ACC AMERICA
Association of Corporate Counsel
Delaware Valley (DELVACCA) Chapter

DELVACCA 2008 * 2010 Chapter of the Year

DELVACCA presents:

Dealing With P.R. Nightmares for Pharmaceutical Companies

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Compliance and Risk Solutions

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P.R. Nightmare Scenarios

- Clinical hold on hopeful market entrant
- Failed efficacy trial in a drug on the market
- Adverse events in a clinical trial of marketed drug
- Adverse events arising out of event reporting, an issue in another drug in class, or a meta-analysis
- Government investigation of off-label marketing or pricing practices
- Manufacturing/tainted product issues/recalls
- Employee misconduct
- Whistleblower
- Government contractor issues

Why a Good Crisis Management Plan Matters

- You cannot expect to “ride out” a crisis without some bruises
- Your goal should be to
  - Prevent the escalation of critical issues into crises
  - Mitigate the impact of an incident/crisis on the people and the business
- The life cycle of the crisis depends on
  - The nature of the problem
  - The effectiveness of the response

Nature of The Problem: From a Minor Incident to The "Perfect Storm"

- Safety-related
- Blockbuster product-killing
- Financial risk
  - Securities issues
- Reputational threat
- Government investigations
- All of the above

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“Constituencies” In Play

- FDA/foreign regulatory
- SEC
  - Private securities class action bar
- Investors
- Media, including foreign media
- Consumers
- Employees
- Personal injury bar
- Medicare fraud enforcers
  - Congress
  - States
- Consumer fraud class action bar
- Third party payors

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No One Has Time for a Crisis

I don't have time for a crisis this week,
my schedule is too full.

Henry Kissinger

Reacting to a Crisis

- PR, Crisis Response or Crisis Communication team should be hired by legal counsel
- Do not make specific statements right off the bat
- First message
  - We take the situation seriously
    - Nobody cares more about patient safety (quality/being truthful) than we do
  - We will communicate more as we get a clearer understanding of the facts
    - May want to arrange regular times for briefings
  - *We will be cooperating with the investigation*

Step 2

- Develop a statement with legal and communications input
  - Consider posting this standby statement and referring to it (and it alone) until you have something more you can say
- Assign a spokesperson
  - Develop Q & A
- Vet all messages through an agreed-upon chain

Doing it Smarter: Advance Corporate Crisis Planning

- A well thought out, coordinated **Communications Plan** can be the difference between success and failure during a crisis:
  - Clearly defined duties
    - Message development, coordination of internal & external communications; interaction with the media
  - Proactive role in preventing crisis situations from occurring
    - Planning, draft statements, spokesperson training, etc.
  - "Hands-on" strategies for managing through a Crisis
    - Messages & the media, internal/external message coordination, including internet, interactions/coordination within the company, such as Investor Relations and Legal
  - Role in after-action assessment & "lessons learned" integration

Working with FDA During A Crisis

- What is FDA's plan?
  - Recall situation?
  - To conduct a review (further review)
  - To convene an Advisory Committee meeting
  - To issue communications
- While recent issues with drug safety have eroded public view of FDA, it is better to be in alignment with FDA than fighting it

Heading off trouble:

✓ Audit documents regarding relationship with FDA

✓ Stay in contact

Securities Issues: Obligations in a Crisis

- You need to disclose **material information**
- Information is “material” if it would be viewed by a reasonable investor as
  - important in decision to buy or sell or
  - significantly altering the total mix of available information

Disclosure of Material Information

- Where/when duty to disclose arises:
- Periodic SEC Reports
  - 10-K (business, risk factors, MD&A, financial statements)
  - 10-Q
  - 8-K [4 business day window]
    - Agreements (entry and termination)
    - Impairment
    - Director or Officer departures
    - Other events
  - Press Release

Disclosure of Material Information

- Different standard when selling securities
- Different standard when “guidance” has been given and it becomes incorrect or incomplete
- Listing Standards: NYSE, NASDAQ, AMEX
  - Obligation to promptly disclose material news about significant legal or regulatory developments

Manner of Disclosure

- Compliance with Regulation FD required...
  - Flexibility of different tactics
- Goal: Contemporaneous investor awareness of material news/developments
  - 8-K is safe harbor
  - Broadly disseminated press release
  - Conference call or webcasts
    - as long as sufficient prior notice and open access

Manner of Disclosure

- Disclosure obligation is not always “absolute”
  - unusual circumstances – disclosure is not required if it prejudices the ability of the Company to pursue its legitimate business goals
  - Prior disclosure patterns are instructive [can increase risk]

    “Live by the pen… die by the pen.”
  - Often, disclosure timing is dictated by needing to answer a question or address an issue from one source in the context of FD compliance

Some Crises Will Get Bigger

Some will see “opportunity” in your crisis . . .

Private Securities Class Action Bar

- While many securities claims relate to financial improprieties (accounting, insider trading, etc.), in 2010, a higher proportion related to alleged misrepresentations about or failures to disclose re:
  - Prospects or delays in FDA approval
    - Reported high settlement $185M
  - Efficacy
  - Safety
  - Marketing practices
  - GMP

Heading off trouble:

✓ Manage your disclosures and safe harbors

✓ Beware of overblown assertions

Personal Injury Bar

- Follows the FDA website
- Looks for changes to labeling, especially boxed warnings, REMS, anything that they can use to suggest harm
- Will say FDA was misled in the approval process, utilized “compromised” Advisory panelists, etc.
- Have relationships with some physicians with anti-pharma biases, who will help them frame issues
- May work with Congressional staff, State enforcement staff to push for documents/publicity

Reimbursement Issues

- The bigger the drug, the bigger the alleged “buyer’s remorse”
  - Hindsight based “we would not have approved reimbursement for drug x had we known _____”
- Medicare payments raise attention at both federal and state level
- Private insurers may want in on the act
- Even consumers may bring suit (for payments/co-pays)

Congressional/State Investigations

- Working with Congress
  - Publicity
  - Documents
    - No recognition of privileges
    - Documents as good as public
- Problem is you become someone's morality tale

Congress

Biotechnology

Amgen Under Fire From Congress

Kerry A. Dolan 03.21.07, 5:45 PM ET

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BURLINGAME, CALIF. - Biotechnology superstar Amgen has taken yet another blow, this time from Congress.

Rep. John Dingell, the Michigan Democrat who heads the Committee on Energy and Commerce, faxed a letter to Amgen (nasda AMGN - news - people) Chief Executive Kevin Sharer expressing concern about reports that Amgen's anti-anemia Epogen and Aranesp drugs, "when used at higher than recommended doses, appear to cause increases in blood clots, seem to grow tumors and are associated with significantly higher mortality rates than placebo."

unnecessary risks to human life from these products." The FDA's Oncolog Drugs Advisory Committee is scheduled to meet May 10 to consider the safety of Epogen and Aranesp as well as that of Procrit, a competing anti-anemia drug marketed by Johnson & Johnson (nyse: JNJ - news - people).

FDA: Johnson & Johnson Concealed Motrin Recall

Ahead of a Capitol Hill hearing today, more details dribbled out on Johnson & Johnson's quality problems with popular over-the-counter medicines.

AP

The Food and Drug Administration has taken the top management of Johnson & Johnson to task for problems at a unit that makes Tylenol.

In late 2008, Johnson & Johnson found that some batches of the painkiller Motrin weren't dissolving the way they were supposed to, according to a Food and Drug Administration summary we got a look at. The company halted distribution and told the agency it would make random checks of retailers' shelves to see if a recall was warranted.

But the FDA found out that instead of just checking a few Motrin bottles here and there, a contractor working for J&J was buying up all the stuff under orders not to mention the word "recall" to the stores.

FDA told J&J about what some call a "phantom recall" to paper over the problems, and the company officially recalled the affected Motrin in July 2009. We called J&J this morning about the allegations, but the company didn't have an immediate response.

Congress probes celebrities in drug ads

Matthew Arnold
January 08 2008
Congress is investigating the use of celebrity endorsements in pharmaceutical advertising – starting with a "celebrity physician," artificial heart inventor Dr. Robert Jarvik.

In a letter to Pfizer honcho Jeff Kindler, Michigan Democrats John Dingell, chairman of the House Committee on Energy and Commerce, and Bart Stupak, chairman of the House Subcommittee on Oversight and Investigations, announced that they are looking into Pfizer's use of Dr. Jarvik in ads for Lipitor.

"We are concerned that consumers may misinterpret the health claims of a prescription drug promoted in a direct-to-consumer advertisement utilizing a celebrity physician," Dingell wrote, adding that consumers might also overestimate the qualifications of Dr. Jarvik "given that he may not be a practicing physician with a valid license in any state."

Federal Reimbursement Issues

Full Text Of Sen. Grassley's Letter
03.31.08, 9:34 PM ET

March 31, 2008

Richard T. Clark

Chairman, President, and Chief Executive Officer

Merck & Co. Inc.

1 Merck Drive

Whitehouse Station, NJ 08889

As Ranking Member of the United States Senate Committee on Finance (Committee), I have an obligation to the more than 80 million Americans who receive health care coverage under Medicare and Medicaid to ensure that taxpayer and beneficiary dollars are spent in a fiscally sound manner. This includes the responsibility to conduct oversight of the medical and pharmaceutical industries to ensure that Medicare and Medicaid dollars are spent appropriately on safe and effective drugs and devices.

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I continue to be troubled by reports that Merck and Schering Plough (M/SP) were delaying results of the ENHANCE trial. This study examined whether Vytorin provides better health benefits than generic simvastatin-a drug that is far less expensive than Vytorin. The ENHANCE trial was completed in April 2006, but the results were not released for almost two years.

I am pleased to see that M/SP finally released the long awaited results of the ENHANCE trial at this weekend's American College of Cardiology (ACC) meeting. However, I am troubled to learn that after careful analysis of the ENHANCE results, medical experts are now calling Vytorin the cholesterol fighter of last resort. According to reports today on CNBC, at least one prominent cardiologist is now referring to Vytorin as an "expensive placebo." Medical professionals should have had the facts about Vytorin much earlier so they could make informed decisions about the care that they provide to patients.

Delaying the release of the results from the ENHANCE trial not only affected medical decisions, but also imposed financial burdens on patients as well as the federal government. Since the ENHANCE trial was completed in 2006, the federal government has paid M/SP hundreds of millions of dollars for Vytorin.

State Reimbursement Issues

- Congress created Medicaid Fraud Control Units (MFCUs)
  - both federal and state-funded enforcement entities to investigate and prosecute Medicaid fraud
  - Also have a National Association of MFCUs (NAMFCU), which runs coordinated investigations
- Bring pricing, efficacy, off-label marketing claims

Consumer Fraud Bar

- Some of the same folks as the personal injury bar;
- Very excited by failed efficacy studies in established drugs or comparator studies where generics beat branded drugs, but also from safety studies;
- Similar buyer's remorse allegation "would not have bought/paid for x had they known _____"
- Sometimes can use federal and state having dropped cases to argue plaintiffs' bar is overreaching (just like you can use the feds dropping to try to get states to drop)

Messaging Around Investigations

- We take this seriously
- We intend to cooperate fully/are cooperating fully
- If you have investigated and taken action, you may wish to proffer that
  - Nobody cares more about quality than we do, which is why within 48 hours of hearing about the allegations, we took the following step . . .

Heading off trouble:

✓ Do advance crisis communications planning

In All of These Hypotheticals

- Communicating with
  - Investors
  - Consumers
  - Media
  - Employees
- Need to express concern for anyone who may have been injured
- Need to show the issue is being taken seriously
- But need to stay on message

Avoid The Self-Inflicted Crisis

- Best practices avoid or mitigate crises:
  - Companies that do not investigate issues they could have will not be regarded favorably later;
  - Companies that have good communications with FDA will look better later;
  - Companies with better securities disclosure systems will fare better than those without;
  - Companies that work on email communication guidelines may benefit for the one never created.

Crisis Planning

- Purpose:
  - Proactively prepare the organization to respond to an Incident or Crisis
  - Manage actual Incidents/Crises in a disciplined, timely manner
  - Facilitate effective internal and external Crisis Communications
- Goals:
  - Act in best interest of employees and public health
  - Protect lives and reduce chances of injuries or deaths
  - Protect Company assets
  - Preserve the Company's reputation with the public and key stakeholders

Crisis Planning

- Use of Plan:
  - Establishes incident and crisis response processes
  - Defines roles and responsibilities within the company during an Incident or Crisis
  - Training of Company leadership
  - Enables after-action assessment and integrates lessons learned

Goals of A Crisis Communication Plan

- Goals of a Crisis Communication Program:
  - Foresee potential crisis situations, try to mitigate, and prepare for them
  - Communicate approved key messages, based on the core values and principal messages of the company
  - Speak publicly through a single spokesperson if possible
  - Assume the worst and plan accordingly

Designated Spokesperson

- The Company spokesperson will vary depending on the nature and severity of the Incident and/or Crisis
- Only the chief spokesperson and back-up spokespeople are authorized to release information to the media and to the public
  - Usually a high level corporate communications lead
    - Sometimes with support from a medical officer
  - For a local, minor incident, the local head of Operations may serve as the spokesperson
- Corporate Communications and Legal should pre-approve all internal and external statements and materials as possible

Creating "Turn-Key" Crisis Communication Kits

- Anticipate the types of crises that the company could likely encounter & proactively develop turn-key Crisis Communications Kits
  - Use the kits to train designated personnel
  - Kit should include:
    - News release and/or pre-approved position statement
    - List of pre-approved potential Q&A
  - Fact Sheets - Background documents needed by the media or other external audiences (Corporate History, Myths vs. Facts on products, product Statistics and Safety Records, Background on each Investigational Product, Disease Backgrounders)

Creating “Turn-Key” Crisis Communication Kits

  - Q&A for Internal/Spokesperson Use
  - Internal communications to employees (e-mail, intranet update)
- Corporate Communications is responsible for keeping all kits current via annual review & update

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- Head of the firms Life Sciences practice and partner in the Corporate and Securities Practice Group.
- Devoted primarily to the areas of securities law, venture capital, mergers and acquisitions, corporate governance, licensing, collaborations, intellectual property and the commercialization of pharmaceutical, biotechnology, medical device and diagnostics products.
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- Partner in the Health Effects Litigation Practice Group, resident in the Princeton office.
- Represents defendants in products liability, consumer fraud and related mass torts litigation.
- Represented biotech and pharmaceutical companies, as well as consumer products manufacturers.
- Recently represented a major biotech company as national coordinating counsel for government investigations and securities, consumer fraud and product liability litigation, and a major pharmaceutical company in the defense of consumer fraud class actions pending around the country.

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- General Counsel and Founding Principal of Core Risks Ltd.
- Formerly was the Senior Vice President, Chief Legal Officer and Secretary for Henkel Corporation.
- Previously served as Vice President, General Counsel and Secretary of Rhone-Poulenc Rorer Pharmaceuticals Inc.
- Co-editor of the popular industry text, An Introduction to Food and Drug Law and Regulation (FDLI), now in its third edition.
- Long-time DELVACCA member, serving on its Board for a number of years and serving as its President in 2005.

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