

# Second Annual FDA Regulatory and Compliance Symposium

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# LESSONS LEARNED

## WHAT SERIAL PRODUCT LIABILITY LITIGATION HAS TAUGHT BIG PHARMA

# Background

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Last few years marked by series of cases against large pharmaceutical companies:

- Phen-Fen/Diet Drugs
- Vioxx
- HRT
- Medical Devices

# Background

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- Shift of emphasis from earlier litigation against drug manufacturers
- Imported theories/strategies from other mass tort litigations, e.g., asbestos, silica, welding fumes
- Emphasis on conduct, marketing, internal company communications and general causation

# Marketing: The Issues

- The tension between marketing and regulatory/legal concerns is palpable
- Successful marketing staff are generally ebullient, outgoing, prone to the “spin” and to aggressively “promote” the product
- Tendency to use rhetorical devices, clever or catchy phrases and other incentives to “close the deal”
- Marketing benefits against “The Science”

# Marketing: The Issues

## Sales Force is Generating Evidence

- Reactions to negative publicity or scientific findings
- Swift, often defensive “circle the wagons” mentality
- Sometimes offensive: aggressively pursue/discredit the “new” science or the scientists who have done the negative study
- Production of sales notes from sales calls – often very colorful

# Marketing: The Issues

## Sales Force is Generating Evidence

- Direct to consumer advertising and promotional items complicate the picture
- Focus of plaintiffs' lawyers on discovery
- The weaker the case for medical causation – the more emphasis necessary on marketing the product

# Marketing: The Issues

## Tips For The “Morning After”

After the first flurry of negative publicity

- Eliminate the Rhetoric
  - > Litigation fueled by the “overweight plaintiffs who smoked”
  - > Eradicate the editorial comments: “Just the Facts”
- Moratorium for a few days on all email
  - > use phone
  - > personal visits
  - > use legal pads



# Marketing: The Issues

## Tips For The “Morning After”

After the first flurry of negative publicity

- Inoculate your staff with email risk management training techniques
- Limit sales call notes to drop down box of choices to memorialize call

# Marketing: The Issues

## Marketing Shouldn't Drive Science

- Maintain process where marketing does not drive/control science
- Direct to consumer already threatens the protection of “learned intermediary”
- Company can nullify its own warnings by over-reaching in touting benefits
- Pharma companies can lose the gloss from their halos if they are viewed as pedaling “Pepsi”

# Marketing: The Issues

## Marketing Shouldn't Drive Science

- In marketing benefits – beware of benefits that have not been tested
- Use “fair balance” of risks and benefits
- Watch promotions to prescribers

# Marketing: The Issues

## The Investigative Phase

After adverse publicity – during the investigative phase:

- Focus on facts not conclusions
- Avoid editorial comments
- Appoint strong leader who drives the process

# Marketing: The Issues

## The Investigative Phase

After adverse publicity – during the investigative phase:

- Prevent “on the fly” decisions
- Beware of concessions about knowledge of the problem
- Do not concede the defect in the product
- Close the circle – bring closure to any open issues

# The FDA As A Shield

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- Vioxx and other adverse publicity undermines protection of FDA
- FDA supports pre-emption in certain circumstances
- Don't "bury" important/adverse information in presentation to FDA
- Make sure marketing does not drive the science
- Avoid the "race to market" impression – don't cut corners in heat of competition to get to the marketplace

# Plaintiffs' Theories Themes

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- Focus on marketing - bad conduct of companies
- Profits over safety
- Rush to market
- “Call to battle” theme

# Plaintiffs' Theories Don't Play Into Their Themes

- Using celebrities to promote products can backfire
- Science bias – “buying research” undermines medical defenses
- Legitimate, arms-length relationships with academic researchers is important
- Bonuses tied to sales
- Avoid sales gimmicks – “obstacle blocker” videos – blocking sales



**THE END**

