



HORIZONS

Think. Challenge. Excel.

RAPS 2008 HORIZONS CONFERENCE & EXHIBITION
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Crisis Management for the Regulatory Professional

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Your Speakers

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Our Objectives Today

- Key Crisis Management Tools Senior Regulatory Professionals Should Know
 - A Crisis History – the Generic Drug Scandal
 - Fundamentals of Crisis Management
 - Complexities of Disclosure and other Corporate Duties Owed By Regulatory Professionals
 - What Does Vioxx and Guidant Got To Do With It?
 - ...

Crisis Management A working definition

- **“Crisis management is the systematic attempt to avoid organizational crises or to manage those crises events that do occur”**
(Pearson, C. M. & Clair, J. A. (1998). “Reframing Crisis Management.” Academy of Management Review, 23, 59-76).
- **“A crisis is a major, unpredictable event that threatens to harm an organization and its stakeholders. Although crisis events are unpredictable, they are not unexpected”**
(Coombs, W. T. (1999). Ongoing crisis communication: Planning, managing and responding. Thousand Oaks, CA: Sage Publications, Inc.)



Crisis Management

The Meaning of Crisis

“when written in Chinese, the word crisis is composed of two characters: one represents *danger* and the other represents *opportunity*” (From the John F Kennedy Presidential Library and Museum -- 4/12/59 in Indianapolis, IN and 10/29/60 campaign address in Valley Forge, PA)

--**John F. Kennedy**
President of United States

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A Crisis History -- the Generic Drug Scandal

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60 Seconds of Generic History

- **1984** – Hatch-Waxman Act passes – liberalizing generic drug approval process
- **Generic Industry's Challenge** – being first to approval for brand name drug
- **Upside** – set price, size, shape & color; ensure market penetration
- **Downside** – if not first, entering a commodity market; price drives & margins disappear

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Then What Happened?

- **Mylan** – thought it kept losing the race; reaction – hired a private eye; went through Charlie Chang's trash
- **Result** –
 - Congressional investigation -- July 1988
 - Gratuity pleas/convictions
 - Industry – including a Par Senior VP
 - FDA Generic Drug officials

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But, we're not finished yet ...

- **Maxzide Samples Switch** – Par – announced just a few weeks after gratuity conviction – July 1989
- **Why FDA asked for sample** – tip from disgruntled fired employee
- **Immediate Consequences**
 - another senior VP resigns in a cloud
 - Voluntary marketing moratorium of all drugs
 - New CEO – and other management team, including: VP/GC, VP/RA, VP/QA, VP/QC, VP/Ops, VP/R&D
 - Additional grand jury proceedings

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How We Faced The Crisis?

- **Honest, Consistent and Balanced Disclosure to all stakeholders**
 - Government
 - Business Partners
 - Public
- **Complete overhaul of corporation and operations**
 - Senior Management and other personnel
 - Procedures
 - Training

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How We Faced The Crisis ...

- **Audits** by outside experts
- **Code of conduct**
- **Ethics training** – access to outside board members
- **Cooperation** with federal investigators
 - “*Voluntary Declaration*” – was the vehicle for expressing the cooperation

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The Cost?

- **Immense**
 - Lost sales -- \$102 mm in '89 vs. \$55 mm in '90
 - Laid off employees – 900 to 450
 - Criminal and civil fines -- \$2.75 mm (high at that time)
 - Shareholder litigation settlement -- \$2.25 mm
 - Stock went from \$27 to < \$3 per share
 - Did not exceed \$10 share again until ~ 1998
 - Outside auditors & attorneys fees -- ~\$5 mm
 - Interference with business operations – little R&D for four years -- incalculable
 - Civil law suits -- ~ \$13 million

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The Long-Term Result

- **Company survived** – one of the few involved in the generic drug scandal
- **Public perception of generic industry tainted for years** – only in past five years or so have generics turned the corner (partially due to the perceived “evils” of the branded industry)
- **Changed dynamics of dealing with FDA** for the next decade and beyond

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Crisis Management –

Fundamentals of Crisis Management

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Be Prepared

- **Have a written crisis management plan**
 - **Key** -- “... is the philosophy of [the executive] management that steers a company through a crisis, not the plan of action on file.”
 - Larry Foster, VP Public Affairs of Johnson & Johnson during the Tylenol Tampering Crisis of 1982, writing in When Lightning Strikes, A How-To Crisis Manual with Classic Case Studies, Pines, Wayne L., Editor. Washington Business Information, Inc., 1994, p. 205.
 - **Johnson & Johnson** – focused on its Credo in making all decisions relating to Tylenol Tampering

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The J&J Credo

- We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality...
- We are responsible to our employees, the men and women who work with us throughout the world....
- We are responsible to the communities in which we live and work and to the world community as well. We must be good citizens ...
- Our final responsibility is to our stockholders. Business must make a sound profit....

Source: www.jnj.com/our_company/our_credo/index.htm
Written by General Robert Wood Johnson, 1943

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Identify Your Corporate Philosophy in Facing a Crisis

- At J&J -- the Credo already existed
- Important to articulate before a crisis hits; because you can't afford – but must -- to take the time later
- The Philosophy will drive your crisis management **goals**, such as:
 - Public health protection
 - Minimizing adverse publicity
 - Cutting products liability and/or shareholder litigation risks
 - Reducing chances – or impact -- of governmental regulatory or legal – civil or criminal -- action

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Identify Crisis Team in Advance

- **Head** – senior member of management. If serious health hazard, CEO should be intimately involved and public face of company
- Ensure all key functions within firm are represented, and at senior levels, such as:
 - Legal
 - PR
 - Regulatory Affairs
 - Medical/Scientific
 - Finance (may have SEC disclosure issues)
 - Other departments as specific to the crisis subject

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Identify Crisis Team ...

- **Outside Counsel**
 - FDA
 - Criminal
 - SEC
 - Products Liability
- **Outside Consultants** – pick with care for both what they know and who they know
 - PR -- e.g., former FDA Affairs staffers
 - Congressional – e.g., at Par, we used Patrick McLain, a former Dingell staffer as our liaison
 - Medical/Scientific – e.g., Guidant Independent Review Panel
 - used David Feigal, ex-head of Device Center at FDA
 - Toxicological
 - Epidemiological

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Preparing the Team

- **Train Your Team**
 - Handling the press and other public inquiries
 - Dealing with documents to ensure that all in company know how documents will be managed:
 - Attorney-client privilege and attorney work-product doctrine is maintained where appropriate
 - Consistency – controlling information flow within and without co.
 - Handling of drafts
 - Record retention
- **Mock Crises** – annually – use outside experts to simulate
- **Revise** the Plan based on the mock crises
- **Documentation** – keep ready on company and products
 - easier today due to websites

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Key Principles in Managing a Crisis

- Take Action Immediately
 - Activating the Plan
 - Internal and external communication
 - Speaking with a single voice
- Obtain as much information as possible
- Isolate the crisis team if needed
- Communicate inside the company with care, but don't let your employees find out from the outside
- Centralize communication through the crisis team
- Vette documents carefully – and through counsel
- Document, but with care – avoid “bad” documents

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Know Your Stakeholders

- Consumers
- General Public
- Media
- Management
- Shareholders
- Regulators
- Congress
- Public Interest Groups
- Plaintiffs' Attorneys
- Prosecutors

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Managing Publicity

- **Break the bad news yourselves**
 - P&G – pulled the Rely Tampon in Sept. 1980 before FDA could take action
- **Centralized spokesperson** – Tylenol – was Jim Burke, CEO of J&J
 - If a geographic focus to crisis – have CEO go there
- **Resist temptation to tell too much** (see Criminal Liability)
- **Be clear and careful** in your message
 - Be honest
 - Distinguish fact vs. speculation
 - Don't minimize the problem

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Managing Publicity ...

- **Inform Key Government Stakeholders before making disclosure**
 - Challenge – but the district office wants to review my recall press release before I send it out
- **Rehearse, Rehearse, Rehearse**
- **Know your press coverage** (harder to do in this Internet age)
 - Remember, they are on deadline -- you have to have your "story" ready or they will write without yours
- **Have key lists ready**
 - Customers in the route of distribution (and make sure they know who their customers are)
 - Doctors, pharmacists, public health officials

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Managing Publicity ...

- **Know What Your Company Has Planned** – e.g., may need to cancel major ad campaign in event of a recall
 - Tylenol – they stopped all TV ads
- **Keep communication lines open**
 - 800 #'s
 - Website frequently updated – and ensure info on the crisis is on your “HOME” page and easily found (you can then link through to more detail)
 - Tylenol – they even used sound trucks in Chicago
- **Keep feedback coming in from outside** – J&J did consumer surveys in Tylenol Crisis to learn public view

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Addressing Criminal Exposure

- Difficult to balance desire to disclose and need to insulate the company from liability
- Need to investigate internally – using counsel -- quickly to know what exposure is to decide:
 - To “roll over” and plea – cooperate
 - Defend to max
- First hint – often is a subpoena for documents

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Addressing Criminal Exposure ...

- Handling subpoenas
 - Custodian of documents – secures documents
 - Communicate to all employees on document retention – must ensure no chance of obstruction claims
- Handling with officers & employees that may have exposure – very delicate – remember that company counsel is just that ... the company's
- Do not discuss facts under investigation outside company

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Crisis Management Mistakes*

1. Don't fall apart. Unraveling is no way to hold things together. If you become a basket case, everyone else will, too.
2. Don't freeze or become immobilized. CM requires action, not paralysis.
3. Don't run away -- physically, mentally or emotionally. The first keys to recovery from mishap are presence and visibility.
4. Don't ignore the problem. Pretending bad things didn't happen won't make them go away. It will only make you look like a fool on top of everything else.
5. **Don't deny the obvious. Denial is a form of lying.**

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Crisis Management Mistakes*

6. Don't attempt a cover-up. It usually makes things worse.
7. Avoid blaming and finger-pointing. These are excuses, not solutions.
8. ***Don't procrastinate. Delaying action only adds to the problem.***
9. Don't just keep on doing what you've been doing. When something goes wrong, more of the same is not an antidote.
10. Don't give up. Once you surrender, there is no possibility for triumph. During the dark hours, avoiding costly mistakes can give you a leg up on out-lasting disaster.

*Robert D. Ramsey in Supervision (Oct 2004, Vol. 65, Issue 10)

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Crisis Management –

Disclosure and Other Corporate Law Duties Owed By Regulatory Professionals at Publicly-Held Companies

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Caveat

- I am an FDA regulatory attorney, not an SEC lawyer
- But, this could happen to you ...
 - My first day as General Counsel of Par Pharmaceutical, a publicly-traded company, the CFO says to me, “we have this situation [*can't tell you what it was*], do we need to disclose this?”
 - *Can't tell you my answer either* -- but there was no press release that day or for a number of days thereafter until we sufficiently completed an internal investigation

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Duties

- **FDA-Regulated Firms**
 - Lawfully market safe and effective products that are not adulterated or misbranded
 - U.S. v. Park – responsible corporate agents in a position to prevent a violation can be criminally liable for FDA violations event w/o intent or knowledge
 - Duty to seek out potential violations
 - No affirmative duty to publicly disclose “material” information
 - Affirmative duties to disclose to FDA
 - Field Alerts – 314.81 – mix-ups or specifications failures
 - Stability commitments

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Duties ...

- **SEC Regulated Firms**
 - Very detailed disclosure requirements
 - But, absent an affirmative duty to disclose, silence is not misleading (except may have a duty to correct prior disclosures now learned to be wrong & if you want to trade, must disclose)
 - *Question* – when are there affirmative duties to disclose under SEC law?
 - *Answer* – focus is usually “materiality” of the event -- we will explore some examples later in the FDA context
 - No overt duty to investigate corporate problems; **however**, under SOX, now are multiple duties on a company to have adequate procedures to ensure accuracy of public reports
- **Stock Exchanges – NYSE ♦ NASDAQ**
 - Have more affirmative duties to disclose – usually done via press release

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Duties ...

- **General Corporate Law –**
 - No overt duty to disclose material information to public
 - Related duties impacting corporate responsibility
 - Delaware law – must have an adequate compliance program to prevent violations and probe to ensure violations did not occur – Caremark (1996)
 - McCall (2001): Columbia/HCA shareholder derivative action against board members;
 - Directors lose protection of “business judgment” rule and are personally liable for failure to detect and correct violations
 - Board’s duty of care breached through nonfeasance: failure to investigate items from internal audit

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Timing Rules

- **FDA**
 - Annual reports – INDs & NDAs
 - Field Alerts – 3 “working” days
 - Adverse Events –
 - Unexpected serious AE -- “as soon as possible,” but no later than 15 calendar days
 - Others – quarterly for first 3 years post-approval; then annually
- **SEC**
 - Annual & quarterly reports – updates since prior
 - 8-K’s – for certain specified and “other events” – supposed to implement SOX “real time issuer disclosure” requirement – within 4 business days of the event

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Codes of Ethics

- **SOX** – for senior financial officers
- **NYSE & NASDAQ** – for whole company
- **FDA**
 - No duty to have a code
 - Exception – Application Integrity Program – then need one

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Record Retention

- **SOX** – 7 years
- **FDA** – vary – but less than that typically
 - Caution – record retention beyond required may come back to both help you or haunt you – implement with care

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Life Sciences Companies Disclosures and the SEC

- **For a disclosure to be actionable**, it usually must be both false or misleading and “material” – thus, these are fact-specific scenarios
- **“Material”** – info would have “actual significance in the deliberations of the reasonable shareholder”

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Life Sciences Companies Disclosures and the SEC ...

- **Forward Looking Statements –**
 - Safe harbor
 - Must be a “meaningful cautionary” statement – and not omit any key information as well
 - Only liable if false statement made with actual knowledge of its falsity
- **Predicting FDA approval -- OK to be wrong as long as there was a reasonable basis for the initial prediction**
 - But, contrast if those making the disclosure knew a key undisclosed fact that seriously threatened the predicted approval time
 - No clear duty to update

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Life Sciences Companies Disclosures and the SEC ...

- **Adverse Events –** must be “statistically significant” to be “material”
- **FDA reports on pending applications – e.g.,** advance copy of a highly negative FDA staff report to an advisory committee
 - Depends on what you do with them; beware continuing to make positive statements (Zila & Zenith)
 - But, just because you get a bad 483 or report on a submitted study, does not mean that a prediction of approval or other statement on a product will be found to be false (Sabratek)

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Life Sciences Companies Disclosures and the SEC ...

- **Clinical Trial Results –**
 - If disclosure involves an interpretation of the results, will only be actionable if not within the range of reasonable science
 - No duty to disclose all facts about a study, as long as those selected are done in a reasonable way and any omissions would not render the disclosure “so incomplete as to mislead”
 - Negative trial results
 - You have a reasonable time to evaluate – until you do, you lack “material information”
 - No overt duty to disclose, except if:
 - Your officers are trading in the stock
 - Public statements are misleading if the results are NOT disclosed

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Life Sciences Companies Disclosures and the SEC ...

- **Pending Investigations and Inspections –**
duty to disclose – company must look at to the probability and magnitude of a particular sanctions in evaluating if it’s material
 - *Abbott Consent Decree* – not material
- **A way to analyze – weigh:**
 - Degree of noncompliance
 - Likelihood of resulting FDA action
 - Projected impact of such action on the company

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Life Sciences Companies Disclosures and the SEC ...

- **Recommendations –**
 - have a prescribed process – and follow it -- for reaching internal consensus on what to publicly disclose on test results so that contrary memos don't come back to haunt you
 - Define terms used to describe test results with precision – and in the disclosure document

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Life Sciences Companies Disclosures and the SEC ...

- **Recommendations ...**
 - Be very careful to not infer FDA's conclusions on a matter – just report actions
 - Once you've made a disclosure about FDA, you have to reevaluate it as time passes and (a) either additional events occur or (b) new SEC reports are required (e.g., quarterly)

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FDA-SEC Cooperation Post-Imclone

- February 2004 – new ground rules on FDA interacting with SEC
 - FDA staff now can refer any information they may have about a suspected misstatement by an FDA-regulated public company to FDA General Counsel for review and tender to SEC
 - Blanket authorization for FDA staff to cooperate with SEC inquiries

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Key Internal Procedures

- Disclosure Committee
 - Executive
 - Financial
 - Legal
 - Other key components depending on maturity of company
 - Clinical or R&D
 - R.A. and Q.A.
- Counsel – SEC, Corporate and FDA

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Crisis Management

What Do Vioxx and Guidant Got To Do With It?

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A New Paradigm? ... or Is Ignorance Not Bliss? ... A Few Thoughts for Later

- Has the bar been raised by what has been reported about corporate handling of drug and device safety?
- If it has, how do you react today?
 - Do you have a duty to investigate even in the absence of any indicia of a problem?
 - Who are the enforcers – FDA or DOJ or Dr. David Franklin or Bill Lerach or Tom Pirtle?

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A Few Parting Thoughts

These are pictures you do not want to see

- in your newspaper*
- on your local news*
- on the Internet*

• or

- in FDA regulatory lawyers' presentations for years to come*

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Ex-Imclone CEO Exits Federal Court After Being Charged with Nine Felony Counts



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Ex-Imclone CEO exits federal court after entering guilty plea ...



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THE RESULT ...

- ***Pled guilty October 15, 2002 to six counts, including:***
 - Bank fraud
 - Securities fraud, aka “insider trading”
 - Conspiracy to obstruct justice, and
 - Perjury
- ***Faced:*** up to 65 years in prison; millions in fines

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THE SENTENCE

- 7- year 3-month prison sentence
 - with no parole
- \$3 million fine
- \$1 million in back taxes
- Where can you find him now?
 - Schuylkill Federal Correctional Institute in Minersville, Pa. (been there since July 2003)

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Let's Go Back to My First Day at Par

- Did I have a duty to disclose?
 - Was the information “material”
 - No – because it had not been investigated
 - Indeed – premature disclosure can harm the markets as well
- Things are not always that easy

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Generic Drug Scandal -- Could it happen again?

- Of course – people are fallible
- Your job – be prepared to be able to address if it happens on your watch
- Risk Management – a key to avoiding crisis management

"The price of freedom is eternal vigilance."

-- **Thomas Jefferson** &/or **Wendell Phillips**

"Noncooperation with evil is as much a duty as cooperation with good."

-- **Gandhi**

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Questions?

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