



Medmarc



Biomedicinsure

COMBINED EXPERTISE ► SUPERIOR PROTECTION™

Products and Professional Liability To Buy or not To Buy

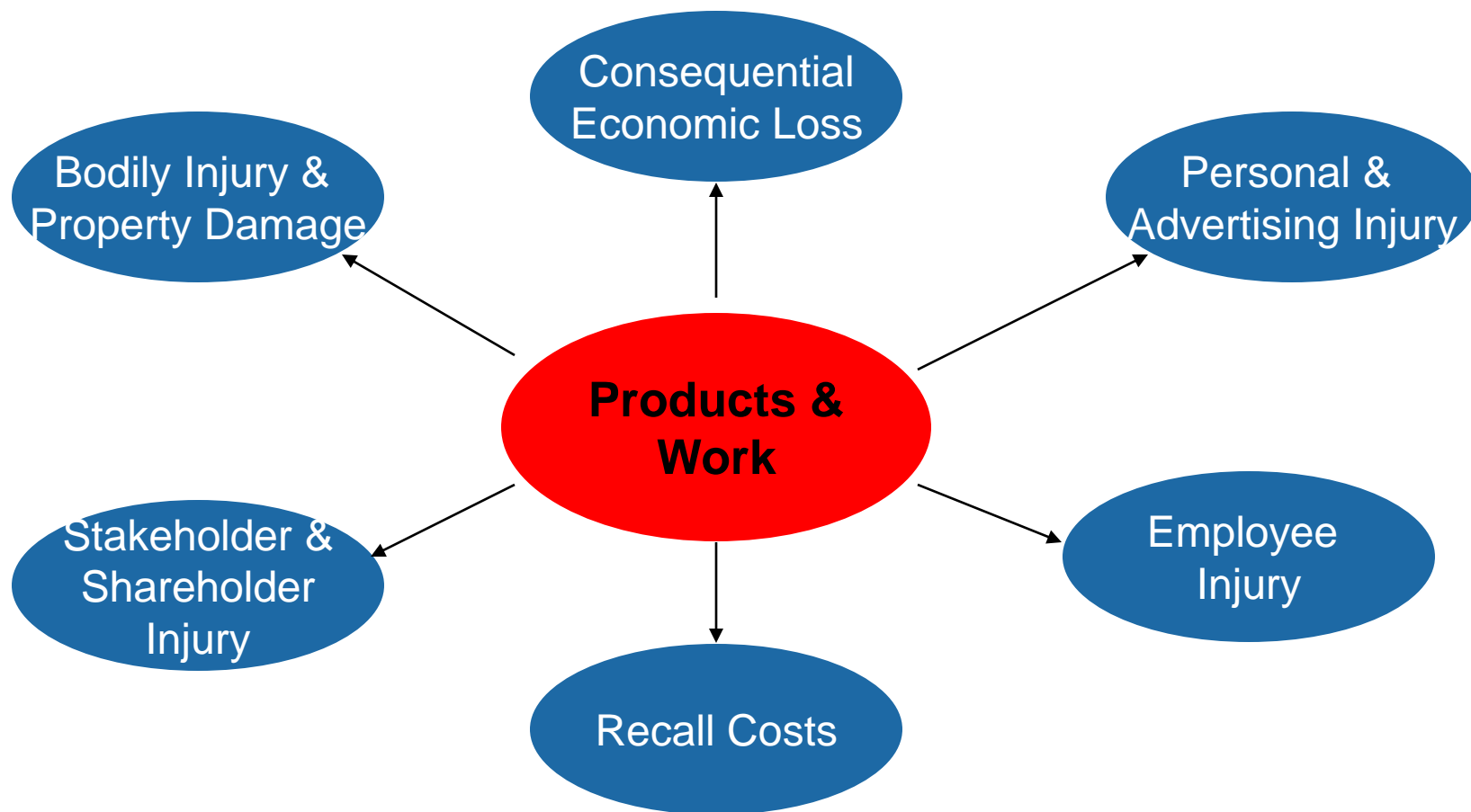
Loss Control Presentation

May 12, 2010

Agenda & Topics

1. What are the Exposures from Products/Work?
2. Products Liability Insurance – What’s covered and what is not covered in the form!
3. Other products related liability situations and related insurance offerings
 - Third-party liability claims for Manufacturer’s defect or impaired property
 - Product Recall Situations: Managing the costs and expenses
 - Employee situations
 - Directors and Officers Liability Exposure from your product
 - Professional Liability – Should you purchase coverage?

Constellation of Exposure from Products



Typical Liability Risks Associated with Medical Technology Manufacturing

- Premises & Operations Liability
- Personal and Advertising Injury Liability
- Products Liability
 - Bodily Injury
 - Property Damage
- Employers Liability
- Management Liability

Products Liability Insurance Coverage

- ISO Products/Completed Operations Liability Form CG 0038
- “Products-completed operations hazard” (12)
 - away from premises, arising out of “your product” and “your work”
 - Product = goods that are manufactured, sold, handled and distributed; containers, warranties, etc. (16)
 - Work = operations or work performed and materials (17)

Limitations or Exclusions in the CGL & Products Liability Forms

- Property Damage to property in insured's care, custody or control (g)
- Property Damage to Insured's Product (h)
- Property Damage to Insured's Work (i)
- Property Damage to Impaired Property or Property not physically injured, due to defect in insured's product or work (j)
 - Failure to deliver or perform
 - Breach of warranty or representation
- Recall of Products, Work or Impaired Property (k)
- Damage to Intangible Property or data (l)
- Injury to employees
- **These are areas of exposure to economic losses;** property damage and/or loss of use or consequential loss

Manufacturer's E & O Liability

- Fills in the gaps where products liability insurances excludes
- Coverage Grants:
 - **Physical Injury to products/work** – if caused by an “wrongful act” or damage to property of others on the insured’s premises for the purpose of having work performed on such property
 - **Business Injury** – customer’s loss of use of tangible property, not physically injured, resulting from failure of an insured’s product to meet level of performance, quality, fitness or durability represented by the insured; or loss of use of property of others on the insured’s premises for the purpose of having work performed on such property

Wrongful act in the design, manufacture, installation or performance of the insured’s product that results in the defect, deficiency, inadequacy or dangerous condition in that product or work

Features of Manufacturer's E & O Coverage

- Claims made trigger
- Basic Limits start at \$100,000; higher limits available
 - \$1,000,000 per claim/aggregate; up to \$3,000,000
 - Contract requirements or risk appetite
- Deductible applies per claim
- Defense within limit; option to change
- Extended Reporting Periods, Prior Acts Coverage
- Based on gross sales, flexible rating/pricing

Recommendation to review your risk profile and determine if this is an exposure to loss

Product Recalls Happen

- More than 500 medical device recalls in US every year
- Types of Recalls: FDA or Voluntary
- Addresses device with potential violation of FDA regulation
- Device is defective, risk to health; device may need to be checked, adjusted, fixed, withdrawn
- FDA may not originate recall, but oversees the company's strategy and assesses adequacy of the recall

Product Recall Costs

- Cost of Recalls: thousands upwards to multi-million; depending on size and recall plan
 - Medtronic recall of Sprint Fidelis implantable defibrillator
 - CareFusion Alaris recall – IV pumps
 - Stabilet Infant warmers
- Managing the Process: recall management industry
- Risks to insured:
 - Basic costs
 - Communications
 - Third party costs incurred on insured's behalf
 - Advertising to regain customer's loyalty

Product Recall Expense Coverage

- First Party Reimbursement
- Coverage Grant: expenses made necessary by reasonable determination or government ruling that the insured's product may cause
- Participation and Deductible: deductible per recall, and participation percentage in excess of deductible
- Optional Extensions: Cost to replace insured's product
- Pricing: flexible and based on quality and product

Risk Management maintains Products Recall Plan, assesses costs and determines if insurance may be needed.

Employee Injury from Products or Work

- Testing or manufacturing the product
- Demonstrating the product
- Injury while working at customer's site
- Contracted Employee, Temporary Employee, or Leased Employee

Workers Compensation/Employers Liability
remedy – include all types of “employees”

Management Liability Exposures from Products

- Directors and Officers Liability – personal assets at risk if/when sued as individuals
- Financial downturn or management failure
- Products event leads to economic loss
- Shareholders allege wrongful acts

Management Liability – D & O Coverage

- Directors and Officers Liability – personal or corporate liability for management actions
- Required by board members or investors
 - Side A coverage for the officers, directors who are not indemnified
 - Side B coverage for corporation which indemnifies its officers
- Defense costs
- Indemnity
- Bundled with employment practices, crime, fiduciary coverages

Claims or Litigation Scenarios

- In 2007 there were 21 lawsuits against companies listed as Surgical and Medical instruments or electro-medical devices SICs 3841 and 3845
- Clinical Trial Failure or unexpected or undisclosed setbacks in regulatory or clinical trial
- Missed sales projections
- Misrepresentations of product efficacy
- Misrepresentations of regulatory approvals

Spectranetics – Case

Stanford Law School

The Spectranetics Corporation Summary: According to a press release dated September 23, 2008, the Complaint charges Spectranetics and certain of the Company's executive officers with violations of federal securities laws. Among other things, plaintiff claims that defendants' material omissions and dissemination of materially false and misleading statements concerning the Company's business and operations caused Spectranetics' stock price to become artificially inflated, inflicting damages on investors. Spectranetics develops, manufactures, markets and distributes single-use medical devices used in minimally invasive procedures within the cardiovascular system for use with Spectranetics' excimer laser system.

The Complaint alleges that throughout the Class Period defendants knew or recklessly disregarded that their public statements concerning Spectranetics' business and operations were materially false and misleading. Specifically, the Complaint alleges that defendants' public statements failed to disclose or indicate the following: (1) that the Company lacked effective regulatory compliance controls; (2) that the Company was illegally and extensively marketing its laser and catheters for uses that had not been approved by the United States Food and Drug Administration ("FDA"); (3) that the Company failed to report to the FDA that tests found its laser caused significant damage to stents it was using in the clinical trial; (4) that the Company illegally tested several products on patients without FDA approval; (5) that the Company lacked effective internal controls; and (6) as a result of the above, the Company's financial results were materially inflated.

On September 4, 2008, Spectranetics shocked investors when reports surfaced that Federal Officials had served search warrants on the Company and NASDAQ halted trading of Spectranetics' common stock. That evening, Spectranetics issued a press release disclosing that the Company was jointly served by the FDA and U.S. Immigration and Customs Enforcement with a search warrant relating to the promotion, use, testing, marketing, and sales of certain Spectranetics products, and payments made to medical personnel and an identified institution for this application. The search warrant also requested information about two post-market studies completed during the period from 2002 to 2005 and payments to medical personnel in connection with those studies, as well as information regarding compensation packages for certain Spectranetics personnel.

INDUSTRY CLASSIFICATION:

SIC Code: 3845

Sector: Healthcare

Industry: Medical Equipment & Supplies

Able Laboratories – Case

Stanford Law School Securities Clearinghouse

Summary: Several purported shareholder class action lawsuits have been filed against Able Laboratories, Inc. and certain of its present and former executive officers charging the defendants with violations of the Securities Exchange Act of 1934. More specifically, **the Complaint alleges that the Company failed to disclose and misrepresented the following material adverse facts which were known to defendants or recklessly disregarded by them: (1) that the Company's laboratory testing practices significantly deviated from standard operating procedures employed in the industry; (2) that as a consequence of the foregoing, the Company suspended shipment of all of its products and had to withdraw seven of its approved Abbreviated New Drug Applications filed with the FDA; and (3) that this disruption of business would have a material adverse effect on the Company's business and results of operations.**

The complaint further alleges that on or around May 19, 2005, Able announced that it had identified apparent departures from standard operating procedures with respect to certain laboratory testing practices. On the same day, Able also announced that defendant, the Company's Chairman and Chief Executive Officer, would be resigning from those positions. The news shocked the market. Shares of Able fell \$18.37 per share, or 74.59 percent, on May 19, 2005, to close at \$6.25 per share.

NOTE: On July 18, 2005, Able filed a petition to reorganize under Chapter 11 of the United States Bankruptcy Code in the United States Bankruptcy Court for the District of New Jersey, Trenton Division. Able is no longer named as a defendant.

On January 26, 2006, the Court entered the Order signed by U.S. District Judge Joseph A. Greenaway, Jr., consolidating the actions with 05-2681. On March 17, 2006, the Court entered the Order granting the motions to appoint of Deka International (Ireland) and the Denver Employees Retirement Plan as lead plaintiffs and Grant & Eisenhofer P.A. and Murray, Frank & Sailer LLP as co-lead counsel. On June 19, 2006, the plaintiffs filed a Consolidated Class Action Complaint, and on September 12, 2006, the defendants filed motions to dismiss the Consolidated Class Action Complaint. On June 29, 2007, the Court entered the Order denying the Defendants' motion to dismiss. Defendants filed motions for reconsideration, which were denied on March 24, 2008.

On March 19, 2009 the judge provisionally closed the case in light on a pending settlement agreement. The order stipulates that the case may be reopened if the settlement is not consummated. On May 14, 2009, the lead plaintiffs filed a motion to reopen the case to allow consummation of settlement. On December 11, 2009, the motion to reopen the case to consummate settlement was granted. On January 4, 2010, a Stipulation and Agreement of Settlement was filed. The proposed settlement is in the amount of \$9,150,000 in cash. On February 24, 2010, the settlement was preliminarily approved. The Fairness Hearing is scheduled on June 16, 2010.

INDUSTRY CLASSIFICATION:

SIC Code: 2835

Sector: Healthcare

Industry: Biotechnology & Drugs

Professional Liability Considerations

Definition: **Professional Liability** insurance covers economic damages for claims of liability that arise from errors, omissions, or negligent acts alleged committed by a Professional in the course of their providing professional services.

Professional Services: traditionally –lawyers, physicians, real estate, consultants, lab technicians, etc.

Should a manufacturing account have professional liability?

- Are you providing a “service” or “work” upon which customer is dependent ?
- Contract breach?
- Failure to exercise standard of care for profession?
- Have employed professionals?

Professional Liability Considerations

Carriers offering combined Products and Professional Forms

- Note exclusions for personal and advertising injury from products – except trials -- and professional coverage part
- Excludes property damage to insureds work, product, or impaired property, and property in care, custody and control
- Excludes recall incurred by insured or others, small give back for bodily injury
- Damages from wrongful acts **only** arising from defined professional services endorsement
- May erode products liability aggregate limit of insurance

Risk Management Assessment

- Products related activities can contribute to losses other than “products liability”
- Risk Management for losses may include insurance coverage products
- Recommend to “think broadly” about exposures to loss from products in these spill over effects – the constellation

Questions and Discussion

Thank you.

Joseph Coray

Vice President, The Hartford
Technology and Life Science Practice Group

Joseph.Coray@thehartford.com

860-547-7393

Medmarc Protect™

Risk management solutions for the medical technology and life sciences industry



Complimentary webinar: "Pharmacovigilance in a Post-Wyeth v. Levine world" - March 24th - Register

Resources

Access important products liability risk management information.

[Browse Top Picks](#)



Webinars & Podcasts

- Podcast Pharmacovigilance in a Post-Wyeth v. Levine World
- FDA Outlook 2010 Webinar
- FDA Outlook for 2010 Podcast



Publications

- Protecting PMA Devices
- Federal Preemption
- The Basics of Contractual Risk Transfer



Training Courses

- Sales Reps in the OR
- Writing Defensively
- Warnings and Instructions

About Medmarc Protect

Through Medmarc Protect, we offer services that are designed to reduce products liability risks. We help you avoid costly litigation. Our services include:



Products Liability Risk Evaluations

Identify and prevent products liability exposures before they arise.

Employee Training

Train your staff to recognize and mitigate products liability risks.

Integrated Risk Management

Incorporate products liability risk management into your quality management system.

Latest Tweets

- MedmarcIns: Problems with heparin suppliers have led to nationwide shortages. To reduce supplier risk see <http://tinyurl.com/yctujtr>. #losscontrol #devis
- MedmarcIns: Drug & device execs in FDA's crosshairs. FDA announces it will increase criminal prosecutions <http://tinyurl.com/yfba3mh> #losscontrol #dysan
- MedmarcIns: After 18 recalls of insulin pumps over the past 5 years, the FDA is taking note. <http://tinyurl.com/ybyp12x> #losscontrol #devis

GOT QUESTIONS?

Ask an Expert

Submit your question related to the medical technology and life sciences industry, concerning:

- Products Liability
- Risk Management
- FDA Compliance

Question of the Month

[Submit a Question](#)

Stay Informed About Our Risk Management Services



[FOLLOW US ON TWITTER](#)



[FOLLOW US ON LINKEDIN](#)

Medmarc Protect™

Risk management solutions for the medical technology and life sciences industry



WEBINARS & PODCASTS

Medmarc's webinars and podcasts address important issues relevant to the medical technology and life sciences industry. Our 50-minute webinars discuss these issues in depth and our podcasts provide general overviews and brief insights. **Presenters are experts** in the industry and the information provided is designed to educate our policyholders on **preventive products liability practices** and **current industry concerns**.

Top Picks

Access some of our educational resources that have been organized by topic for your convenience. These resources contain comprehensive and current information about a variety of topics relevant to the medical technology and life sciences industry.

[Browse Top Picks](#)

UPCOMING WEBINAR

Products Risk and Professional Liability: To Buy or Not to Buy
May 12, 2010 2:00 PM EDT



Joe Coray is the Vice President and Global Practice Leader for The Hartford in the Technology Practice Group. In this capacity, he is responsible for all execution activities of the group, including overseeing field sales, underwriting and strategy for the Practice, including Information Technology, Electronics, Telecommunications and Life Sciences & Medical Technology sectors. Mr. Coray will host this webinar intended to help the financial manager/insurance buyer understand and make informed decisions about coverage, risk and premium.

Stay Informed About Our Risk Management Services



[FOLLOW US ON TWITTER](#)



[FOLLOW US ON LINKEDIN](#)

Introduction to the CE Mark

- Webinar, Slides
- Podcast (15 minutes)

Pharmacovigilance

- Webinar, Slides
- Podcast (15 minutes)

FDA Outlook for 2010

- Webinar, Slides
- Podcast (15 minutes)

Warnings & Instructions

- Webinar, Slides
- Podcast (9 minutes)

Managing the Risk of Off-Label Promotion

- Webinar, Slides

Non-Manufacturer Sellers of Medical Products

- Webinar, Slides

Sales Representatives in the OR



Medmarc *Protect*™

Risk management solutions for the medical technology and life sciences industry



PRODUCTS RISK AND PROFESSIONAL LIABILITY

Many medical technology and life sciences companies purchase products liability insurance; yet there are **risks which may not be covered** by these policies. Faced with a myriad of options from insurance carriers, insureds must choose which coverages are needed to manage risk that arise from products. This webinar helps financial managers/insurance buyers **understand and make informed decisions** about coverage, risk and premium.

Top Picks

Access some of our educational resources that have been organized by topic for your convenience. These resources contain comprehensive and current information about a variety of topics relevant to the medical technology and life sciences industry.

[Browse Top Picks](#)

WATCH



Webinar
Products Risk and Professional Liability
Register
05/12/2010
2:00 PM EDT



LISTEN



Podcast
Q&A with Expert (12 min)

READ



Medmarc Announces
Product Recall Coverage Options