



ENTERPRISE RISK MANAGEMENT
ERM
Symposium
Where Cutting Edge Theory Meets Some of the Art Practice

Counterfeit and Tampering Risk Modeling for Pharmaceuticals

Canadian Institute of Actuaries / Institut canadien des actuaires, PRMIA, and other professional organizations.

Agenda

- ↳ Introductions
- ↳ Background on Genentech
- ↳ Risk assessment
 - Popular Method
 - Pitfalls
- ↳ Solution
- ↳ Case study
- ↳ Q&A

AON

Introductions

- ↳ Eric Stocker
 - Associate Director, Risk Management
 - Genentech (Roche)
- ↳ Christopher (Kip) Bohn
 - Director and Actuary
 - Aon Global Risk Consulting
- ↳ Barry Franklin
 - Principal
 - Towers Watson



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Genentech's Corporate Context

- ↳ Cutting edge therapies for unmet patient needs
- ↳ Delivery to patients must not be interrupted
 - Life-saving therapies without substitute
 - Reputation
 - Financial impacts
- ↳ Regulation around drug safety and security are evolving
- ↳ High profile incidents in the media



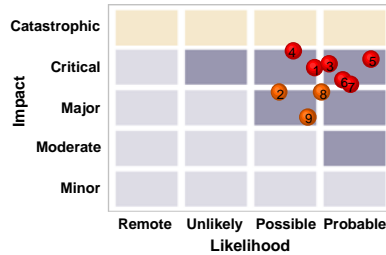
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Risk Assessment

Scoring method

- Arguably the most popular assessment tool for non-financial organizations
- Easy to understand
- Scoring usually defined on an ordinal scale (1-5, 1-9, HML, etc.)
- Data generally gathered through
 - Surveys
 - Workshops
- Often collect 2 scores
 - Frequency or likelihood
 - Impact or severity
 - Some collect other scores (e.g. duration)

Sample Risk or Heat Map



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Risk Assessment

Pitfalls of scoring methods

- Framing (see example to the right)
- Illusionary superiority (or the "Lake Wobegon Effect" where "all the children are better than average.")
- Range compression – limiting choices from 1-5, 1-10, small change in opinion can result in large change in scale
- Is 2 twice as big as 1? Is 5 five 2.5x worse than 2?
- Other biases based on perception of risk, where you sit in the organization, etc.
- Correlation is not captured

Scoring results

- Often Frequency and Impact scores are multiplied
- Often clustering in the upper right if placed on a heat map
- Don't represent risk – point estimates

A survey was given to two groups of people around a new treatment program to be administered to 600 patients

- Group A: Choose between
 1. Program 1 will save 200 people (72% selected)
 2. Program 2 has a 1/3 chance of saving everyone and a 2/3 chance of saving no one (18% selected)
- Group B: Choose between
 1. Program 1 will kill 400 people (12% selected)
 2. Program 2 has a 1/3 chance that no one will die and a 2/3 chance 600 will die (78% selected)

The Failure of Risk Management: Why it's Broken and How to Fix it, Douglas W. Hubbard



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Solution

↳ Goal: Develop a model that

- Sells the services of the Risk Management methodology to other parts of the organization
- Is understandable to the organization and has buy-in
- Describes the entire distribution of potential outcomes
- Based model on actuarial and quantitative concepts
- Utilize as much industry data on which to base assumptions on as possible
- Pull as much industry expertise from the “risk owners” while not putting too much weight on scoring methods in the model
- Accounts for key costs that could be incurred
- Consistent model to consider impact of mitigation



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Solution

↳ Models that were considered

- Qualitative scoring
- Frequency and severity model
 - Model of choice for P&C actuaries
 - Easily overlay insurance structures – other mitigation can be tricky
 - Break problem into two main components
 - Frequency distribution
 - Severity distribution
 - Ultimate goal is to determine aggregate distribution
- Decision tree
 - Based in the frequency and severity concept
 - Potential for many paths



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Solution

- ↳ Chosen solution was a hybrid of all three model types
- ↳ Overview of process
 - Interview “risk owners” to better understand the risk as well as current mitigation
 - Identify key areas of vulnerability surrounding the risk in the organization
 - Supply chain
 - Internal and external factors
 - Define rules for assigning a relative score to each area
 - Remove as much qualitative aspect as possible
 - Attempted to “calibrate” experts
 - Completely removed severity from the exercise



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Solution

- ↳ Overview of process (continued)
 - Develop overall frequency assumption
 - Based on historical, industry and insurance data
 - Tie back frequency to each individual drug using the frequency relativity
 - Develop severity modules
 - Based on FxS and decision tree models
 - Tie models together
 - Understand mitigation options
 - Incorporate mitigation via adjustments to frequency
 - Recommend course of action to management



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Case Study

Counterfeit and Tampering Prevention Program



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Executive Summary

We assessed Genentech's commercial product portfolio for vulnerability to counterfeiting and tampering risk. Our evaluation included an assessment of the various risk drivers such as the supply chain vulnerability, loss history, and competition. We considered the economic effect based on recall costs, lost market share, product liability losses, and shareholder lawsuits.

LIKELIHOOD	
Product	Risk Ranking
	2.68
A	2.61
B	2.36
C	2.29
D	2.29
E	2.11
	2.07
	2.04
	2.00
	1.93
	1.89
	1.75
	1.46

Risk Ranking: 1-5 with 5 being highest risk

Of Genentech's marketed products, A is the most likely to be counterfeited.

- > On a severity basis, XXX represent the largest risk at \$\$\$ (99% confidence level, 5yr 10% NPV)
- > Total risk is \$\$\$ (99% confidence level 5yr 10% NPV) for all commercial products
- > 5yr 10% Expected NPV of loss is \$\$\$ for all commercial products

While we have experienced counterfeit events, our controls have proved generally effective. Implementing a comprehensive track and trace program will further protect patients from receiving counterfeit drugs. Our analysis shows this is an NPV positive investment for Genentech.



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Facts & Figures

The US based Center for Medicines in the Public Interest predicts that counterfeit drug sales will reach US \$75 billions globally by 2010

	Counterfeit as % of Market Value
Industrialized Countries (US, EU, AU, etc)	Less than 1%
Developing Markets (Africa, parts of Asia and Latin America)	10% - 30%
Former Soviet Republics	Over 20%
Medicine Purchased over the Internet (sites concealing their physical address)	Over 50%

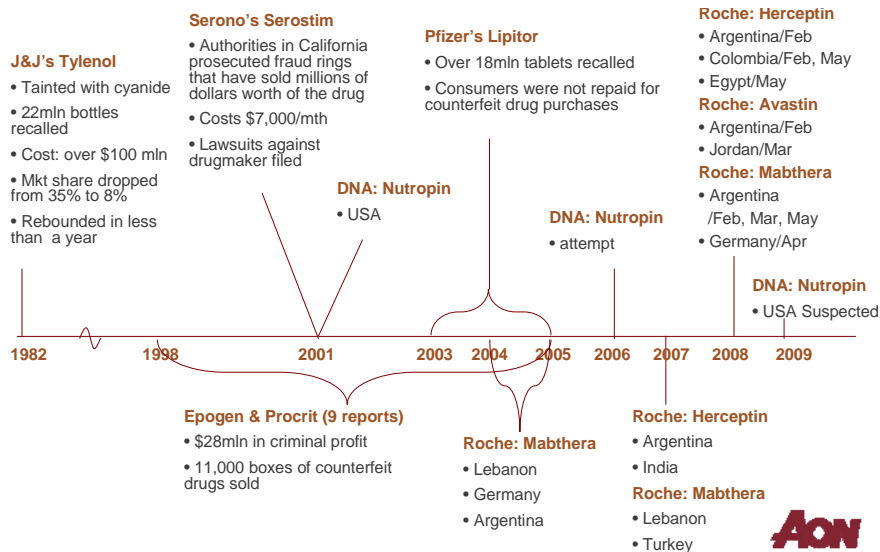
GNE US Commercial Sales

GNE Ex-US Sales & Royalties
~\$\$\$ at Risk



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Counterfeit & Tamper Cases



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Case Study – Baxter’s Heparin

- Heparin is an anti-coagulant. The supplier provided substituted chondroitin sulfate as a drug that mimics the effects of Heparin, in the raw material stage
- Prior to this event, Baxter sold approx 50MM vials per year (avg \$1/dose), supplying 50% of US market
- Dec 2007 Baxter noted an increase in allergic type reactions. January 17, 2008 issues voluntary recall of 9 lots. ◊
- February 28, 2008 Baxter recalls all remaining lots, assured by the FDA that there is adequate supply in the market to meet demand ○
- Over 800 Heparin-related adverse reaction reports to date, between 60 to over 200 deaths linked to Heparin (depending on the source)
- Chinese manufacturer – Techpool Bio-Pharma created JV with Scientific Protein Laboratories called Changzhou-SPL. Prior history: 12 years successful API mfg, over 500,000,000 finished doses, four FDA inspections / audits, five Wyeth/Baxter inspections/audits.



The Heparin counterfeit event does not appear to have materially impacted Baxter's reputation when looking at it from a valuation perspective.

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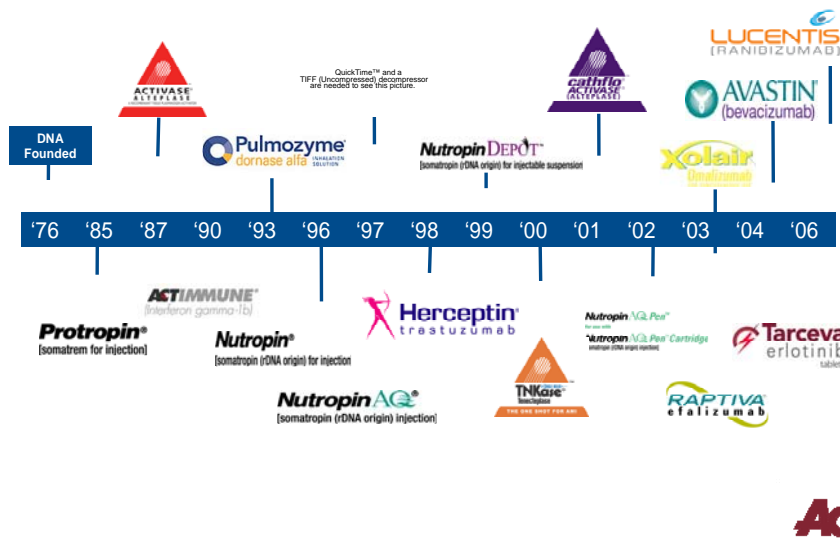
California Pedigree Update

- ↳ SB 1307 - Signed by Gov. Schwarzenegger Sep. 30, 2008
 - Extends implementation deadline and calls for phased in approach
- ↳ Pedigree / serialization
 - Manufacturers - 1/1/2015 (50%); 1/1/2016 (50%)
 - Distributors - July 2016
 - Pharmacies – July 2017
- ↳ Other Provisions
 - Inference, grandfathering, 3PL , reverse logistics
 - Federal preemption language
 - Exemptions

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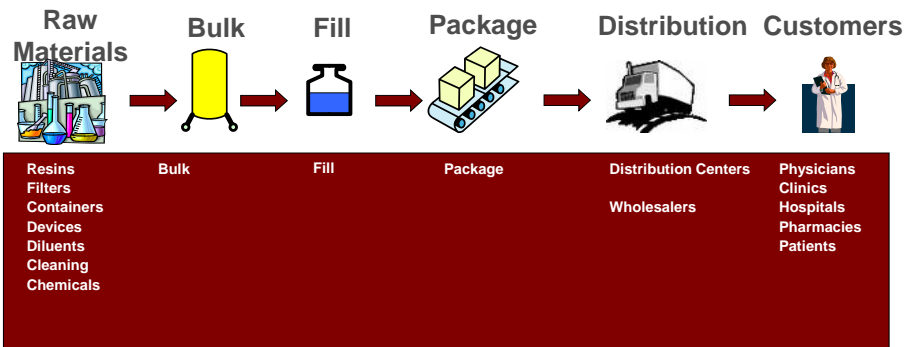
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What's at Risk for Genentech?



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Where is the Risk?



Active Mitigation Strategies

- Supplier Selection
- Supplier Audits
- Internal Business Controls
- Packaging Controls
- Overt packaging technologies
- Direct purchase agreements
- Controlled distribution
- Security & Quality language added to agreements
- Monitor 852/867 data files for trends
- Return vendor audits
- Secure transportation
- Overt packaging features
- Counterfeit Response Protocol & Communications
- Partner with law enforcement

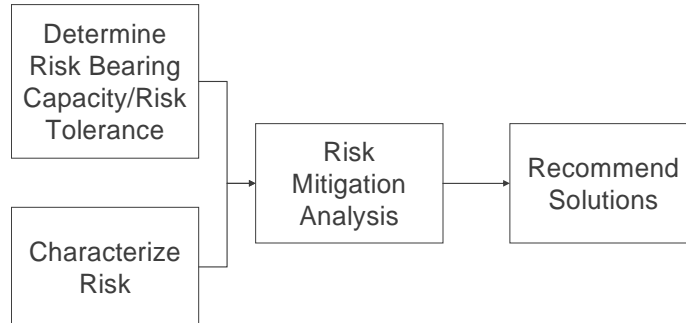


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Risk Analysis Process

Objective

Minimize the Total Cost of Risk to Genentech while operating within our Risk Bearing Capacity & Risk Tolerance.



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Risk Characterization: Likelihood of Occurrence

LIKELIHOOD	
Product	Risk Ranking
	2.68
	2.61
	2.36
	2.29
	2.29
	2.11
	2.07
	2.04
	2.00
	1.93
	1.89
	1.75
	1.46

Risk Ranking: 1-5 with 5 being highest risk

These rankings are mapped into loss probabilities

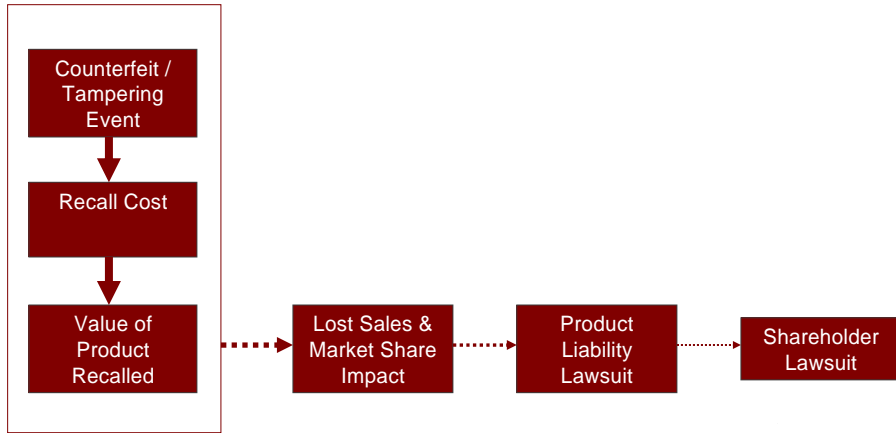
- Supply Chain Vulnerability
 - Raw Material - Distribution
- Black Market Demand
- Administration Type
 - Pill, IM, IV, Inhaler
- Site of Administration
 - Hospital, Clinic, Home
- Counterfeit / Tamper History
- Packaging Controls
 - Bottle, Vial, Device



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Risk Characterization – Severity Drivers

Multiple loss scenarios are possible:



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Risk Characterization - \$ Impact

LIKELIHOOD		5 YR 10% NPV OF IMPACT (\$MM)		
Product	Risk Ranking	Product	Mean	Percentile
	2.68			99.00%
	2.61			99.90%
	2.36			
	2.29			
	2.29			
	2.11			
	2.07			
	2.04			
	2.00			
	1.93			
	1.89			
	1.75			
	1.46			

Risk Ranking: 1-5 with 5 being highest risk

99% confidence considered "reasonably foreseeable"



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Summary of AC Technologies

OVERT (Visible) Examples



- Enables end users to verify the authenticity of a pack
- Normally prominently visible and difficult or expensive to produce. However, Overt features can be simulated
- There are no overt features that are 100% effective

COVERT (Hidden) Examples

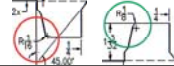


Charms™ in Phantom Ink

Chemical taggants in ink or varnish

- Enables the brand owner to identify counterfeited product
- Eye-visible with a tool
- The general public will not be aware of its presence and simulating is very difficult
- *Details must be controlled on a "need to know" basis*

SEMI-COVERT Marker Examples



- Slight intentional structural irregularities
- Microtext
- *Counterfeiter may detect but is unlikely to copy*

FORENSIC Markers



- Usually requires laboratory testing or dedicated field tests to scientifically prove authenticity.



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Effect of Mitigation on Likelihood

LIKELIHOOD							
CURRENT STATE Risk		PACKAGING ONLY Risk		SERIALIZATION / E-PEDIGREE/ AUTHENTICATION ONLY Risk		BOTH MITIGATIONS Risk	
Product	Ranking	Product	Ranking	Product	Ranking	Product	Ranking
	2.68		2.61		2.36		2.29
	2.61		2.54		2.07		2.00
	2.36		2.29		1.93		1.86
	2.29		2.21		1.89		1.82
	2.29		2.21		1.68		1.61
	2.11		2.04		1.64		1.57
	2.07		2.00		1.64		1.57
	2.04		1.96		1.64		1.57
	2.00		1.93		1.57		1.50
	1.93		1.86		1.50		1.43
	1.89		1.82		1.46		1.39
	1.75		1.75		1.39		1.32
	1.46		1.39		1.00		1.00

Risk Ranking: 1-5 with 5 being highest risk



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Effect of Mitigation on \$ Impact

5yr 10% NPV IMPACT (\$MM)								
Confidence Level	1/N Year Event	CURRENT STATE	PACKAGING ONLY		PEDIGREE/ AUTHENTICATION ONLY		BOTH MITIGATIONS	
		C/T Risk	C/T Risk	SAVINGS	C/T Risk	SAVINGS	C/T Risk	SAVINGS
75%	4							
80%	5							
90%	10							
95%	20							
96%	25							
97%	33							
98%	50							
99.0%	100							
99.5%	200							
99.9%	1,000							
Expected Value								
Standard Deviation								



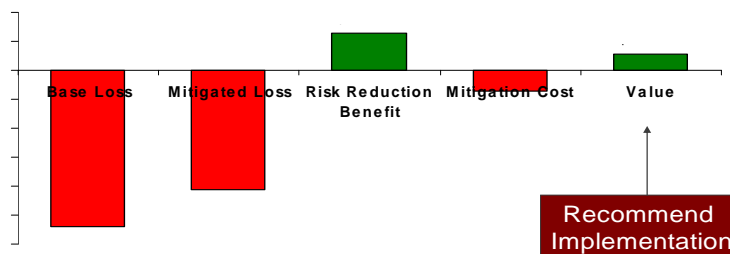
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Mitigation Benefits: Serialization/E-Pedigree/Authentication & Packaging

Mitigation Costs (\$MM)	
Serialization/E-Pedigree/Authentication	
NPV of Packaging* Costs (5 years)	
NPV of E-Pedigree Operational Costs (5 years)	
TOTAL	

Value-Added Analysis

Serialization / ePedigree /Authentication AND Packaging



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Potential Future Improvements

- ↳ Update severity parameters
- ↳ Track predictive value of the relative frequency scoring method
- ↳ Develop more quantitative methods for assessing frequency
- ↳ Develop industry loss database



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Q & A



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