A Crisis History – The Generic Drug Scandal

RAPS Annual Convention 2014
Austin, Texas

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2014 RAPS
THE REGULATORY CONVERGENCE
27 September–1 October
Austin, Texas

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Crisis Management

The Meaning of Crisis

When written in Chinese, the word "crisis" is composed (theoretically) of two characters:

"*danger*"

and

"*opportunity*"

--**John F. Kennedy**

(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)

60 Seconds of 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

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/founder and the President of Par's Quad subsidiary
    - FDA Generic Drug officials

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 Par senior VP/founder 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

How We Faced The Crisis?

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

How We Faced The Crisis …

- **"Voluntary Declaration"** – was the vehicle for expressing the cooperation
  - Audits by outside experts
    - Integrity
    - GMP
    - Batch releases
  - Code of conduct
  - Ethics training – access to outside board members
  - Cooperation with federal investigators
- **Today** – likely would be done via a consent decree

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

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

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

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

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

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

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

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
  - Often required as part of a Corporate Integrity Agreement (CIA) required by the Office of Inspector General (OIG) of HHS as part of settlement of criminal charges

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"

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
  - 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)

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

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

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

- 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 (before he went to prison) or Tom Pirtle?

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 – so you need to be prepared:**
  - Crisis Committee – identify the spokesperson
  - Crisis Procedure
  - Mock Crises – unannounced to simulate "real"
  - crisis

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 – (see prior slide)

"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**

Closing Sermon

- **P**lease -- *P*rocedures
- **T**each – *T*raining
- **R**isk – *R*ecords
- **A**voidance – *A*udits
- **V**igorously – *V*alidate
- **C**omprehensively – *C*ommunication – Open Lines – *and*
- **C**orporately -- *C*orporate *C*ulture of *C*ompliance

Questions?

- ***Call, e-mail or fax:***

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About Your Speaker

Michael A. Swit, Esq., is a Special Counsel in the San Diego office of the international law firm, Duane Morris, LLP, where he focuses his practice on solving FDA legal challenges faced by highly-regulated pharmaceutical and medical device companies.

Before joining Duane Morris in March 2012, Swit served for seven years as a vice president at The Weinberg Group Inc., a preeminent scientific and regulatory consulting firm in the Life Sciences. His expertise includes product development, compliance and enforcement, recalls and crisis management, submissions and related traditional FDA regulatory activities, labeling and advertising, and clinical research efforts for all types of life sciences companies, with a particular emphasis on drugs, biologics and therapeutic biotech products.

Mr. Swit has been addressing vital FDA legal and regulatory issues since 1984, both in private practice with McKenna & Cuneo and Heller Ehrman, and as vice president, general counsel and secretary of Par Pharmaceutical, a top public generic and specialty drug firm. He also was, from 1994 to 1998, CEO of *FDANews.com,* a premier publisher of regulatory newsletters and other specialty information products for FDA-regulated firms. He has taught and written on many topics relating to FDA regulation and associated commercial activities and is a past member of the *Food & Drug Law Journal* Editorial Board.

He earned his A.B., *magna cum laude*, with high honors in history, at Bowdoin College, and his law degree at Emory University, and is a member of the California Bar and previously was admitted in both Virginia and D.C., but is inactive in those jurisdictions.