



Stericycle<sup>®</sup>  
**Expert**

**RECALL™  
RETURN  
RETRIEVAL/QA  
SUSTAINABILITY**

For Audio Dial

1-800-732-6870



Stericycle<sup>®</sup>  
**Expert**

**RECALL™  
RETURN  
RETRIEVAL/QA  
SUSTAINABILITY**

# Mike Rozembajgier

## Recall Best Practices

# RECALL GOALS



**Protect the  
Public**



**Protect Your  
Brand**



**Protect the  
Environment**



**Close Out ASAP**

# SEIZE OPPORTUNITIES



## ▶ **Protect the Public**

- ▶ **Take Control; Display Leadership**
- ▶ **Increase Customer Loyalty**

## ▶ **Protect the Brand**

- ▶ **Maintain & Build Brand Integrity**

## ▶ **Close out Recall Quickly & Efficiently**

- ▶ **Gain Competitive Advantage**
- ▶ **Minimize Environmental Impact**

# MEDICAL DEVICE ENVIRONMENT



- ▶ **Customer**
  - ▶ Patient
  - ▶ Physician
  - ▶ Hospital
- ▶ **Complex Products**
  - ▶ Sourcing considerations
  - ▶ Testing / Quality
- ▶ **Implantable**



RECALL  
RETURN  
RETRIEVAL/QA  
SUSTAINABILITY

# MINIMIZE IMPACT/ MAXIMIZE OPPORTUNITY



- ▶ **Be Ready**
- ▶ **Communication**
- ▶ **Remedy Management**
- ▶ **Data Management**



RECALL  
RETURN  
RETRIEVAL/QA  
SUSTAINABILITY

# BE READY



***Failing to Plan, is Planning to Fail!***

## ▶ Pre Crisis

- ▶ Establish a Recall Plan
- ▶ Conduct a Mock Recall
- ▶ Review & Update Recall Plan
- ▶ Develop Checklist
- ▶ Supply Chain Partners

## ▶ During Crisis



RECALL  
RETURN  
RETRIEVAL/QA  
SUSTAINABILITY

# KNOW YOUR AUDIENCE



- ▶ **Customize Messaging & Notifications**
- ▶ **Place Consumers First**
- ▶ **Communicate Well**

# BE RESPONSIVE



- ▶ **Respond Quickly & Effectively to Inquiries**
  - ▶ Consumers, Media
  - ▶ Multiple methods (web, call center)
  - ▶ Be consistent
- ▶ **Offer Proactive Solutions & Reassurance**
  - ▶ Product Retrieval and Fulfillment
  - ▶ Simple, Effective Remedies
  - ▶ Safe, Compliant Destruction
    - ▶ Reduce waste, maximize sustainability

# DOCUMENT EVERYTHING



- ▶ **Data Shows Due Diligence**
  - ▶ Notification & Response Rates
  - ▶ Effectiveness Checks
  - ▶ Product Returns
  - ▶ Resolution
- ▶ **Agency Compliance**
- ▶ **Public Perception**



# DATA MANAGEMENT



- ▶ **Data Shows Due Diligence**
  - ▶ Notification & Response Rates
  - ▶ Effectiveness Checks
  - ▶ Product Returns
  - ▶ Resolution
- ▶ **Agency Compliance**
- ▶ **Public Perception**

# RECALL LIFECYCLE



# Product Liability Implications

- What to say & what not to say
  - Monetary considerations
  - Patient/customer considerations
  - Unaffected lots
  - Recalled products that have already been used and/or implanted
- Training prior to any recalls is essential to avoid lawsuits
  - Has there been training regarding e-mail best practices?
  - Is there a trained Crisis Management Team?
  - Has the company tried to identify weaknesses before a recall?
- Attorney-client privilege
- Evidence preservation

# Product Liability Implications

- Thoroughly review insurance policies for insurance limitations, deductibles, and exclusions
  - Is there an obligation to provide prior notification of a recall?
  - Is there a restriction on admitting liability?
  - Other rights/obligations?
- Indemnification Provisions
  - Are there adequate assets and/or insurance supporting any indemnification provisions?
  - Does the company have adequate recourse against any foreign suppliers and/or their insurers?
  - Other rights/obligations?



Stericycle®  
**Expert**

**RECALL™  
RETURN  
RETRIEVAL/QA  
SUSTAINABILITY**

# Willie Bryant

## Tips for Working with the FDA

# Areas for Discussion

- FDA districts and headquarters organization
- Recall Trends 2008-2010
- Importance of Relationships with FDA or other regulators.
- Recall actions – first 24 hours
- Follow-up steps
- Communications with the FDA district recall coordinator
- Recall termination documentation

# FDA field and hdqtrs organization

- 19 district offices
- Major cities/population areas across the USA.
- One recall coordinator, most district offices: For locations and coordinators  
<http://www.fda.gov/ICECI/Inspections/IOM/ucm124008.htm>
- Seven Centers in FDA hdqtrs. Five primarily involved with recall operations (CDRH, CDER, CVM, CFSAN, and CBER) and ORA/OE/DCMO, which is hdqtrs for district's recall operations.  
<http://www.fda.gov/AboutFDA/CentersOffices/default.htm>
- Two to four recall officers per center office and OE/DCMO

## FDA recall trends, 2008 – 2010

- Upswing in numbers across the agency
- Increased congressional scrutiny
- The multiplier effect
- One ingredient/component supplier equals multi recalls by multi companies

# The First 24 Hours

- Notification of illness, adverse event, defect or contamination received.
- Investigation initiated. When, how, who, seriousness of incident, other complaints received, product(s) involved (how extensive or widespread is the problem), area and time of distribution, root cause of the problem.
- Notify FDA if required
- Requested or required reporting: 21 CFR part 7.59, FDA's Regulatory Procedures Manual (RPM) chapter 7, Field Alert Reports (pharmaceuticals), 806 Report of corrections or removals (medical devices)

# Follow-up Recall Steps

- Notify Your Recall Coordinator.
- Bring Senior Management on Board.
- Notify Entire Recall Team and 3<sup>rd</sup> Party Assistance
- Each Team Member initiates responsibilities.
- Prepare Formal Health Hazard (FDA template)
- Develop the Recall Strategy.
- Draft Recall Communication Documents
- Notify FDA District Office Recall Coordinator
- Initiate the recall.

# Communications w/District Office

- Within 24 hours of decision to recall. (Basic Info)
- ASAP, details of recall with strategy. (See Industry Guidance document for info needed.)  
<http://www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm>
- Include:
  - Draft recall letter/communications
  - Draft press release
- Firm receives written classification, any recommended changes to strategy, and recommended “effectiveness check” level.
- Submit bi-weekly or monthly status reports as requested.
- Provide a written final status report and request for termination.
- Firm receives written termination letter.

# Recall Termination Documentation

- Dates of notification to each type consignee
  - Include date of press issued, Details of product distribution
- Number and type of consignees notified
- Number of direct account responders
- Number of direct account non-responders
- Description and quantity of product on hand at consignees
  - Removed or corrected
- Status of effectiveness checks conducted
- Details of product disposition
- Root cause of the problem (if not previously provided)
- Corrective and Preventative Action taken



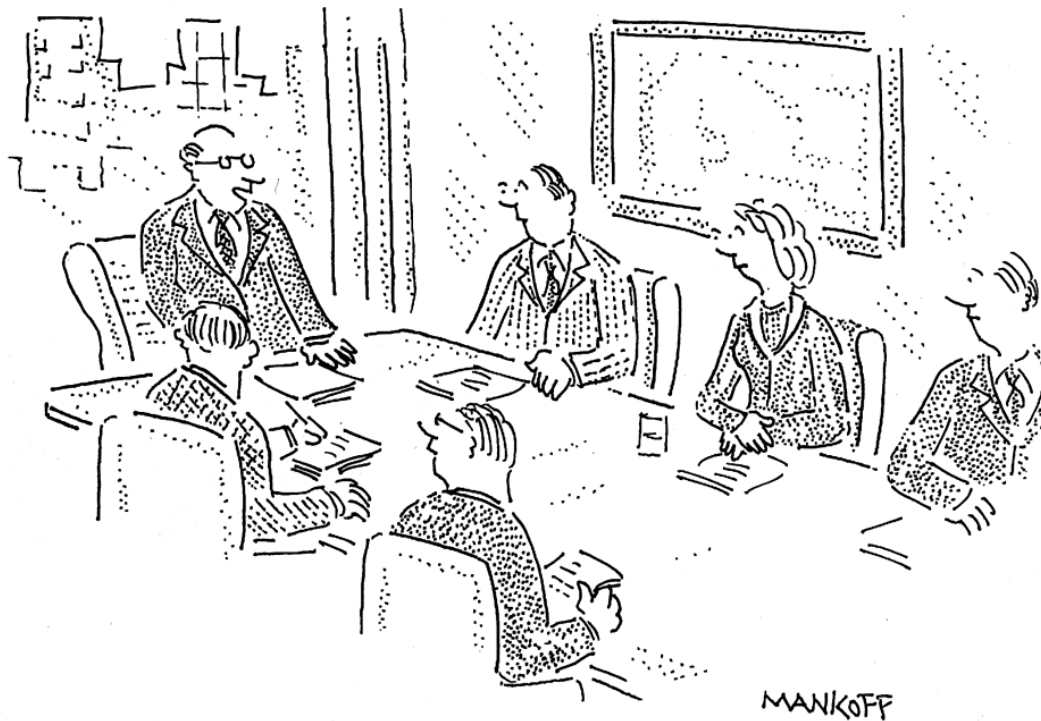
Stericycle<sup>®</sup>  
**Expert**

**RECALL™**  
**RETURN**  
**RETRIEVAL/QA**  
**SUSTAINABILITY**

**Dave Bartlett**

Minimizing Risk to Company Reputation

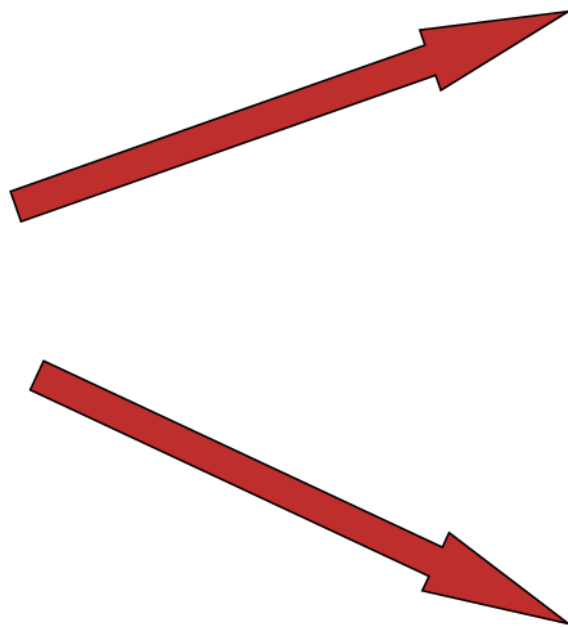
# Recall Communication



*"Let's never forget that the public's desire for transparency  
has to be balanced by our need for concealment."*

# Shaping the Story

**FACTS**



***POSITIVE* THEME**

What you say  
How you say it  
When you say it  
Who says it

***NEGATIVE* THEME**

# Recall Impact

- **Objective impact**

*Illness, injury, death*

- **Subjective impact**

*Perceptions, feelings, emotions*

# Strategic Questions

- **Who are the audiences?**
- **What are their concerns?**
- **What is your strategic objective?**
- **What is your story?**
- **What is your picture?**

# Communicating During a Recall

- **Have a plan and follow it**
- **Monitor and engage the media**
- **Engage digital and social media**
- **Present a human face**
- **Describe what happened**
- **Describe what you are doing to fix the problem**
- **Tell consumers what they can do to be safe**

# Communicating During a Recall

- **Get out in front of the story**
- **Think like your audience**
- **Choose the right spokesperson**
- **Ensure your statements match regulatory actions**
- **Know your regulators and stay in touch**

# Effective Messages

- **Positive**  
*Never defensive*
- **Factual**  
*Supported by strong evidence*
- **Responsive**  
*To audience concerns*

# Effective Messages

- **We care**
- **We are committed**
- **We are taking action**

# Cast of Characters

- **Victims**
- **Villains**
- **Vindicators**

**BE THE VINDICATOR**

# Strategic Communication

The image shows a large, bold Chinese character '胜' (shèng), which means 'victory' or 'win'. It is written in a traditional calligraphic style with thick, expressive strokes. The character is centered on a light-colored rectangular background.

Strategy without tactics is the slowest route to victory. Tactics without strategy is the noise before defeat.

- Sun Tzu



Stericycle<sup>®</sup>  
**Expert**

**RECALL™**  
**RETURN**  
**RETRIEVAL/QA**  
**SUSTAINABILITY**

Q&A

# Medmarc *Protect*™

Risk management solutions for the medical technology and life sciences industry



## Resources

### Top Picks

- ❖ Medical Device Recalls: Are You Ready?
- ❖ The Foreign Corrupt Practices Act
- ❖ The Discovery Process

### Webinars & Podcasts

- ❖ Podcast- Medical Device Recalls.mp3
- ❖ Podcast Foreign Corrupt Practices Act
- ❖ The Discovery Process

### Publications

- ❖ A Clinic on Employee Participation
- ❖ Warnings and Instructions
- ❖ NEJM Government Payment for Healthcare Causes and Consequences

### 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** and 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: Are you ready for a recall? Free webinar on best practices for conducting a medical device recall: <http://tinyurl.com/3autojr>

 MedmarcIns: Ongoing surge in product-liability litigation means listing numerous side effects on labels unlikely to change. <http://tinyurl.com/449vcn3>

 MedmarcIns: Thank you to Atty Carlos Ortiz for a great webinar on the Foreign Corrupt Practices Act, now accessible here: <http://tinyurl.com/3te3wne>

## 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](#)

## WEBINARS & PODCASTS

Medmarc's webinars and podcasts address important issues relevant to the medical technology and life sciences industry. Our webinars discuss these issues in depth and our podcasts provide brief overviews and insights.

### UPCOMING WEBINAR

#### Medical Device Recalls: Are You Ready? June 22, 2011, 2:30 PM EDT

This webinar is designed to help you and your company prepare for the unexpected. Three industry experts will share their expertise on how to develop a comprehensive and effective recall plan for your organization.


**Willie R. Bryant, Jr.**, was with the U.S Food and Drug Administration (FDA) for 41 years. He served in the Emergency Operations Branch, providing guidance, policy, and coordination of all recall functions to the FDA. Additionally, Mr. Bryant led the development of the FDA's newest technology for recalls, the Recall Enterprise System (RES). For the past several years, Mr. Bryant has shared his expertise with business leaders and clients as a distinguished fellow at ExpertRECALL™.

**David Bartlett** is the Senior Vice President of Levick Strategic Communications. Mr. Bartlett is one of the most highly regarded communications strategists and crisis management experts in the country. He is the author of *Making Your Point* (St. Martin's Press), a practical guide to communication strategy and tactics.


**Mike Rozembajgier** is Vice President of Recalls for Stericycle ExpertRECALL™. Mr. Rozembajgier is responsible for all aspects of recall service offerings, including development of strategic recall business initiatives, product enhancements, pricing and contracts, and marketing. Mr. Rozembajgier has more than 10 years' experience in the healthcare industry, including positions at Guidant Corp. (now Boston Scientific) and at Deloitte.


#### The Foreign Corrupt Practices Act

 Webinar, Slides

 Podcast (14 minutes)

#### Off-Label Promotion: Allergan's Pre-emptive Strike Against the FDA

 Webinar, Slides

 Podcast (15 minutes)

### 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](#) ▶

### 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



## MEDICAL DEVICE RECALLS: ARE YOU READY?

In spite of the high standards most medical device companies strive to maintain, it is sometimes necessary to recall a product or part. This page contains general information on recalls, including best practices, tips for working with FDA and other regulatory entities, and brand protection. The webinar and podcast feature experts from Stericycle, a leading provider of recall services to the medical device industry.

Register Now



## 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



### VIEW



Webinar

Wednesday  
June 22, 2011  
2:30pm EDT

### LISTEN



Podcast

(11 minutes)

### READ



Risk Management

101  
Coming Soon