The Tipping Point:
Managing Crises in the Pharma Industry

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What is a Crisis?

• Any matter that:
  — Is perceived to pose a significant threat to health and safety of employees, customers, or the public;
  — Puts material business operations at risk;
  — Creates significant financial, legal, or regulatory risk; and/or
  — Adversely affects company reputation or goodwill.
A Crisis Can Happen Before You Know It
Top 10 Crisis-Prone Industries in 2012

- Banking
- Security Brokers/Dealers
- Pharmaceutical
- Air Transport
- Petroleum and Natural Gas
- Software
- Telecommunications
- Surgical/Medical Equipment
- Education
- Automobile

Source: Institute for Crisis Management – 2012 Annual Crisis Report
Top 10 Crisis-Prone Industries

• The Pharmaceutical industry ranked as one of the most “crisis-prone” industries in 14 of the last 19 years.

Source: Institute for Crisis Management – Annual Crisis Reports
Another Day . . . Another Crisis

Sample of Health LAW360 Headlines from November 2013

• FDA rips Aegerion CEO for comments made on CNBC—viewers left with the faulty impression that cholesterol drug (Juxtapid) isn’t risky and by itself can ensure they live long enough to “meet their grandkids.”

• AstraZeneca discloses US DOJ investigation into Heart Drug clinical trial

• Clinical Trial deaths lead Ariad to halt Iclusig sales—Ariad suspended sales of Leukemia drug at the request of FDA after a dozen participants in clinical trials died

• J&J inks $2.2 billion settlement for off-label marketing, kickbacks

• 25 Drug Cos Put Up $88 Million to Escape Price-Rigging Suits

• Kaiser Permanente Says Data Breach May Affect 49K Patients

• Boehringer Fined $1M for Withholding Docs in MDL

• NJ Hospital Gets Criminal Docs on Bristol-Myers Black Widow—Princeton HealthCare System won access to a New Jersey county prosecutor’s files in its effort to dodge a suit brought by the estate of a Princeton patient who died after being poisoned by his wife, an ex-employee of co-defendant Bristol-Myers Squibb
Examples of Pharmaceutical Crises

- **Product Quality**
  - Drug trial failure
  - Product contamination or adulteration
  - Product recall
  - cGMP issues
- **Product Availability or Access**
  - Manufacturing shortages
  - Pricing issues
- **Government Investigations**
  - DOJ, Congressional, OIG and/or State Ags
- **Corporate Shake-ups and Competitor/Competitive Challenges**
Examples of Pharmaceutical Crises

• Legal/Regulatory Violations
  — Warning letters, etc.

• Negative Press
  — Products allegedly caused significant number of deaths or other serious side effects
  — Adverse data were allegedly withheld or mischaracterized
  — Physicians were allegedly misled

• Injury to a Celebrity or his/her Family

• High-Profile Lawsuits or other Legal Disputes
  — Whistleblower
  — Class actions
  — Discrimination or harassment
  — Big-dollar settlements or verdicts
Potential Outcomes from Pharmaceutical Crises

• Reputational damage
• Reductions in stock price and other corporate devaluation
• Loss of customers or market share
• New or expanded Congressional/government investigations
• Enforcement actions
• Lawsuits
• Employee morale
• Contractual challenges
Consumer Product Industries perceived dedication to making products that protect the safety, health and well-being of the public.

CRISIS MANAGEMENT IS AN UPHILL CLIMB IN THE PHARMA INDUSTRY

Consumers' level of trust to provide reliable information about risks to their safety, health, and well-being.

Pharmaceutical Company Websites

TV Doctors such as Dr. Phil or Dr. Oz

Crisis Management Principles

- Crisis management seeks to prevent or lessen the negative outcomes of a crisis and thereby protect the organization, stakeholders, and industry from harm.

- Interrelated factors:
  - Preparation/Prevention
  - Response
  - Recovery
Crisis Management Plan: Key Components

- Conduct a Risk Assessment
  - Most issues that result in a crises are known or knowable in advance
- Establish a Crisis Team
- Prepare an internal communication plan
- Develop a media strategy
  - Focus on known areas for potential crises
  - Identify and prepare spokespeople
  - Recognize importance of social media
- Implement processes and protocols
Crisis Management Plan: Key Components

• Identify priority and most likely scenarios and develop plans to address them
  — Account for low probability/high consequence situations
  — Prepare to address community upheaval and new or renewed government scrutiny

• Implement a crisis training program

• Test preparation for a crisis with drills or simulations
Identify Key Stakeholders - External

- Emergency responders
- Government regulators
- Key politicians and elected officials
- Trade associations
- Patient/disease-focused organizations
- Media, including social media
- Media, including social media
- Oversees markets, regulators, governments
Identify Key Stakeholders – Business

• Board of Directors
• Senior Management
• Legal/Compliance
• Employees, especially those with public interaction
• Insurers
• Customers
• Suppliers
• Business Partners/Vendors
• Investors
• Bankers/Financial analysts
Crisis Recovery/Revision

• Root cause correction/mitigation

• Restoration
  — Physical assets, business, reputation

• Analyze and incorporate lessons learned
  — Prevent recurrence; improve response to next crisis

• Identify positive aspects of crisis
  — Strengthen the company

• Dispute resolution
  — Internal/external investigations; litigation

• Insurance
Social Media is Critically Important During a Crisis

• A company dealing with a crisis cannot avoid social media, e.g., Facebook, Twitter, YouTube, blogs
  — Now initial source of information for most mainstream reporters

• But, messaging through social media should be approached with caution
  — Poorly or ambiguously drafted message points could be turned against the Company in litigation, regulatory, or political challenges
The Power of Social Media is Indisputable

- **At 1.1 billion** active members, Facebook would be the second largest country
- **78%** of consumers say corporate social media posts impact their purchase making decisions
- Twitter reports more than **400 million** tweets per day
- **93%** of newspaper websites use social media to develop story content
- Journalists use an average of **2.6** social media channels when researching a story
Social Media: Basic Guidelines

• Engaging or not engaging on social media is a FALSE CHOICE. IT IS A MUST.

• The process represents a “loss of control,” but it is not as ominous as it feels.

• Social media must be seen as both an offensive and a defensive resource.

• The critical strategic guidelines for managing social media in a crisis can and must be decided in advance.
Social Media: Pre-Crisis Recommendations

• Approach social media with respect and enthusiasm
  — A lack of interest or commitment will be obvious
• Commit to a serious engagement on multiple platforms
  — Twitter, Facebook, and YouTube at a minimum
• Engage legal, operations and communications in creating operational guidelines
• Develop social media audiences in advance of crisis
  — It is an enormous disadvantage if key audiences have their initial exposure to an organization’s social media activities in the midst of a crisis.
  — It is too late to make friends as a crisis is erupting.
Lessons Learned

• Complacency is a killer. Be vigilant.
• Don’t cover up bad facts. “Tell it all and tell it fast.”
• Internal communications about “issues” are critical
• Maintain the confidence and respect of internal audiences
• Most common problems are missteps or misstatements in the first hours and days of crisis.
• Identify – and train – Company spokespeople in advance of crisis.
• News travels at lightning speed; rumors and inaccuracies take hold quickly
• Analyze and incorporate lessons learned to strengthen company, prevent recurrence, and improve response to the next crisis
Questions?