Managing Products Liability Risk in the Supply Chain

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Disclaimer

Information in this presentation is neither an official statement of position nor should it be considered professional legal advice to individuals or organizations.

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Introduction

- Medmarc has been providing **products liability insurance** to the life sciences industry since 1979
  - Medical devices, in vitro diagnostics, biotechnologies, and pharmaceuticals
  - Clinical trials, both U.S. and foreign
- Medmarc now also offers manufacturer's **errors & omissions** coverage

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What Is Risk Management?

- Risk Management Objectives:
  - Identify potential products liability **exposures**
  - Develop products liability **risk management strategies** to mitigate risk

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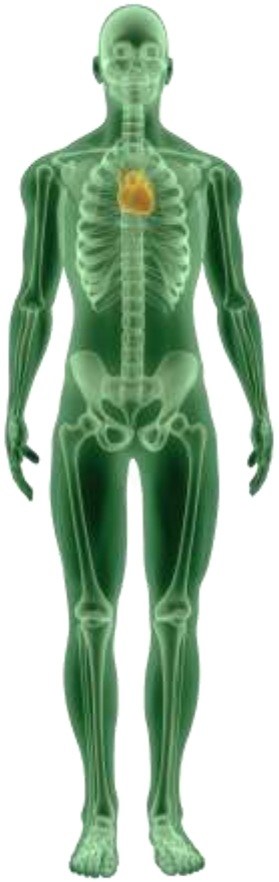
Agenda



- Products Liability Overview
- Supply Chain Risks
  - What goes wrong with suppliers?
  - How do you manage the risk?

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Products Liability Overview

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What Is Products Liability?

Black's Law Dictionary
Abridged Seventh Edition

products liability, *n.* **1.** A manufacturer's or seller's tort liability for any damages or injuries suffered by a buyer, user, or bystander as a result of a defective product. **2.** The legal theory by which liability is imposed on the manufacturer or seller of a defective product.

Large Losses For The Industry 2000 – 2016

- Arthritic Devices
- Vaginal Mesh
- Pain Relievers
- Contact Lens Solution
- Pain Pumps
- Contrast Media
- Oral OTC Laxatives
- Contraceptive Devices
- Drug Eluting Stents
- Injectable Microspheres
- Cosmetic Lasers
- Orthopedic Implants
- Bone Mesh Graft
- Cold Therapy Devices
- Dietary Supplements
- Testosterone Replacement

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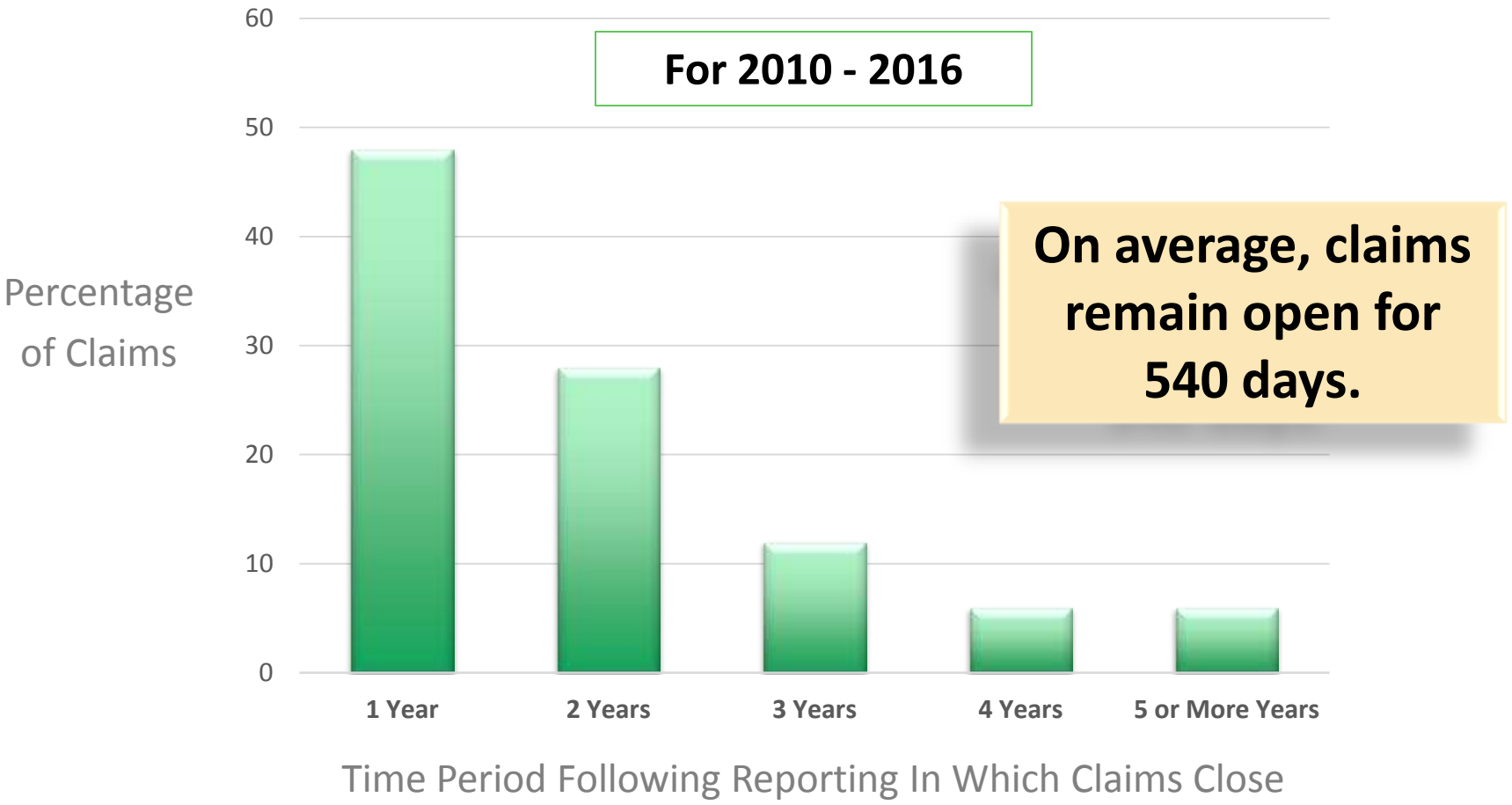
Elapsed Time: Claim-to-Resolution



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The Practical Realities of Litigating Products Liability Claims

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Successful Plaintiffs

- For life sciences companies, 61% of claims result in a **monetary award** to the plaintiff.
- By comparison, the national average is 55% for all civil claims.
  (eLocal Lawyers)

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"Judicial hellholes are places where judges systematically apply laws and court procedures in an inequitable manner, generally against defendants in civil lawsuits."

— American Tort Reform Association in the Executive Summary to *Judicial Hellholes 2008/2009*

JUDICIAL HELLHOLES

For 2015/2016

1. California
2. New York City Asbestos Litigation (NYCAL)
3. Florida
4. Missouri
5. Madison County, Illinois
6. Louisiana
7. Hidalgo County, Texas
8. Newport News, Virginia
9. U.S. District Court for the Eastern District of Texas

American Tort Reform Association

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Medtech As A Target

Heather Bresch, Mylan Pharmaceuticals CEO, before the House Committee on Oversight and Government Reform. From "Mylan CEO Defends Epipen Pricing in Congressional Testimony," ABC News, September 21, 2016.

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An Organized Plaintiffs' Bar

An Informed Plaintiffs' Bar

59% of our attorney-respondents indicated that in *at least half* of their cases, plaintiffs (or plaintiffs' attorneys) became aware of the potential cause of action because of an FDA enforcement action, like a recall, 483, or Warning Letter.

From a poll conducted by Medmarc in 2015 of its panel counsel – attorneys who defend insureds in products liability actions

From www.fda.gov/AboutFDA/Transparency

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The Legal Theory

When a product causes an injury, all members of the product's supply chain are subject to being named in the lawsuit brought by the plaintiff.

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The Practical Reality of Litigation Involving OEMs & Suppliers

- Plaintiffs sue the entity that puts its name on the package.
  - Until discovery, the **supply chain is often invisible** to the plaintiff
- For a variety of business reasons, manufacturers often choose to **protect suppliers**.
  - Difficult to replace the relationship
  - Costs associated with switching suppliers
  - Protect the reputation of your business partner
- It can sometimes be difficult to get your **supplier into court**.
  - Foreign suppliers
  - Dissolution of the company (bankruptcy)

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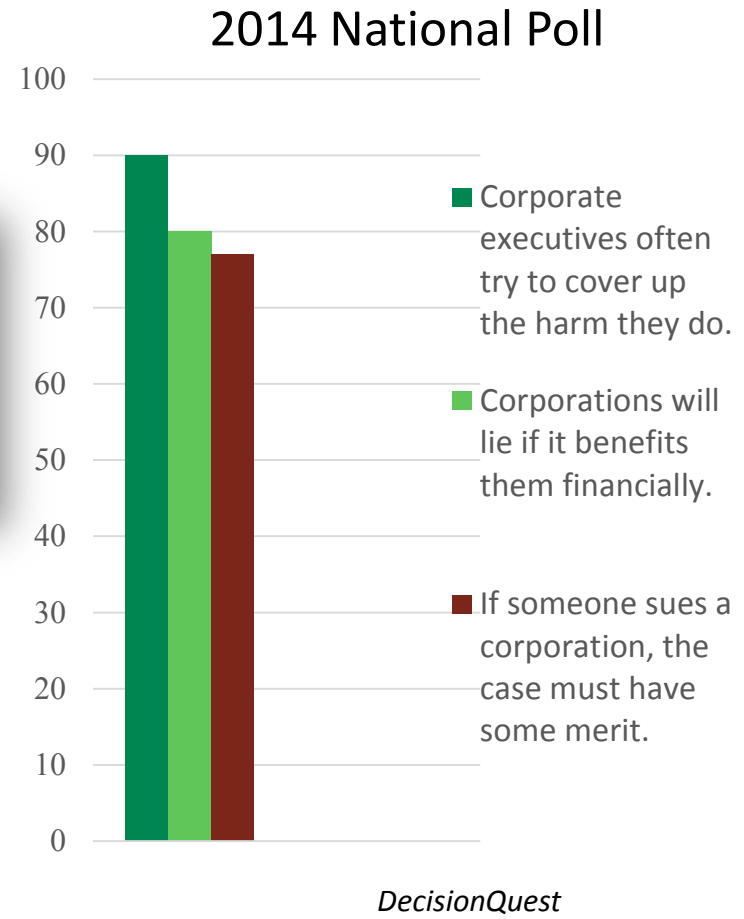
Jury Biases

- The U.S. currently experiencing undercurrent of strong anti-corporate sentiment.

- Juror polls by DecisionQuest indicate that general public does not see FDA as effective in ensuring safe products.
  - Common view of the agency as "rubber stamp" organization.



DecisionQuest

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When a defective article enters the stream of commerce and an innocent person is hurt, **it is better that the loss fall on the manufacturer, distributor or seller than on the innocent victim**. This is true even if the entities in the chain of production and distribution **exercise due care** in the defective product's manufacture and delivery. They are simply in the best position to either insure against the loss or spread the loss among all the consumers of the product.

Ogle v. Caterpillar Tractor Co., 716 P.2d 334, 342 (1986)

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State & Federal Laws

- **Closed Container Rule** — protects manufacturers when suppliers provide "closed container" items
- **Sophisticated User/Bulk Supplier** – protects suppliers
- **Biomaterials Access Assurance Act** – protects bulk suppliers of raw materials/components for implants

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The Legal Theory

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Joint & Several Liability

- Joint and several liability is a doctrine that makes each defendant liable for the entire amount of a plaintiff's award, regardless of each defendants' proportional fault.
- It is intended to ensure that a plaintiff obtains their whole damages award against multiple defendants, even if one or more of the defendants goes bankrupt or is otherwise unable to pay.
- It has unique applications for medical device companies because of their common co-defendants:
  - Health care professionals
  - Foreign entities

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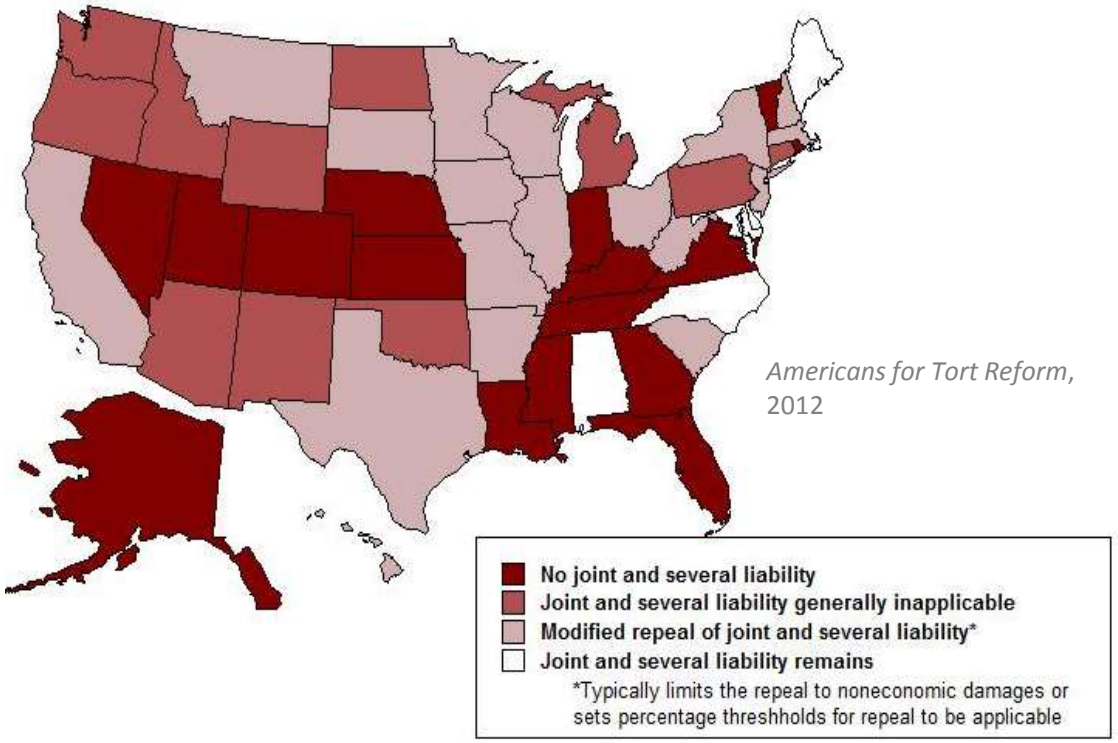
Joint & Several Liability: Landscape

- It is retained today in some form (pure or modified) by the majority of (36) states.
- Pure form in 9 States:
  - Alabama
  - Delaware
  - Maryland
  - Massachusetts
  - North Carolina
  - Pennsylvania
  - Rhode Island
  - South Carolina
  - Virginia



Americans for Tort Reform, 2012

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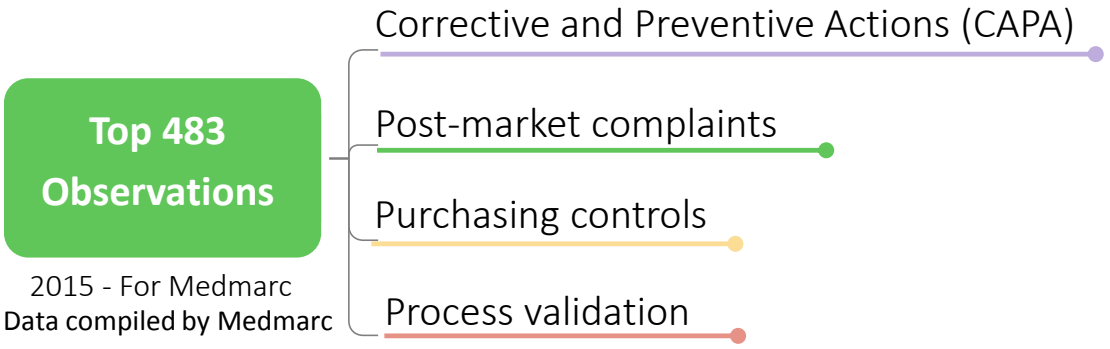
Supply Chain Risks

FDA & Supply Chains

- **Emphasis on supply chains by FDA**
  - Strategic priority for the agency for the last several years
  - New legislation, including FDASIA Title VII
  - One of the most frequently cited observations on Form 483s in 2015

21 CFR 820.50 Purchasing controls. Sets forth the procedural framework that companies must use when selecting suppliers.



2015 - For Medmarc
Data compiled by Medmarc

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Industry & Supply Chains

Top 25 Risk Factors for the 100 Largest U.S. Life Sciences Companies

2014 Rank		2014	2013
1.	Supply Chain and Supplier/Vendor Concerns	100%	93%
2.	Federal, State and/or L	98%	100%
2t.	Intellectual P	98%	96%
4.			
4t			
4t			
7.	Product Liability and Insurance Costs	95%	87%
8.	Ability to Attract and Retain Key Personnel	94%	96%
8t.	FDA Approvals and Compliance	94%	94%
10.	Legal Proceedings	91%	84%
11.	Collaborations and Relationships with Other Companies	89%	92%
12.	Product Complications, Recalls and Side Effects	88%	88%
13.	Delays or Unfavorable Results from Clinical Trials	87%	80%
14.	Reimbursement from Third Party Payers	85%	87%
14t.	Inability to Acquire Capital	85%	79%
16.	Changes to Healthcare Laws & Regulations	77%	78%
17.	Changes to Accounting Standards and Regulations	76%	68%
18.	Anti-Takeover and Change-in-Control Provisions	75%	66%
19.	Environmental, Health and Safety Laws	73%	66%
20.	Threats to International Operations	71%	79%
21.	Inability to Manage or Complete M&A	69%	79%
22.	General Economic Conditions	67%	84%
22t.	History of Operating Losses	67%	68%
24.	Failure to Properly Execute Strategy	66%	69%
25.	Breaches of Technology Security, Privacy and Theft	61%	46%

*t – indicates a tie in the risk factor ranking

1. Supply Chain and Supplier/Vendor Concerns (#1)

By comparison, "**Product Liability and Insurance Costs**" ranks #7 out of 25.

From the ***2014 BDO Life Sciences RiskFactor Report,*** an analysis of risk factors noted in the most recent SEC 10-K filings of the 100 largest US life-sciences companies.

BDO USA, LLP, provides assurance, tax, financial advisory and consulting services to a wide range of publicly traded and privately held companies.

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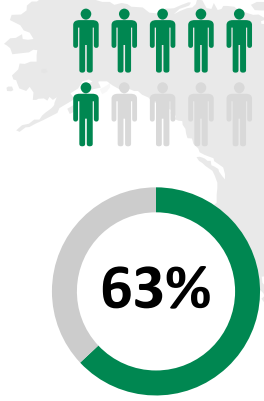
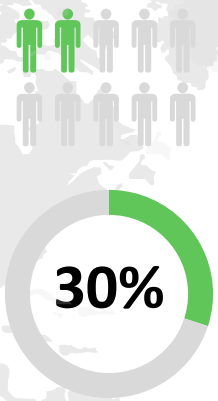
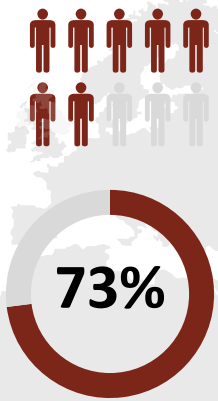
Medmarc's Defense Panel & Supply Chains



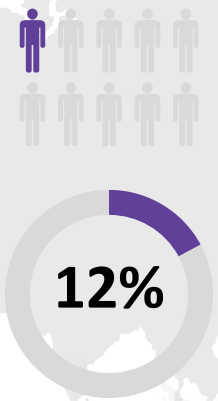
Reported that a defective component part was the root cause of the plaintiff's alleged injury in nearly a *quarter* of their cases. 30% said that a defective component was to blame in *at least half* of their cases.



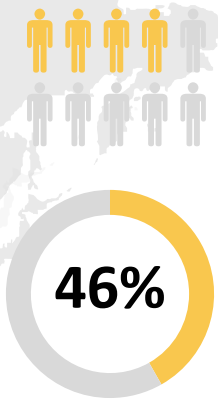
Agreed that when a defective component was to blame, in *most cases,* the suppliers had made changes to the component without the knowledge of the OEM-defendants.



Believe that OEMs are informed of only very significant changes made by their suppliers.



Described OEMs as "generally in the dark" about changes made by their suppliers.



Indicated that in at *least half* of their cases, a purchase order was the only document governing the relationship between their clients and the suppliers.

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Manufacturers don't audit their supply chains.

Manufacturers ignore "subsequent-tier" suppliers in the supply chain.

Manufacturers don't transfer risk through contract.

Auditing Suppliers

Case Study - Disclaimer

- None of the information presented in the case study comes from Medmarc's **claim files**.
- A case study is a **composite story** intended to represent the type of claim that could arise within a product category or from a typical set of facts.
- All company and product names are fictitious names, and information presented as **facts may be entirely fictitious**.
- Information in this case study is neither an official statement of position nor should it be considered professional legal advice to individuals or organizations. It is intended to help you recognize some of the common causes of products liability claims.

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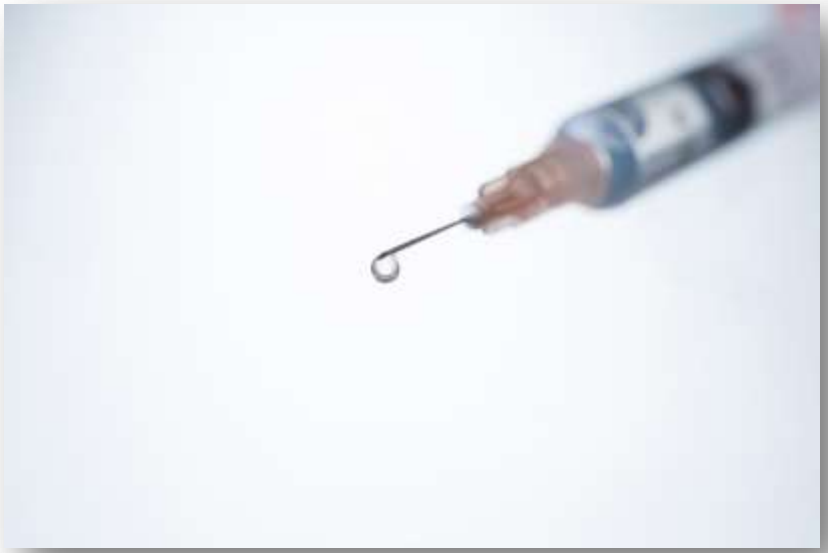
Case Study

- “MedInject” is a mid-size life sciences company that sells a variety of products from cutting-edge devices to simple surgical tools.
- Included in its product line are heparin-filled syringes.
- MedInject purchases the syringes from “PreFillCo,” the supplier, though the MedInject name is on the product’s label.



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Case Study (cont.)

- In 2013, MedInject becomes aware that patients who have received injections from its syringes have experienced a variety of serious complications, including **bacterial infections** and **spinal meningitis**.

- Healthcare providers isolate the source of the problems to a bacteria contaminating the syringes.
- MedInject inquires with PreFillCo and learns that it has experienced **sterilization problems** at its manufacturing facility, leading to contamination of its product.

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Case Study (cont.)

- Throughout 2014 and 2015, products liability lawsuits are filed against MedInject by patients who were sickened by the contaminated syringes.
- **Twenty-two plaintiffs** seek damages ranging between $50K and $3M for “severe, permanent and life-threatening injuries” and death.
- MedInject intends to litigate the cases and argue that it was not responsible for the contamination of the product and thereby **push liability back onto the supplier**, PreFillCo.
  - The “closed container rule” may apply in some jurisdictions.

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Case Study (cont.)

- When counsel for MedInject begins to investigate the underlying facts of the case, including the contamination of the syringes, counsel learns that PreFillCo was **out of compliance** with GMP requirements.
- In fact, as demonstrated by information available from the FDA, including enforcement action reports, a **simple investigation** into PreFillCo would have revealed problems with the supplier.
- FDA records indicate that it **first began receiving complaints** about PreFillCo as early as 2010.
- In late 2011, an FDA inspection resulted in a **Warning Letter** to the company that detailed the egregious conditions under which the syringes were being manufactured.

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Case Study (cont.)

- The inspector notes that the company has minimal policies to assure that syringes are sterile.
- She finds glue traps loaded with insects and an employee chewing gum while filling syringes.
- She watches workers standing in front of a fast-moving conveyor belt of syringes, barely able to complete all of their assigned tasks.

Image from FDA as published by ProPublica news source

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Case Study (cont.)

- The facility was “rundown.”
- Syringes were piled on tables.
- A “clean room” was ventilated with a window fan patched with duct tape.
- Doors leading to the production rooms could not be closed completely.
- Employees did not have the educational backgrounds to support their titles and roles.

Image from FDA as published by ProPublica new source

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Case Study (cont.)

- Counsel advises MedInject that it will ultimately be difficult to disclaim liability for the contamination when MedInject *should have known* the conditions under which the product was being manufactured.
  - i.e., MedInject was negligent in its selection of suppliers
- Meanwhile, MedInject learns that PreFillCo has filed for bankruptcy, is dissolving, and is essentially "judgment proof."
- MedInject is only one of numerous companies that sourced product through PreFillCo, which has exhausted its (limited) insurance and assets in resolving other claims.
- Counsel for MedInject advises the company to settle the claims.

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Common Scenarios

No Audits

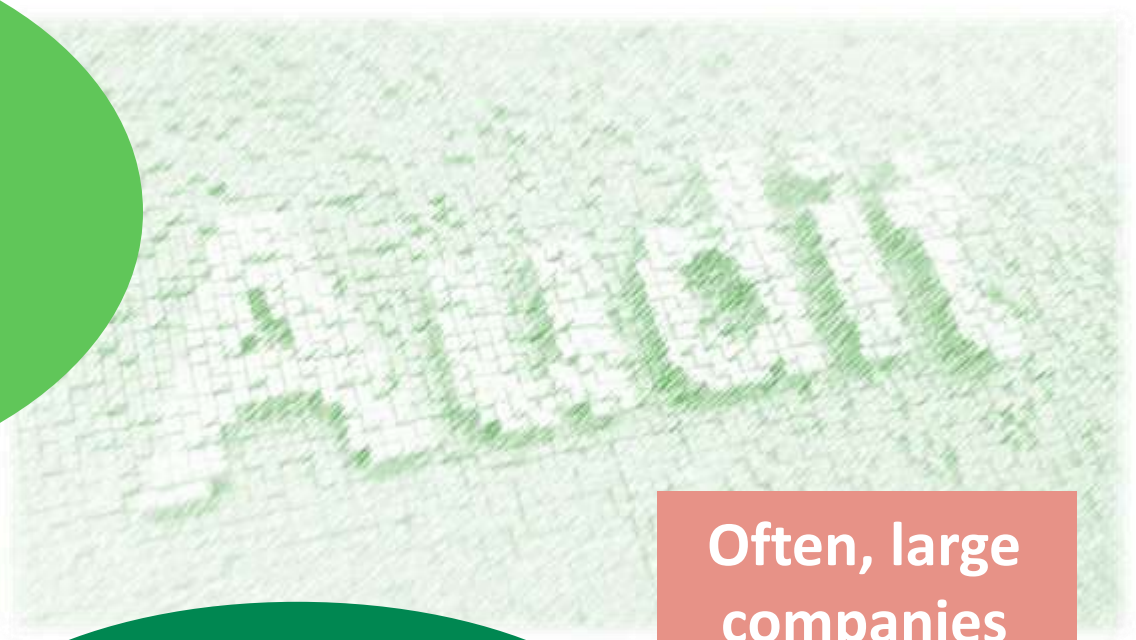
Costs

Manpower

Expertise

Language Barriers

Often, small companies



Often, large companies

Riskiest Only

Costs

Manpower

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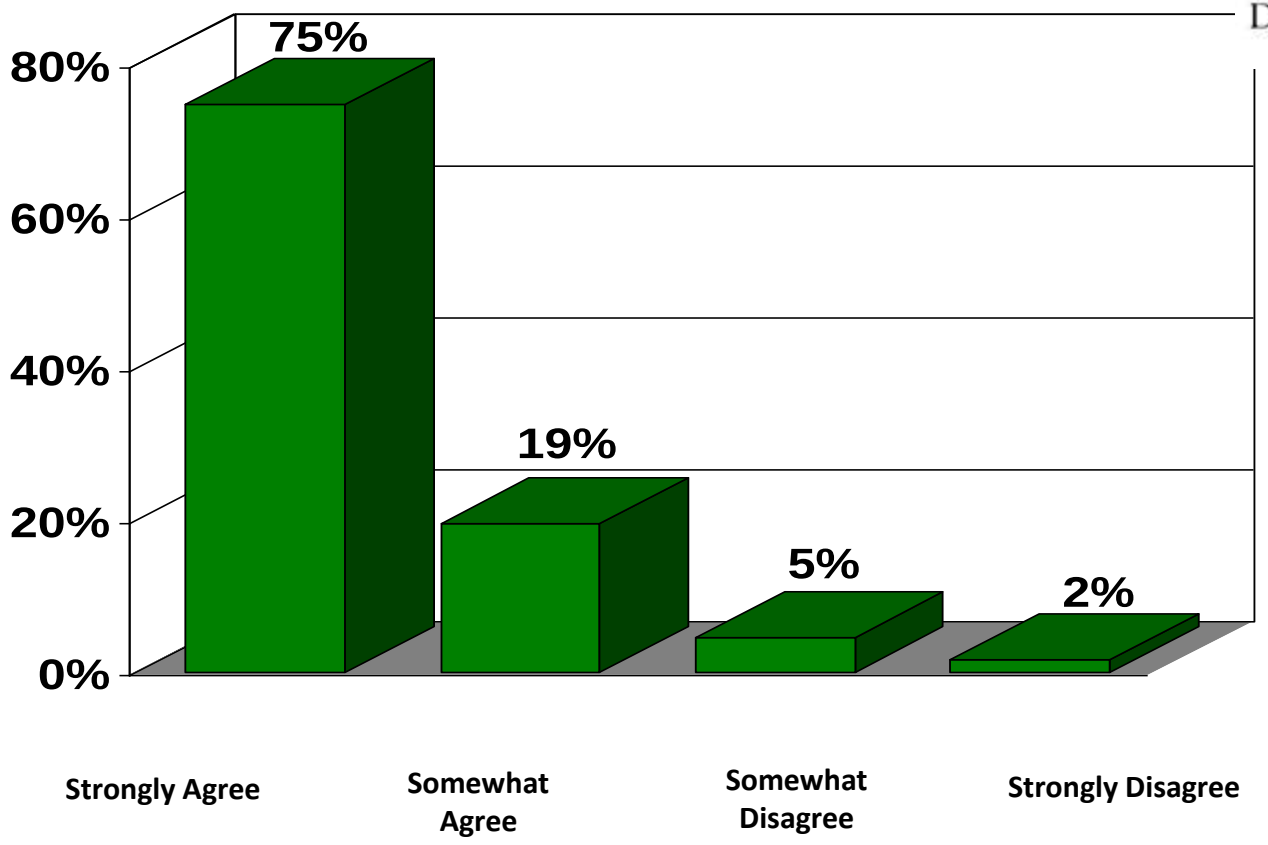
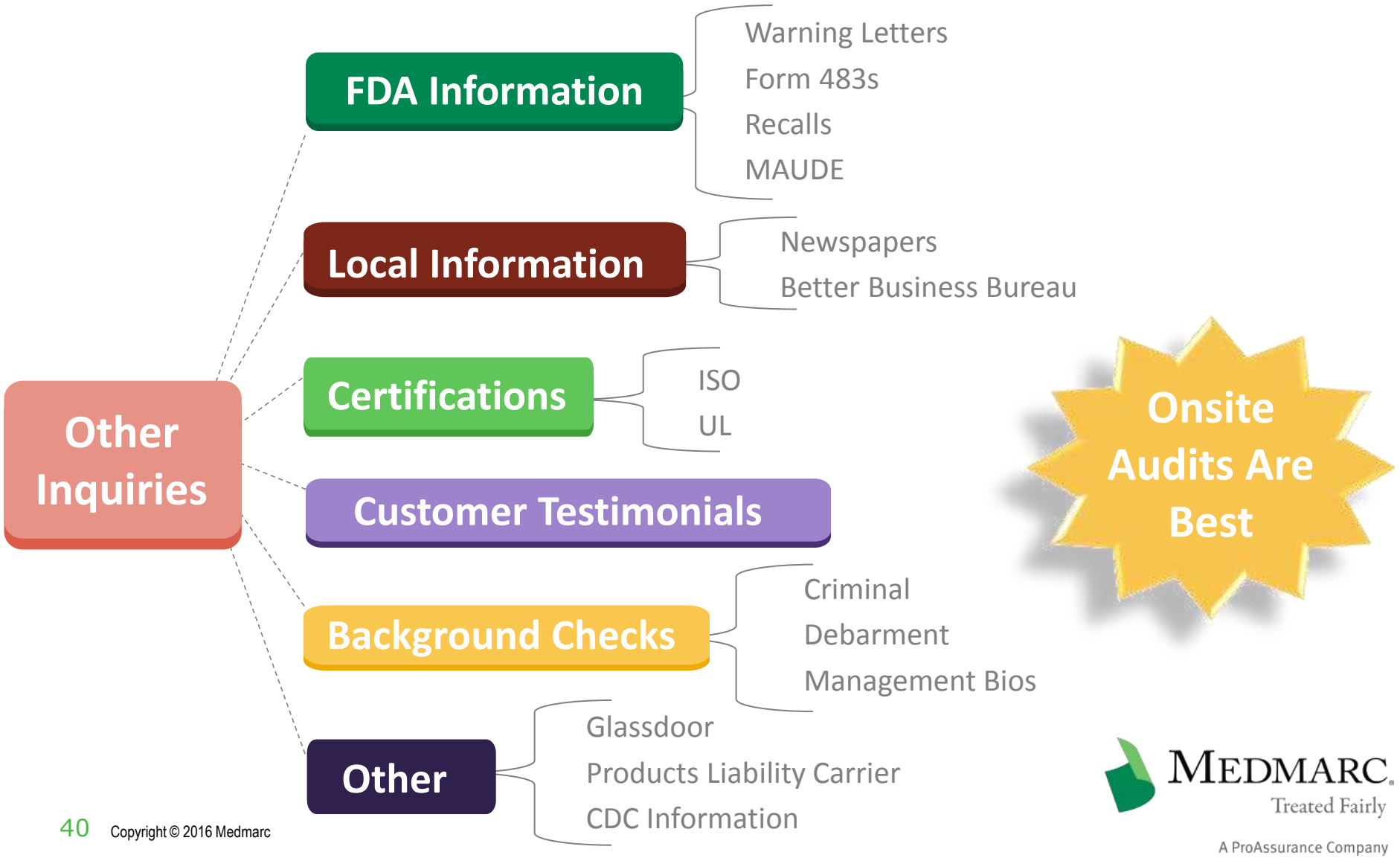
A product manufacturer should take any and all precautions, no matter how impractical or costly, to ensure the safety of their products.



Percentages may not add up to 100%.

Alternative Audit Solutions



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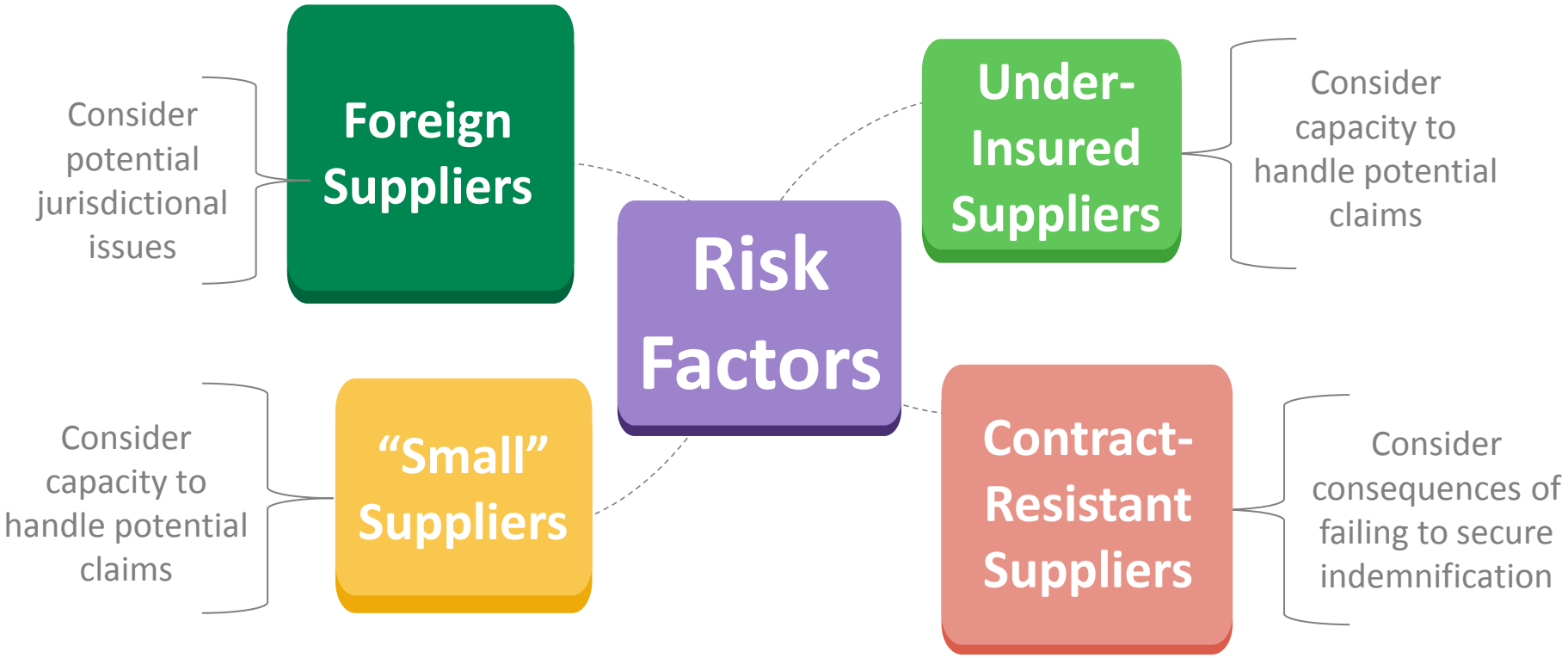
Alternative Risk Factors



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Auditing the Length of the Supply Chain

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Subsequent-Tier Suppliers

- Too frequently, manufacturers exert oversight over first-tier suppliers only.
- FDA does not require manufacturers to monitor subsequent-tier suppliers.
- However, products liability risk can arise from subsequent-tier suppliers and become a problem for the length of the supply chain, thereby creating a need to investigate the length of the supply chain.

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Case Study

- "OrthoImplant" is a large manufacturer of orthopedic implants.
- They also sell "**convenience kits**" as an accessory product to be used during procedures involving their implants.
- FDA defines a convenience kit as "two or more different medical devices packaged together for the convenience of the user." (21 CFR 801.3)
- OrthoImplant's convenience kit includes several different **surgical implements** and **sterile gauze**.

Case Study (cont.)

- OrthoImplant does not manufacture any of the component pieces that compose the kit, though the company's name is on the label.
- OrthoImplant sources the product from "**KitPacker**," a company which purchases the components from suppliers and packages the kit.
- OrthoImplant has reasonable policies and procedures in place to monitor KitPacker and **inspects their facility** annually.
- In late 2013, "Charlie Smith" undergoes a procedure that involves an OrthoImplant device and convenience kit.
- The procedure goes as planned and Charlie begins his recovery in the hospital.

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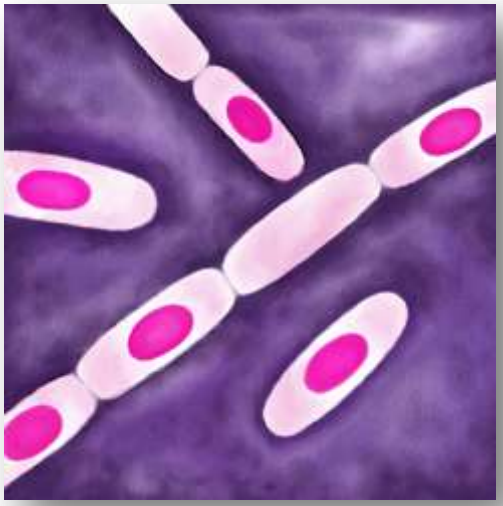
Case Study (cont.)

- Hours before Charlie is to be discharged, he experiences a high fever, vomiting, and seizures.
- As Charlie's condition worsens, he stops breathing and is placed on a ventilator. It is eventually determined that Charlie is brain dead.
- Within three days, Charlie passes away.



- After running numerous tests, it is determined that Charlie suffered from **bacterial meningitis** caused by Baccilus cereus, a potentially life-threatening bacteria usually associated with foodborne illness.

Case Study (cont.)

- The hospital that treated Charlie traces the source of the *Baccilus cereus* to the gauze included in the OrthoImplant convenience kit.
- OrthoImplant contacts KitPacker to inform them of the event and learns that the gauze was manufactured by "2nd Supplier, Inc."
- About the time of Charlie's death, 2nd Supplier, Inc. discovers that its product is contaminated with *Baccilus cereus* and informs KitPacker that it has found *Baccilus cereus* at its facility.
- KitPacker **begins its first inspection** of 2nd Supplier, Inc. and learns that the company is out of compliance with GMP requirements.

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Case Study (cont.)

- KitPacker discovers that contaminated **water pipes** at 2nd Supplier, Inc.'s facility lead to vats used in the manufacturing process.
- Employees of 2nd Supplier, Inc. packed product into containers with their **bare hands**.
- 2nd Supplier, Inc. was **understaffed** and management did not have the requisite manufacturing **expertise**.
- Equipment and utensils were not cleaned, maintained, and sanitized appropriately to prevent contamination.

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Case Study (cont.)

- Gauze passed through machinery with debris built up on it.
- Two-thirds of the gauze manufactured by 2nd Supplier, Inc. is contaminated.
- OrthoImplant, undertaking its own investigation, learns that FDA documents indicate that it had been aware of problems at 2nd Supplier, Inc. since 2011.
- The FDA received 142 reports of adverse events related to 2nd Supplier, Inc.'s products.
- The FDA completed its most recent inspection of 2nd Supplier, Inc. in 2012, finding multiple violations of GMP requirements.
- OrthoImplant initiates a **global recall** of its convenience kits, which ultimately costs the company several million dollars.

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Case Study (cont.)

- In early 2014, Charlie's widow sues OrthoImplant, KitPacker, and 2nd Supplier, Inc.
- Charlie's widow alleges strict liability claims as well as negligence claims against OrthoImplant.
- She maintains that OrthoImplant "knew or *should have known* through the exercise of reasonable due diligence" that the gauze was being manufactured under conditions that were not GMP-compliant.
- She seeks $40M in damages.
- Ultimately, OrthoImplant settles with Charlie's widow for $1.2M.

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Investigate The Length Of Your Supply Chain

Focus on your supplier's purchasing controls and supplier selection criteria. Ask them to implement best practices. Review their supplier contracts.

Leverage whatever bargaining power you have to learn this information. You will likely be most effective if you include this as part of your initial contract negotiations.

At a minimum, conduct whatever ALTERNATIVE oversight activities are possible under the circumstances for suppliers you have identified.

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Contracting With Suppliers

Suppliers & Contracts

- Drug and device companies frequently **do not enter formal, contractual agreements** with their suppliers and/or customers.
- Many companies operate “contract free”—or they **merely accept the terms and conditions** printed on the back of purchase orders submitted by their customers.
- Purchase order terms and conditions are often **“one-sided”** agreements that shift liability and insurance obligations without providing reciprocal protection.
- Companies often end up **indemnifying their supply chain partners** for liabilities that exceed the scope of their insurance coverage.

Case Study

- A ventilator is a machine designed to **move breathable air** into and out of the lungs, to provide breathing for a patient who is physically unable to breathe sufficiently.
- VentCo manufacturers both non-invasive and invasive ventilators, which are used primarily in intensive care, emergency, and home care settings.

Case Study

- Each of VentCo's ventilator units includes a set of **three durable, yet lightweight plastic tubes**, that are separated by function (e.g., inhaled air, patient pressure, exhaled air).
- While VentCo is the original equipment manufacturer (OEM) for the control console and related parts, it obtains the unit's tubing from a **contract manufacturer**, TubeCo.

Case Study

- VentCo and TubeCo have a longstanding and productive relationship, and VentCo has never used any other supplier for its tubing components.

- TubeCo sources raw materials for its plastic products from numerous suppliers from around the globe.
- It seeks the highest-quality raw materials and is consistent with its testing protocols to ensure that its products are safe and durable.

Case Study

- Betsy Barbour is admitted to Mercy Hospital's intensive care unit, where she is intubated and connected to a ventilator manufactured by VentCo.
- Later that day, in a routine check of Betsy's condition a nurse detects that Betsy is showing signs of asphyxia.
- The nurse initiates an emergency response, and Betsy's doctors discover that she is suffering from **laryngeal edema**, which causes an obstructed airway.

Case Study

- This condition can be caused by an **allergic reaction** that causes an inflammatory response in the patient.
- Upon further investigation, doctors learn that Betsy has a yet-undiagnosed **latex allergy**.
- As a result of oxygen depravation, Betsy experiences permanent and irreversible **brain injury** (which later becomes the subject of a products liability lawsuit that is filed on Betsy's behalf against VentCo.)

Case Study

- VentCo receives a report from Mercy Hospital that details Betsy's allergic reaction, which her doctors believe was triggered by her contact with the VentCo machine and breathing circuit.
- VentCo launches an immediate investigation and learns that TubeCo has recently experienced some quality problems with one of its foreign suppliers.
- Routine testing of the raw ingredients had recently revealed the presence of latex.
- TubeCo company believed that is had isolated the contaminated product, though it confirms following Betsy's allergic reaction that several lots of finished tubing contain latex.

Case Study

- Those lots were distributed by VentCo and have reached the inventory of several of VentCo's hospital-customers.
- According to the American Latex Allergy Association, the incidence of latex allergy throughout the general population is estimated between 1% and 6%.
- VentCo contacts TubeCo to urge a recall of the product.
- TubeCo disclaims responsibility for the recall, citing its comparably smaller size, lack of preparedness, and limited resources as factors that would delay and complicate the recall process.

Case Study

- TubeCo also claims that VentCo verbally assumed responsibility for any recalls as part of the basis of their agreement to do business.
- TubeCo eventually stops communicating with VentCo.
- VentCo consults with legal counsel and is advised to undertake a recall of the product immediately, given the potential risk to patients.

Case Study

- Ultimately, the recall costs VentCo $2M.
- VentCo wants to pursue legal action against TubeCo to recover costs associated with conducting the recall.
- Legal counsel examines the “terms and conditions” on the back of the purchase order that the companies had used to conduct business and determines that none of the language establishes a contractual right for VentCo to seek contribution or indemnification for recall costs.
- Further, TubeCo is under-insured, under-capitalized, and unlikely to pay any judgment in VentCo’s favor.
- VentCo decides *not* to file a lawsuit against TubeCo and absorbs the recall costs.

What Should They Contract For?

- Seek **indemnification** from the supplier for any liability that originates with the supplier.
  - Include defense costs, specifically.
  - Ask to become an "additional insured" on the supplier's products liability insurance coverage.
- Require the supplier to purchase a certain **type and amount of insurance**.
  - Request certificates of insurance.
- Establish procedures for a **recall**.
- Include contractual provisions that describe how the supplier will be **audited**.

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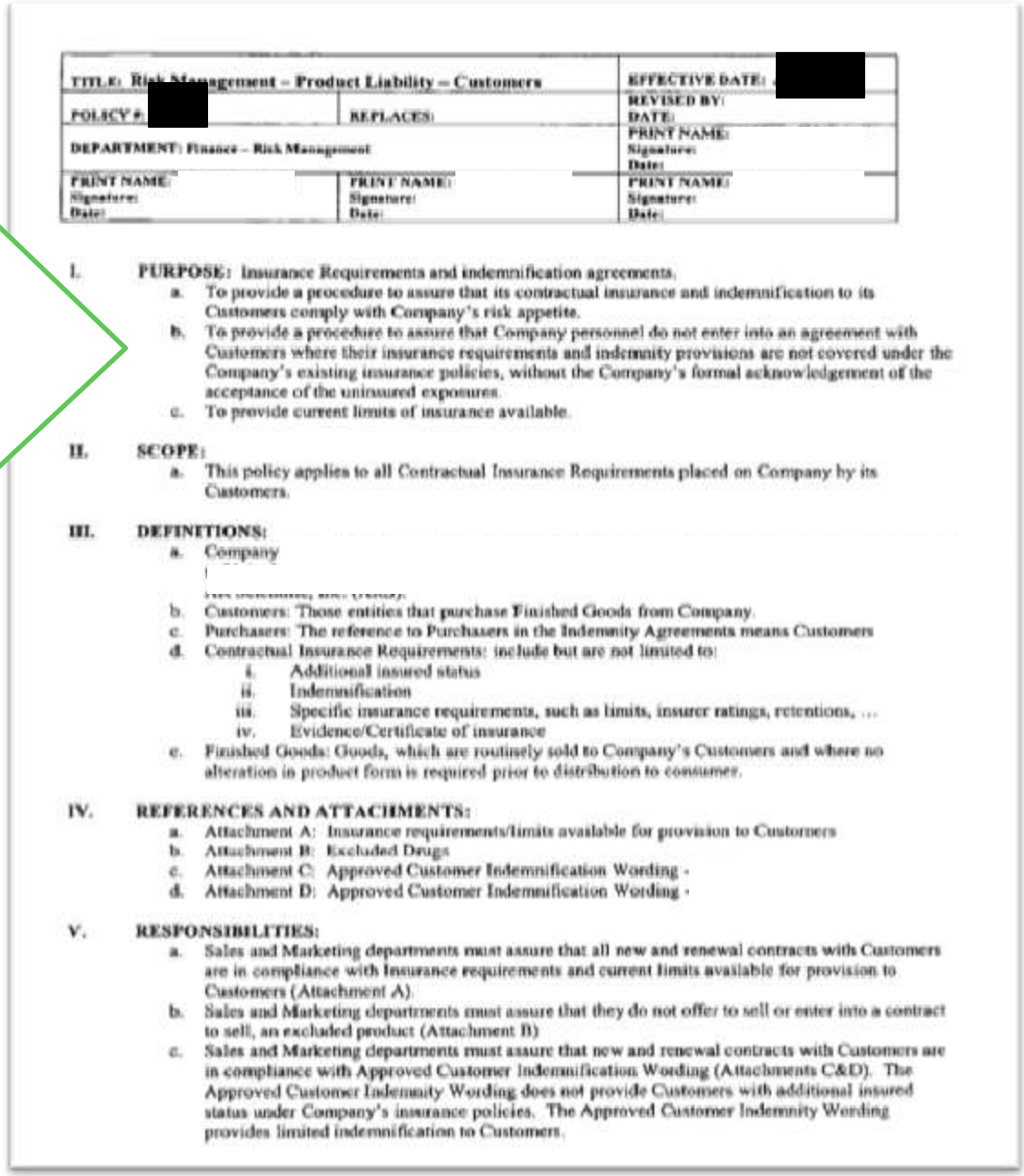
PURPOSE:

Negotiating Agreements with Customers

DESCRIBES:

- Who will conduct the review
- What will be reviewed
- What risk is acceptable to the company
- What the company will ask for:
  - Mutual Indemnification
  - Type of Insurance Coverage and Limits
  - Certificates of Insurance



TITLE: Risk Management – Product Liability – Customers		EFFECTIVE DATE: [redacted]
POLICY #: [redacted]	REPLACES:	REVISED BY: DATE:
DEPARTMENT: Finance – Risk Management		PRINT NAME: Signature: Date:
PRINT NAME: Signature: Date:	PRINT NAME: Signature: Date:	PRINT NAME: Signature: Date:

I. **PURPOSE:** Insurance Requirements and indemnification agreements.
   a. To provide a procedure to assure that its contractual insurance and indemnification to its Customers comply with Company's risk appetite.
   b. To provide a procedure to assure that Company personnel do not enter into an agreement with Customers where their insurance requirements and indemnity provisions are not covered under the Company's existing insurance policies, without the Company's formal acknowledgement of the acceptance of the uninsured exposures.
   c. To provide current limits of insurance available.

II. **SCOPE:**
   a. This policy applies to all Contractual Insurance Requirements placed on Company by its Customers.

III. **DEFINITIONS:**
   a. Company
   b. Customers: Those entities that purchase Finished Goods from Company.
   c. Purchasers: The reference to Purchasers in the Indemnity Agreements means Customers
   d. Contractual Insurance Requirements: include but are not limited to:
      i. Additional insured status
      ii. Indemnification
      iii. Specific insurance requirements, such as limits, insurer ratings, retentions, …
      iv. Evidence/Certificate of insurance
   e. Finished Goods: Goods, which are routinely sold to Company's Customers and where no alteration in product form is required prior to distribution to consumer.

IV. **REFERENCES AND ATTACHMENTS:**
   a. Attachment A: Insurance requirements/limits available for provision to Customers
   b. Attachment B: Excluded Drugs
   c. Attachment C: Approved Customer Indemnification Wording -
   d. Attachment D: Approved Customer Indemnification Wording -

V. **RESPONSIBILITIES:**
   a. Sales and Marketing departments must assure that all new and renewal contracts with Customers are in compliance with Insurance requirements and current limits available for provision to Customers (Attachment A).
   b. Sales and Marketing departments must assure that they do not offer to sell or enter into a contract to sell, an excluded product (Attachment B)
   c. Sales and Marketing departments must assure that new and renewal contracts with Customers are in compliance with Approved Customer Indemnification Wording (Attachments C&D). The Approved Customer Indemnity Wording does not provide Customers with additional insured status under Company's insurance policies. The Approved Customer Indemnity Wording provides limited indemnification to Customers.

Wrap-Up

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Summary

- Under products liability law, you can become responsible for the acts and omissions of your suppliers and subsequent-tier suppliers.
- Make visiting your suppliers a top priority.
- If you cannot visit a supplier, conduct an investigation using “alternative” methods.
- Audit the length of your supply chain to the extent possible.
- Ensure that your supplier has excellent supplier oversight practices.
- Avoid purchase order terms and conditions and put contracts in place with your suppliers that allow you to spread risk among supply chain members.
- Contract for indemnification and assistance with recalls and set forth requirements for your supplier’s insurance coverage.

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Thank you.

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