



Pharmaceuticals - Risk Assessment

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XL INSURANCE

Risk Assessment of Pharmaceuticals

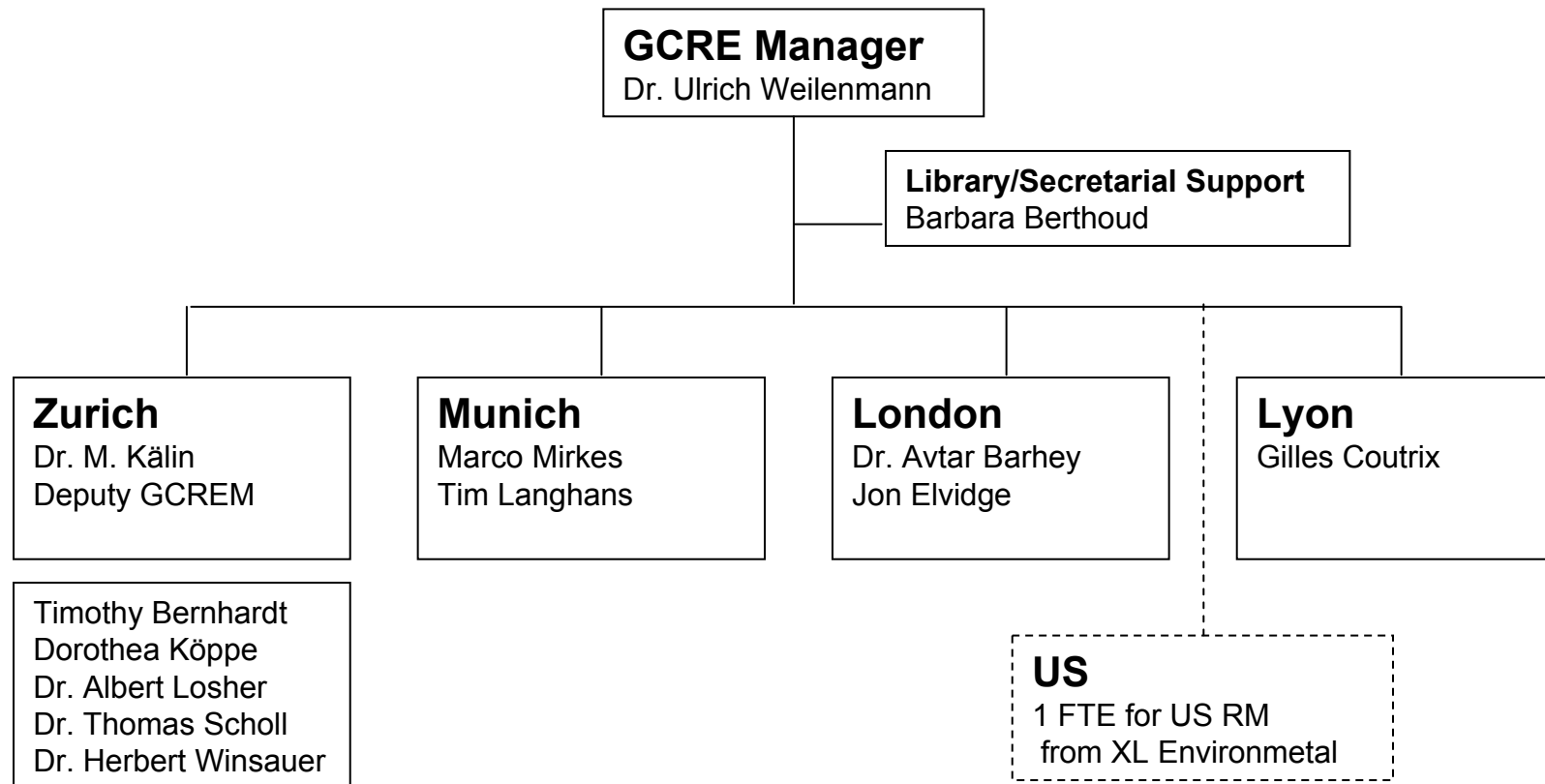
What are the two major reasons why insurance companies assess pharmaceutical risks?

Major reasons for pharmaceutical risk assessments



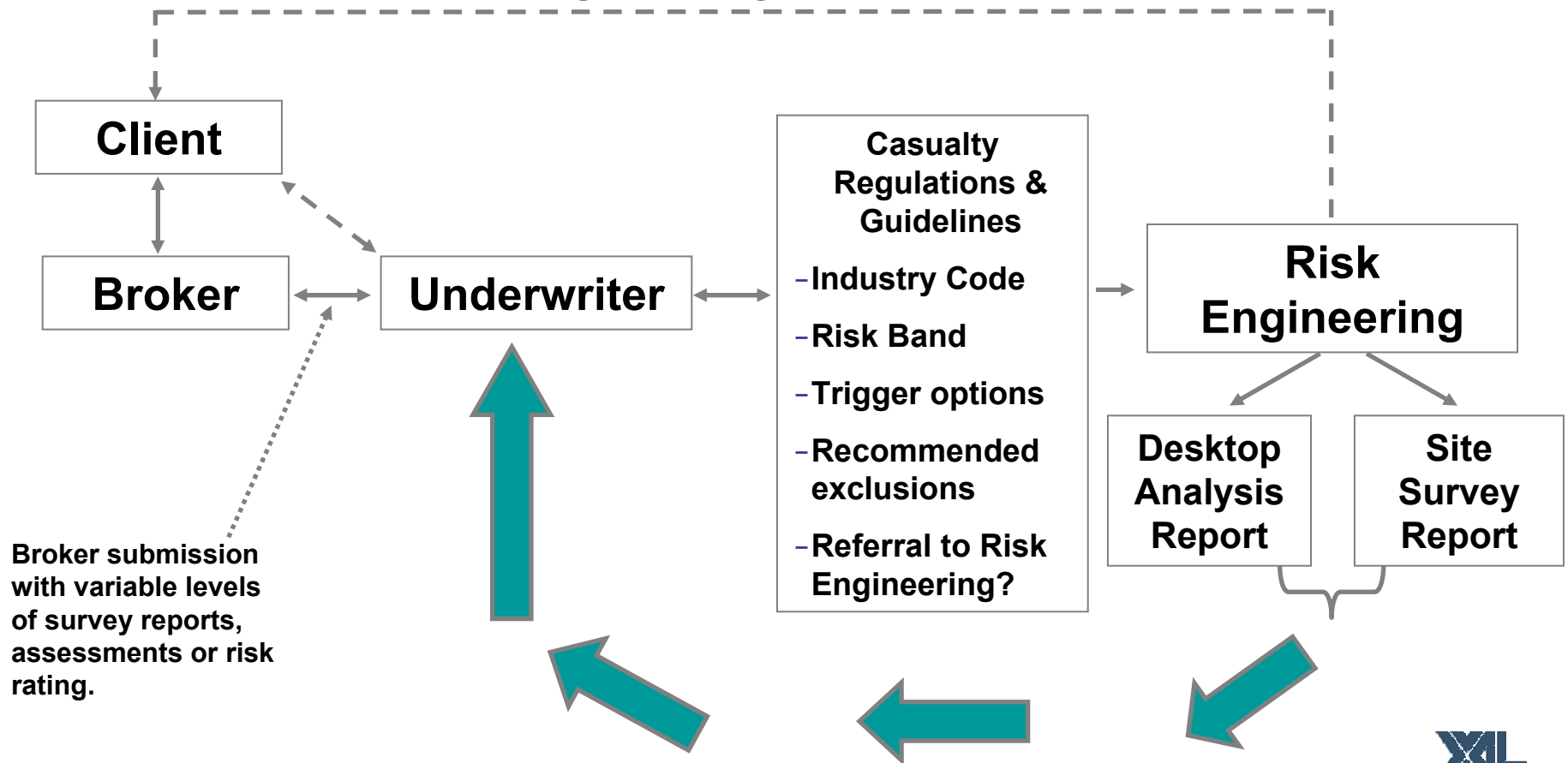
“We decided to recall our new drug because a common **side-effect** is **lawsuit**”

Global Casualty Risk Engineering Organisation 2009



Casualty Risk Engineering Service Offerings

Risk Engineering Services



Casualty Risk Engineering Know-how / Specialist Areas

Engineering Disciplines:

Civil Engineering

Mechanical Engineering

Electrical Engineering

Chemical Engineering

Environmental Engineering

Pharmacology (Dorothea Köppe)

Biotechnology/Genetic Engineering (Markus Kälin)

Questions from Underwriters to Risk Engineering?

Question 1:

Does Viagra have any side effects?

Answer:

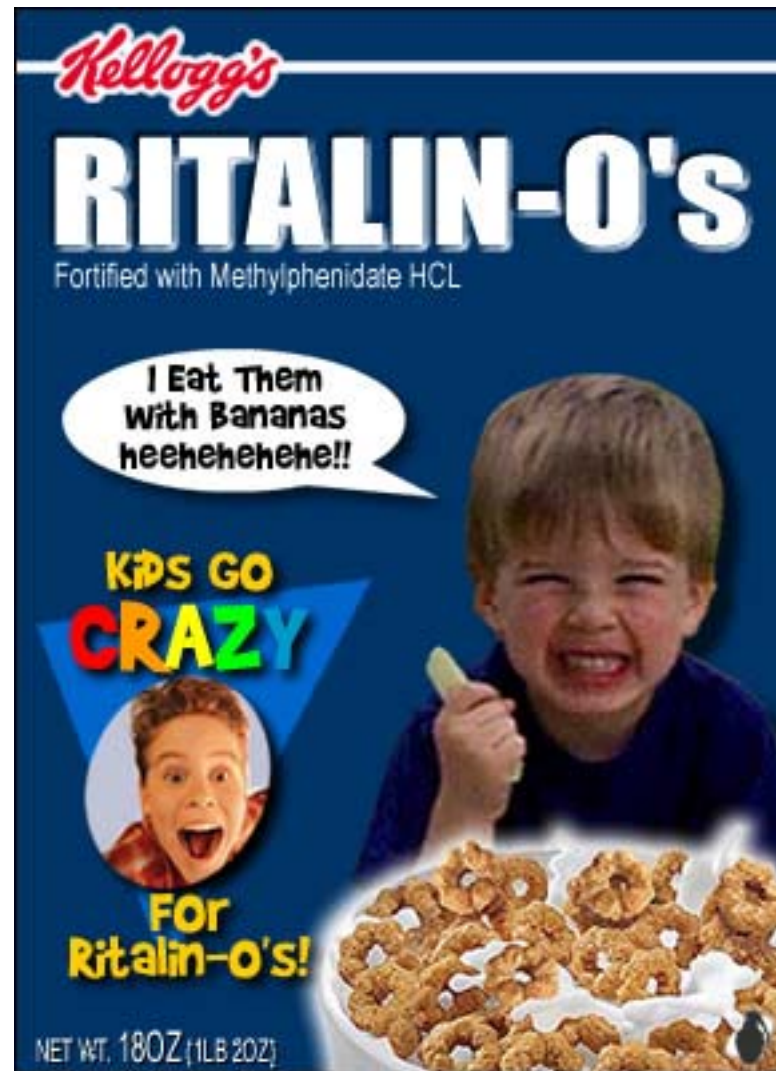
Misuse might create some problems



Questions from Underwriters to Risk Engineering

Question 2:

Is Ritalin a drug or a dietary supplement?



XL's tools to assess pharmaceutical risks

- Pharmaceutical know-how
- Submission information from clients and brokers
- Assessment of clinical trials (existing clients)
- Scientific Papers
- FDA MedWatch Safety Alerts
- Internet pages of US law firms (e.g. www.yourlawyer.com)
- XL Insurance Product Exclusion and Watch List
- Non governmental organisations (NGOs, e.g. Public Citizen)

FDA MedWatch Safety Alerts

- Changes in prescribing information (e.g. black box warnings)
- Early Communication About an Ongoing Safety Review (new)
- Dear Doctor Letters
- Recalls, Market Withdrawals and Safety Alerts

PROZAC®
FLUOXETINE CAPSULES, USP
FLUOXETINE ORAL SOLUTION, USP
FLUOXETINE DELAYED-RELEASE CAPSULES, USP

WARNING

Suicidality and Antidepressant Drugs — Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of Prozac or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. Prozac is approved for use in pediatric patients with MDD and obsessive compulsive disorder (OCD). (See WARNINGS, Clinical Worsening and Suicide Risk, PRECAUTIONS, Information for Patients, and PRECAUTIONS, Pediatric Use.)

Internet pages of US law firms

- List with 191 “Defective Drugs”
- Detailed chronology for each drug
- About 50 articles for Baycol case
- On-line form for free case review

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DEFECTIVE DRUGS



Have You or Someone You Love Been Injured by a Defective Drug?

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Parker Waichman Alonso LLP is a leader in a defective drug litigation. We are currently evaluating cases involving the prescription drugs listed below. Please click on a specific drug or fill out the form at the right for a free case evaluation by a qualified attorney.

Defective Drugs		
Abilify	Ephedra	PPA
Accutane	Epilepsy Drugs	Premarin
Accutane (IBD)	Epogen	Prempase
ACE Inhibitors	Estratest	Prempo
Actonel	Ethex	Prevacid
Actos	Ethex Morphine	Prilosec
Adderall	Evista	Procrit
Advair	Een Phen	Propylthiouracil-Liver-Damage
Advanced Medical Optics (AMO) Complete MoisturePlus	Fentora	Proton Pump Inhibitors
Advil	Fleet Enema	Protonix
Aldara	Fleet Phospho-soda	Protopic
Ambien	Recall	Provigil
Amiodarone	Foradil	Prozac
Aptivus	Fosamax	Raptiva
Aranesp	Gadolinium	Reglan
Arava	Gardasil	
	Geodon	

FREE CASE REVIEW

DEFECTIVE DRUGS

* DENOTES REQUIRED FIELD

TITLE

* FIRST NAME

* LAST NAME

* EMAIL ADDRESS

* PHONE NUMBER

CELL PHONE NUMBER

OFFICE PHONE NUMBER

STREET ADDRESS

APARTMENT/SUITE

CITY

STATE


-Choose State-

ZIP CODE

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XL HEADLINES



Product Exclusion and Watch List

Product Exclusion and Watch List

Back to Menu

Search in all fields for following criterion

Enter one or more values to search on:

Brand/Trade Name

Generic/Chemical Name

Manufacturer

Product Category

Exclusion Category

ATC 1st Level

ATC 2nd Level

Clear

ATC	Generic/Chemical Name	Brand/Trade Name	Manufacturer	Product Category	Exclusion Category
C09A	ACE Inhibitors (angiotensin-converting enzyme)	Lotrel, Altace, Lisinopril, Capoten, Lotensin, Vasotec, Aceon, Accupril, Univasc, Mavik, Monapril	Divers	Pharmaceuticals	3
N02BE01	Acetaminophen	Tylenol	Johnson & Johnson (McNeil-PPC)	Pharmaceuticals	3
D05BB02	Acitretin	Soriatane	Hoffman La Roche	Pharmaceuticals	3
L04AB04	Adalimumab	Humira	Abbott Laboratories	Pharmaceuticals	1
L01XC04	Alemtuzumab	Campath	Schering	Pharmaceuticals	3

- Data base with 253 pharmaceuticals
- Detailed information set for each substance (e.g. side effects, litigation status, drug classes)
- Divers searching and reporting functions

Life Science Initiative by Risk Engineering

Definition of Life Science

- Pharmaceuticals
- Medical Devices
- Cosmetics
- Professional, Scientific and Technical Services
- Nutraceuticals



Life Science Initiative by Risk Engineering

Goal:

- Define parameters to select potential new Life Science clients
- Demonstrate profitability of the Life Science business by analysing XLI's loss histories
- Convince Underwriting Management that pharmaceutical companies can be underwritten with profit

Life Sciences Statistical Information

Period 2000-2008 (world-wide)

	Range of annual loss ratios
Major Pharmaceutical companies (> \$5 billion)	150% – 1200 % (2000-2003)
Other Pharma (< \$5 billion)	10% - 60%
Implant manufacturers	20%- 700%
Medical devices manufacturers (without implants)	10%- 70%

Major (Big) Pharma – What are the problems?

- Large US sales
- Several “blockbuster” drugs (sales per product > \$1 billion)
- Target of consumer organisations and lawyers (deep pocket)
- Very fast growing products
- Large number of therapeutic areas (difficult to assess for RE)
- Reputation problems

Life Science Initiative – Preferred new clients

Pharmaceutical Companies

- Veterinary companies
- Phytotherapeutic companies
- Homeopathic companies
- Pharmaceutical/Biotech companies (sales < \$1 billion and other criteria)
- Biotech companies with no products on the market
- Pharmaceutical wholesaler
- Clinical Research Organisations (CROs)
- Contract manufacturers

Medical devices

- Medical devices Class I and II companies
- In-vitro Diagnostics / Clinical Biomarkers companies
- Instruments and reagents for the Life-Science industry providing companies

Cosmetic companies

- Cosmetic companies of the luxury segment or niche market

Conclusions

- Most pharmaceutical companies are not as bad as their reputation
- Risks can be assessed like in any other industries
- Risk Engineering can be a differentiator in this business