



Privileges Associated with Product Safety Teams

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The Focus & Purpose

- Product Safety Teams
- Prevention - Not Reaction
- Practical Tips for Preserving Privilege

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Overarching Themes



- Focus on 3 specific privileges
- Key Q:
 - » Routine business purpose or for other purpose?
- Courts sensitive to impeding discovery process
- Different from jurisdiction to jurisdiction
- Fact intensive
- Pre-claim

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Agenda



- Why important?
- The product safety team
- The privileges
- Role of counsel
- Case studies

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Why is this important?

Product Liability is Broad



- **The routine:**
 - » Manufacturing defects
 - » Design defects
 - » Failure to warn
- **Definitely PL, but rarely considered:**
 - » Warranty claims (express or implied)
 - » Repairs or service failures

Benefits of Avoiding Product Liability



- **Legally required**
 - » Subject to Legal Liability
 - » Regulatory Requirements
- **The right thing to do – ethics**
 - » Subjective
 - » Voluntary
 - » Not legally required
 - » May be facially inconsistent with maximizing profit/revenue/shareholder value
- **Competitive advantage**
 - » Reputation, brand & corporate advantages
 - » Cost savings

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The Product Safety Team

Product Safety Committee - Setup



- **Diverse representation**

- » Engineering
- » Legal
- » Compliance
- » Service
- » Risk Management
- » Sales
- » Operations
- » Other

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Product Safety Committee - Charge



- **Establish:**

- » Criteria
- » Best practices
- » Procedures
- » Enforcement

- **Learn from past experience - evolve**

- **Guidelines/criteria for warnings/ advertising**

- **Regulatory reporting procedures**

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The Privileges

Attorney-Client Privilege

- Federal vs. State
- Two Primary Federal Tests
 - » Primary Purpose
 - » Because of
- State Law
 - » Statutorily guided
 - » Fed. R. Evid. 501

Attorney-Client Privilege – Federal Level



■ “Primary Purpose” Standard

- » the party must show that where counsel is involved, the primary purpose of the document or communication was to obtain or seek legal advice. Some courts have made this extremely subjective determination by asking whether a lawyer was necessary for the task or whether other business personnel could have handled the information generation.

■ “Because of” Standard

- » using the totality of the circumstances, could the document fairly have been prepared or obtained for the purposes of legal advice. The focus is on the nature of the document and the factual situation in each particular case.

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Attorney-Client Privilege – Federal Level (cont.)



■ Works:

- » In-house counsel’s advice reflected in communications and draft documents related to FDA warning letter
- » Communications between in-house, outside counsel, and management where legal advice given
- » Documents and communications connected to internal company investigation led and instituted by in-house where documents on their face showed request for legal advice and attorneys included on communications

■ Fails:

- » Non-substantive comments on drafts
- » CC’ing in-house counsel without any indicator of seeking/obtaining legal advice
- » Communications re: invoices, billing, and service
- » Risk management reports prepared by non-lawyer corporate officials based on costs of product liability
- » Information in risk management report related to characterization of previous claims against company

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Attorney-Client Privilege – State Level



- Guided by state law – usually in state statute
- Examples:
 - » Virginia
 - » Maryland
 - » California

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Work Product Doctrine



- Protects documents created “in anticipation of litigation”
 - » Fed. R. Civ. 26 (b)(3)(B): “*Protection Against Disclosure*. If the court orders discovery of those materials, it must protect against disclosure of the mental impressions, conclusions, opinions, or legal theories of a party's attorney or other representative concerning the litigation.
- States consistent
 - » Some states have absolute immunity for work product while others simply adopt federal rule

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Work Product Doctrine – Litigation Holds



- Notice of potential or anticipated litigation
- Party reasonably knew or should have known that future litigation was a possibility
- If work product doctrine, then also affirmative duty to preserve evidence
- Potential to lose work product protection without litigation hold

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Self-Critical Analysis Privilege



- Protects self-critical assessments and subjective determinations made by reviewing bodies (like Safety Teams!)
- Protects reports, summaries, and other documents created by teams BUT NOT routine safety documents or underlying objective data
- Federal vs. State
 - » Under federal law, two general approaches
 - » Under state law, statutorily guided
 - » State law and federal law can conflict

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Self-Critical Analysis – Federal Level



■ Expansive View

- » the privilege will apply if the information results from a critical self-analysis, there is a strong interest in preserving the free flow of the information, the information is of the sort whose free flow would be curtailed if discovery was allowed, and the information was always intended to be confidential

■ Courts

- » 9th Circuit
- » District Court of New Jersey
- » Middle District of Georgia
- » Eastern District of Pennsylvania
- » Northern District of Illinois
- » Eastern District of Kentucky
- » District Court of Montana
- » Northern District of Ohio

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Self-Critical Analysis – Federal Level (Cont.)



■ Restrictive View

- » requires the document to be prepared for a mandatory government report and that the policy favoring exclusion outweighs the party's need for the document

■ Courts

- » Eastern District of Michigan
- » Northern District of Indiana
- » District Court of Oregon
- » District Court of Massachusetts

■ Note some jurisdictions have employed both standards

- » Northern District of Illinois
- » Northern District of Georgia

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Self-Critical Analysis – State Level

- **Generally Statutorily Guided**
- **No statute, no privilege**
 - » Indiana
 - » Rhode Island
 - » New York
 - » Vermont
 - » Montana
- **Statute or judicially established**
 - » Missouri
 - » Virginia (only in medical peer review context)

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Role of Legal Counsel

Role of Counsel

■ In-House Counsel

- » Lead the safety team
- » Clear the legal purpose
- » Substantive, legal role – presence alone not enough
- » Working in legal capacity

■ Outside Counsel

- » Work in conjunction with safety team
- » Clear legal purpose
- » Substantive legal role
- » Brought in early – expertise and higher likelihood of presumption of confidentiality

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Case Studies

Case #1



■ Facts:

- » House fire allegedly caused by defect in manufacturer's furnace
- » Party wanted all safety documents and reports created for and/or provided to Consumer Product Safety Commission

■ Question :

- » Self critical analysis privilege stop disclosure?

■ Outcome:

- » Documents only covered if required by government
- » Documents given to government as a part of the required disclosure but created in ordinary course not privilege (*i.e.* internal meeting minutes, reports)
- » Only documents specifically generated for government reporting and only those portions that have subjective evaluations are privileged

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Case #2



■ Facts:

- » Action against a railroad for injuries sustained while working on rail train
- » Railroad conducted internal investigation that generated two reports intended to examine the facts surrounding the incident, identify its possible causes, and suggest recommendations to prevent recurrences
- » Party wanted railroad to produce the two reports

■ Question:

- » Self critical analysis privilege protect two reports?

■ Outcome:

- » Can be covered by privilege, regardless whether government mandated, because promotes public safety via voluntary and honest self-analysis
- » Not covered because railroad failed to show that the documents were intended to be confidential and were in fact kept confidential
- » Need showing the actions were taken to preserve confidentiality

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Case #3

■ Facts:

- » Action vs. truck manufacturer for brake defects that caused accident
- » Since accident, in-house counsel involved with investigation/litigation preparation
- » Party sought investigation documents, memoranda, and notes from investigation, meetings, and various conversations with employees and retained counsel

■ Question :

- » Was disclosure of this information protected by work-product doctrine?

■ Outcome:

- » Noted distinction between:
 - **Ordinary work product** (raw factual information made in anticipation of litigation) and
 - **Opinion work product** (mental impressions, conclusions, opinions, theories of counsel)
- » Documents like risk management reports from investigation are protected to extent that they “that they disclose the individual case reserves for files and any mental impressions, thoughts, and conclusions of an attorney in evaluating a legal claim”
- » Documents that contain facts but do not reveal opinions or legal impressions or the defendant’s attempts to prepare for litigation are not protected

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Case #4

■ Facts:

- » Eye condition allegedly caused by defects in contacts solution
- » Plaintiff sought documents related to defendant's post-recall product testing, its "root cause" analysis, its health hazard analysis and reports submitted to FDA, etc.
- » In-house counsel initiated and lead investigation

■ Question :

- » Was disclosure of this information protected by attorney-client privilege?

■ Outcome:

- » Under CA law, party must make *prima facie* case that communication falls within privilege and once relationship established, communications between attorney and client are presumed confidential
- » Upheld claim of privilege because an attorney was involved in every communication and the dominant purpose of confidential transmittal to an attorney involved in the investigation was clear on each communication

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Key Takeaways



- **In-house counsel leads and guides**
 - » Significant role
 - » Legal in nature –in-house counsel business roles
 - » Make sure legal purpose is clear – even with simultaneous business and practical purposes
- **Engage outside counsel early**
 - » Expertise
 - » Presumption of legal advice

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Key Takeaways (Cont.)



- **Make sure the legal purpose is clear**
 - » Attach legal advice to business purpose
 - » Segregate business vs legal advice (if possible)
 - » Lawyers simply on “to” or “cc” lines not enough
- **Restrict information**
 - » Confidential info must be treated confidential
 - » Only select individuals with access

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Key Takeaways (Cont.)

- Counsel – inside or outside – must clearly be providing legal advice
 - » Editorial comments not legal advice
 - » Key question: something a business executive with no legal training could do just as effectively?
- Know legal framework in jurisdiction

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THANK YOU!



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