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.
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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**Superior Insurance Solutions**
for the Medical Technology and Life Sciences Industry.

Medmarc is the leading expert in the products liability risks facing medical technology and life sciences companies.

**Industry Specialists.** Medical technology and life sciences companies are vulnerable to a variety of products liability risks that are unique to their industry. We understand these risks and specialize in providing insurance and risk management solutions designed to respond to the industry’s particular needs.
What Is Risk Management?

Risk Management Objectives:

- Identify potential products liability exposures
- Develop products liability risk management strategies to mitigate risk
Agenda

- Products Liability Overview
- Supply Chain Risks
  - What goes wrong with suppliers?
  - How do you manage the risk?
Products Liability Overview
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
Elapsed Time: Claim-to-Resolution

For 2010 - 2016

On average, claims remain open for 540 days.

Time Period Following Reporting In Which Claims Close
The Practical Realities of Litigating Products Liability Claims
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)
“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
Medtech As A Target

An Organized 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.
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.
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)
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.

2014 National Poll

- Corporate executives often try to cover up the harm they do.
- Corporations will lie if it benefits them financially.
- If someone sues a corporation, the case must have some merit.

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.

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
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
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

*Typically limits the repeal to noneconomic damages or sets percentage thresholds for repeal to be applicable.
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.

Top 483 Observations

- Corrective and Preventive Actions (CAPA)
- Post-market complaints
- Purchasing controls
- Process validation

2015 - For Medmarc
Data compiled by Medmarc
Industry & Supply Chains

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.
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.
Manufacturers don’t audit their supply chains.

Manufacturers ignore “subsequent-tier” suppliers in the supply chain.

What goes wrong?

Manufacturers don’t transfer risk through contract.
Auditing Suppliers
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.
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.
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.
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.
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.
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.
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.
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.
Common Scenarios

No Audits
- Costs
- Manpower
- Expertise
- Language Barriers

Riskiest
- Costs
- Manpower

Often, small companies

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

- **FDA Information**
  - Warning Letters
  - Form 483s
  - Recalls
  - MAUDE

- **Local Information**
  - Newspapers
  - Better Business Bureau

- **Certifications**
  - ISO
  - UL

- **Customer Testimonials**

- **Background Checks**
  - Criminal
  - Debarment
  - Management Bios

- **Other**
  - Glassdoor
  - Products Liability Carrier
  - CDC Information

**Onsite Audits Are Best**
Alternative Risk Factors

- Foreign Suppliers
  - Consider potential jurisdictional issues

- “Small” Suppliers
  - Consider capacity to handle potential claims

- Under-Insured Suppliers
  - Consider capacity to handle potential claims

- Contract-Resistant Suppliers
  - Consider consequences of failing to secure indemnification

Consider potential jurisdictional issues.
Consider capacity to handle potential claims.
Consider capacity to handle potential claims.
Consider consequences of failing to secure indemnification.
Auditing the Length of the Supply Chain
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.
“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.
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.
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.
The hospital that treated Charlie traces the source of the *Bacillus 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 “2<sup>nd</sup> Supplier, Inc.”

About the time of Charlie’s death, 2<sup>nd</sup> Supplier, Inc. discovers that its product is contaminated with *Bacillus cereus* and informs KitPacker that it has found *Bacillus cereus* at its facility.

KitPacker *begins its first inspection* of 2<sup>nd</sup> Supplier, Inc. and learns that the company is out of compliance with GMP requirements.
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.
Gauze passed through machinery with debris built up on it.

Two-thirds of the gauze manufactured by 2\textsuperscript{nd} Supplier, Inc. is contaminated.

OrthoImplant, undertaking its own investigation, learns that FDA documents indicate that it had been aware of problems at 2\textsuperscript{nd} Supplier, Inc. since 2011.

The FDA received 142 reports of adverse events related to 2\textsuperscript{nd} Supplier, Inc.’s products.

The FDA completed its most recent inspection of 2\textsuperscript{nd} Supplier, Inc. in 2012, finding multiple violations of GMP requirements.

OrthoImplant initiates a \textbf{global recall} of its convenience kits, which ultimately costs the company several million dollars.
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.
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.

I have very little bargaining power.

Even if I know who they are, I cannot conduct onsite audits of subsequent-tier suppliers.

I have no idea who my supplier’s suppliers are or what they are up to.

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

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.
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.
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 deprivation, 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 it 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**.
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:
  o Mutual Indemnification
  o Type of Insurance Coverage and Limits
  o Certificates of Insurance
Wrap-Up
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.
Thank you.

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