

# WINNING STRATEGIES:

How to Create, Grow, and Sustain  
a Successful Life Sciences Company



## WINNING STRATEGIES: How to Create, Grow, and Sustain a Successful Life Sciences Company



### From Office to Off-Label: Managing Risk and Protecting Assets

## Panelists



### **Moderated by:**

Emily Urban, Senior Vice President, Berkley Life Sciences

### **Speakers:**

Anne Nevard, Risk Management Executive

Judith Waltz, Partner, Foley & Lardner LLP

George Ward, Director of Risk Management, Corporate  
Compliance, Amylin Pharmaceuticals, Inc.



Anne Nevard, Risk Management Executive

## Developing a Risk Management & Insurance Program



- Determine a Company's Risk Tolerance
- Implement Risk/Insurance Programs
- Communicate Risk Philosophy

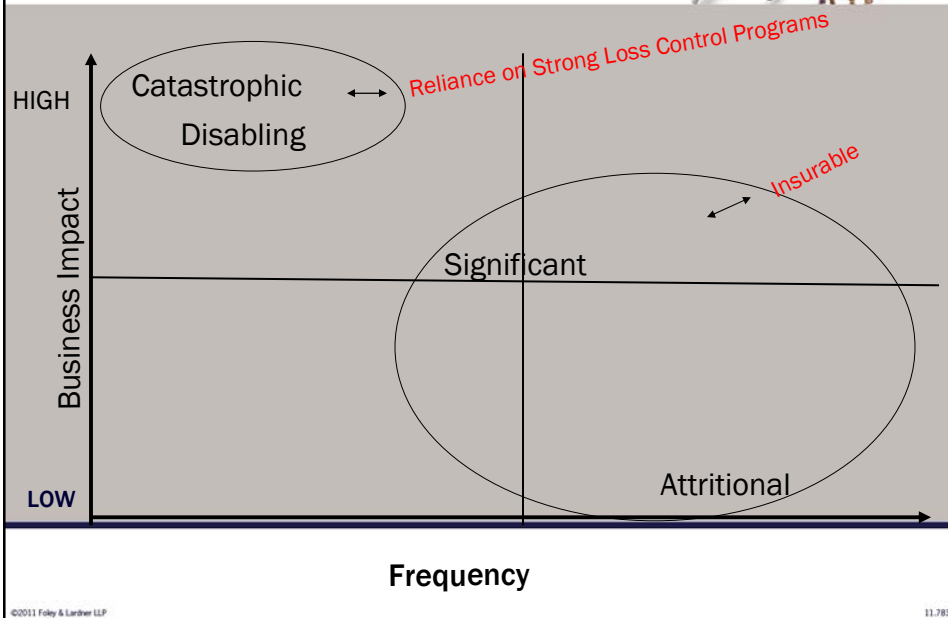
## Determining Company's Risk Tolerance



### Growth Stages

Start Up Company	Mid-Size Company	Industry Leader
<b><i>Risk Averse</i></b>	<b><i>Some Risk Acceptance</i></b>	<b><i>Not Risk Averse</i></b>
<ul style="list-style-type: none"> <li>▪Restricted Cash</li> <li>▪Purchase insurance limits=value at risk/low deductibles</li> </ul>	<ul style="list-style-type: none"> <li>▪Some Free Cash Flow</li> <li>▪Insurance limits increase while deductibles increase</li> </ul>	<ul style="list-style-type: none"> <li>▪Reliance on cash flow/reserves/bank relationships.</li> <li>▪Large self-insurance programs</li> </ul>
<b><i>Exposures</i></b>	<b><i>Incremental Exposures</i></b>	<b><i>Incremental Exposure</i></b>
<ul style="list-style-type: none"> <li>▪Localized/regional</li> <li>▪Patents</li> <li>▪Contractual obligations</li> <li>▪Suppliers/contract mfg</li> <li>▪Clinical Safety</li> </ul>	<ul style="list-style-type: none"> <li>•Global expansion/mfg</li> <li>•Product injuries/recall</li> <li>•Marketing &amp; Sales Behaviors/Reputation</li> <li>•Board/Management Decisions</li> </ul>	<ul style="list-style-type: none"> <li>•Stock volatility</li> <li>•Global/large M&amp;As</li> <li>•Public Scrutiny</li> <li>•Competition (generics)</li> <li>•Gov't regulations</li> </ul>
<b><i>Stakeholders</i></b>	<b><i>Additional Stakeholders</i></b>	<b><i>Additional Stakeholders</i></b>
<ul style="list-style-type: none"> <li>•Venture Capitalists</li> <li>•Employees</li> <li>•Patients</li> </ul>	<ul style="list-style-type: none"> <li>•Shareholders</li> <li>•Local Environment (neighbors/community)</li> </ul>	<ul style="list-style-type: none"> <li>•Counterparties/third parties</li> <li>•Global Environment</li> </ul>

## Risk Acceptance/Risk Transfer



## Implementing Risk Management/Insurance Programs



### Start Up Company

Insurance usually purchased by finance employee  
Reliance on brokers and outside resources

#### Risks

- Document retention (for potential future claims)
- Over/under insured (no loss history)
- Misunderstanding of what is/is not insured
- Mishandling of claims/limited or no loss control programs

#### Risk Mitigation Techniques

- Implement and record archive system for policies, renewal records, etc for potential future use (claim could be filed years later)
- Evaluate company's risk tolerance and insure accordingly
- Benchmark with like-size peers
- Read policy and questions what you don't understand
- Ask internal legal staff to read policy
- Establish and communicate claims handling procedures (broker will help you write) specific for your company
- Contract risk management professional to conduct renewals and implement programs

## Implementing Risk Management/Insurance Programs



### Mid-Size Company

Insurance usually purchased by staff insurance professional  
Reliance on brokers & outside resources for guidance, marketing, modeling

#### Risks

- Lack of policies and procedures
- Insurance professional not known within company, “silos”
- Complex insurance applications signed by officers
- Focus is on insurance, not risk management
- Lack of uniform metrics across company

#### Risk Mitigation Techniques

- Write policies and procedures for such things as obtaining clinical trial insurance, claims reporting (auto, workers comp., property, product, D&O, etc.), contract insurance language templates
- Build cross-functional relationships. Conduct “Show and Tell” cross-functional meetings to communicate and implement policies and procedures.
- Ensure all insurance applications are reviewed by legal prior to obtaining officer’s signature
- Utilize risk modeling to evaluate insurance limits/deductibles and to assess supply chain, distribution, and other risks. Possible implementation of ERM study using outside resource

## Implementing Risk Management/Insurance Programs



### Industry Leader

Insurance Negotiated by Risk Management/Insurance Professional  
Reliance on brokers & outside resources for modeling, marketing, advice

#### Risks

- Budget restrictions
- Risk Management not integrated across company
- No assigned accountability for risk mitigation
- Risk program not aligned with business objectives/strategic planning

#### Risk Mitigation Techniques

- Build case studies showing financial benefit for implementing programs and obtaining headcount
- Create an internal risk committee
- Quantify hazard, financial, operational and strategic risks, sophisticated modeling
- Implement global ERM program
- Present ERM findings showing potential impact on business objectives/planning

## Communicating Risk Philosophy



### -Top Down Communication

- A letter from the “C Suite”

### -Educate employees

- Internal contacts for risk management guidance
- Reporting of incidences/claims
- Internal/external behaviors
- Social media use
- Employees authorized to sign contracts

## Implementing Risk Management/Insurance Programs



### Take Aways

- Risk tolerance varies, depending on company’s growth stage, loss history & cash
- Focus on establishing policies and procedures during start-up phase
- Build cross-functional relationships for an integrated approach
- Quantify financial impact to justify implementing mitigation programs, building risk management/insurance teams. Launching company-wide initiatives
- Have “C Suite” communicate corporate risk management philosophy



**George M. Ward, Director of Risk Management and Compliance, Amylin Pharmaceuticals, Inc.**

**Insurance and Risk Management Techniques to Treat Risks**



- **Typical Risks to a Life Science Risk Company**
  - Regulatory Actions
    - FDA Actions/Alerts/Correspondence/Statements/Warning Letters
    - Public Company Risks - SEC and Shareholder Activism
  - Compliance with GXP Standards at your labs, clinics, and plants
  - Strategic Relationships
    - Contract Manufacturing Organizations
    - Clinical Research Organization
    - Outsourced R&D
    - Collaboration Partnerships
    - Supplier Performance
  - Supply Chain and Distribution Risks
  - Trend to Virtual Companies to save expenses

## Risk of Potential Claims



- All of these can generate claims that might trigger Clinical Trial/Product Liability or D&O Insurance
- Regulatory Actions can generate attorney advertising by “Bad Drug Injury Legal Center” or “Shareholder Rights Organization”
  - Funnel consumers, customers and shareholders to law firms who solicit cases via the internet
  - Risk Management Implications are the risk of product liability claims or management liability claims against directors and officers or securities claims against the entity
  - Product Liability Causes of Action
    - Strict Liability – Failure to Warn
    - Negligence in advising consumers or healthcare providers
    - Fraud – failed to advise despite knowledge of an issue or suppression of facts
    - Negligent Misrepresentation
    - Consumer Legal Remedies Act
      - Off-Label Promotion or representing approved for a use when not
      - Promotion of products as safe and effective when not , etc.
  - D&O Causes of Actions
    - Sec 10b5-1 (Insider Trading)
    - Sec 11 (Disgorgement of ill gotten gains)
    - Reg FD (Disclosure of risks to investors, at the same time!)

## Insurance Techniques to Transfer the Risk



- Why buy insurance?
- Transfer the risk
- Claims are expensive!
  - Product /Clinical Trial Liability Claims
  - D&O Claims
- Individual Claims
- Mass tort or shareholder claims
- Legal Costs, eDiscovery Costs
- Liberalization of Statute of Limitation Rules
- Plaintiff Attorney Networks – the finders, the minders and the grinders
- Soft Market – lots of capital – the perfume of the premium can overcome the odor of the exposure
- Insurer can be a source of information to control and manage the risks



## Insurance and Risk Management Techniques



- **Product/Clinical Trial Liability Policies Points**
  - Batch or related occurrence endorsement/deductible?
  - Expected or intended exclusion modified to cover known side effects or injuries (label, informed consent)
  - Policy complies with contractual requirements
    - Clinical investigators or site organizations or scientific advisory boards are a blanket additional insured
    - Vendor endorsement or additional insured where required by written contract
  - Duty to defend or duty to indemnify
- **D&O – Management Liability Policies**
  - Basic policy designed to fail
  - Multiple endorsements and definitions are usually added to a D&O policy
  - Claim reporting, choice of counsel, non-rescindable, advance expenses, severability, investigation costs, modification of Insd. v. Insd. exclusion, outside entity, punitive damage claim, notice of potential claim, discovery periods, order of payments, definition of claim, etc.
- **Crisis Management Services**
- **Enterprise Risk Management Programs**



Judith Waltz, Partner, Foley & Lardner LLP

## What Is the Price to Pay for Off-Label Promotional Violations?



- Warning Letters from FDA
- Increased Regulatory Scrutiny
- Investigation into Reimbursement Issues – False Claims Allegations
- Criminal Penalties for Misbranding
- Civil Penalties
- Corporate Integrity Agreement (Part of Civil Settlement)
- Potential Exclusion from Federal Healthcare Programs
- Shareholder Suits
- Personal Liability for Officers
- Adverse Event Liability
- REMS

## What is a “label”?



- FDCA Section 201(k) – “display of written, printed, or graphic matter upon the immediate container of any article.”
  - 21 U.S.C. § 321(k).
- FDCA Section 201(m) – labels and other written, printed or graphic material.
  - (1) Upon any article or any of its containers or wrappers;
  - or
  - (2) Accompanying such articles.
- 21 U.S.C. § 321(m).

## FDA – 3 Important Principles



- A manufacturer or company can (subject to numerous caveats and other laws):
  - Respond to unsolicited requests for clinical and scientific data from a physician
  - Provide information as part of independent continuing medical education (CME)
  - Provide information contained in peer-reviewed scientific and medical journals

## Enforcement Focus on Promotion, Not Use



- Under most circumstances, it is not illegal, or even improper, for a physician to prescribe, or for a patient to use, prescription drugs in for off-label purposes.
- 21 U.S.C. § 396 – Nothing in the FDCA shall be construed to limit or interfere with the authority of a HCP to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate healthcare practitioner-patient relationship.

## Evidence of Promotional Activities



- Small market for approved use; large market for off-label use
- Increases in off-label use after conferences hosted by manufacturer
- Business Plans
- Hidden (or overt) company funding for research, articles, speeches
- Promotional activity aimed at off-label prescribing
- Financial incentives for off-label use
- Negative health effects of off-label use
- History with FDA

## Primary Theories of Liability for Improper Off-Label Promotion



- Criminal violations
  - FDCA
  - Anti-Kickback Statute
- Civil Violations
  - False Claims Act
  - Anti-Kickback Statute (resulting in civil false claims or as a basis for a CMP)

## Criminal Prosecutions



- Unapproved “New Drug” – 21 U.S.C. § 331(d) – company distributed “labeling” that accompanied the drug and prescribed, recommended or suggested the drug for an unapproved use
  
- Misbranding – 21 U.S.C. § 331(a) – labeling bears inadequate directions for use or its labeling is false or misleading. See 21 U.S.C. § 352(a)

## False Claims Act (31 U.S.C. § 3729)



- The False Claim Act imposes liability for persons who
  - Present or cause to be presented
  - A false or fraudulent claim for payment to the U.S. government
  - With knowledge the claim is false
    - Deliberate ignorance or reckless disregard will satisfy the knowledge element
  - Includes qui tam (whistleblower) provisions

## FCA Whistleblower Recoveries



- FCA relators are generally given a significant financial incentive to “blow the whistle” – percentages and reasonable attorney fees and costs paid by the defendant.
- *If the government intervenes*, the relator is entitled to not less than 15% and not more than 25% of the recovery.
- *If the government does not intervene*, the court will decide what is reasonable from 25% to 30%, plus reasonable expenses.

## Novartis – May 2010



- \$72.5 million to resolve civil False Claims Act allegations arising from the marketing of the cystic fibrosis drug TOBI, . . .
- The United States alleges that Chiron, and then Novartis, marketed TOBI for unapproved uses, such as diseases other than cystic fibrosis, and for cystic fibrosis patients who did not meet the parameters of the FDA-approved indication and for which TOBI was not a medically accepted use.

Source: U.S. Dept. of Justice Press Release: *Novartis Vaccines & Diagnostics to Pay More Than \$72 Million to Resolve False Claims Act Allegations Concerning TOBI* (May 4, 2010)

## Ortho-McNeil – Criminal -April 2010



- \$81 Million - Civil and Criminal (misdemeanor) Settlement.
- \$6.14 million criminal fine for the misbranding of Topamax in violation of the Food, Drug and Cosmetic Act;
- \$75.37 million to resolve civil allegations under the False Claims Act
- "Doctor-for-a-Day" program - Ortho-McNeil hired outside physicians to join sales representatives in their visits to the offices of health care providers and to speak at meetings and dinners about prescribing Topamax for unapproved uses and doses.

U.S. Dept. of Justice Press Release, *Two Johnson & Johnson Subsidiaries to Pay Over \$81 Million to Resolve Allegations of Off-Label Promotion of Topamax* (April 29, 2010).

## AstraZeneca – April 2010



- \$520 Million
- Anti-psychotic Seroquel marketing directed towards doctors who do not typically treat schizophrenia or bipolar disorder, such as physicians who treat the elderly, primary care physicians, pediatric and adolescent physicians, and in long-term care facilities and prisons. . . .
- Improperly and unduly influencing the content of, and speakers, in company-sponsored continuing medical education programs.
- The company also engaged doctors to give promotional speaker program.
- In addition, the company recruited doctors to serve as authors of articles that were ghostwritten by medical literature companies and about studies the doctors in question did not conduct.

Source: U.S. Dept. of Justice Press Release, *Pharmaceutical Giant AstraZeneca to Pay \$520 Million for Off-label Drug Marketing* (April 27, 2010)

## Atricure - February 2010



- \$3.76 Million
- Allegedly marketed its medical devices to treat atrial fibrillation (the most common cardiac arrhythmia or abnormal heart rhythm),
- Promoted expensive heart surgery using the company's devices when less invasive alternatives were appropriate, advised hospitals to up-code surgical procedures using the company's devices to inflate Medicare reimbursement, and paid kickbacks to health care providers to use its devices.

Source: U.S. Dept. of Justice Press Release, "Atricure To Pay U.S. \$3.76 Million To Resolve Medicare Fraud Allegations" (February 2, 2010)

## Quest Diagnostics - April 2009



- \$302 million
- NID manufactured, marketed and sold the Intact PTH and Bio-Intact PTH test kits, despite knowing that between May 1, 2000 and April 30, 2006, some of these kits produced results that were materially inaccurate and unreliable,

Source: Press Release from the U.S. Attorney's Office for the E.D.N.Y., "QUEST DIAGNOSTICS INCORPORATED TO PAY \$302 MILLION TO RESOLVE ALLEGATIONS THAT A SUBSIDIARY SOLD MISBRANDED TEST KITS" (April 15, 2009)





# QUESTIONS?

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