reform of General Product Safety Directive under way

Hot legal issues in Europe

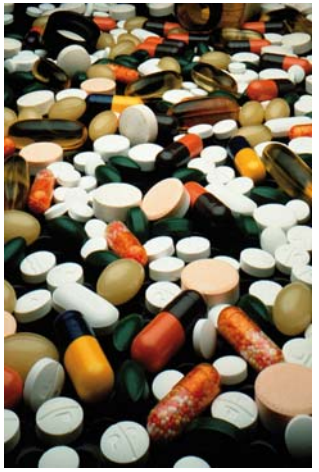
- Collective/class actions

- Procedural reforms, esp.:
  - legal costs
  - funding
  - contingency fees

- Reform of compensation rules: punitive damages coming?

Target industries in litigation

- Life sciences
  - Pharma as traditional focus of Plaintiffs
  - Medical devices with innovative products (especially implantable) and rising regulatory requirements



- Chemicals
  - Rising regulatory requirements (REACH, CLP)
  - Nanomaterials

- Energy
  - Deep water horizon effect

Q&A

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