An Approach to Modeling Pharmaceutical Liability

Casualty Loss Reserve Seminar

Boston, MA
September 2013

Deloitte.

Overview

Introduction

Background

Model Inputs / Outputs

Model Mechanics

Q&A

Introduction

Business Issue

Pharmaceutical companies are challenged by a lack of quantititative analytic tools to determine the optimal balance of self insured and insured liabilities, especially in high frequency/low severity loss considerations.

The commercial insurance market is inefficient, subject to volatility in capacity and cost.

Enterprise financial strength and capital are often underutilized

Solution

Develop a stochastic model, using a mixture of industry and company-specific data.

Estimate ultimate losses by layer, to facilitate insurance-related decisions and negotiations.

Provide the ability to forecast financial impacts of large loss scenarios, under various insurance and self-insurance structures.

Risk Finance Modeling Tool - Principal Attributes

The modeling tool incorporates the following inputs:

- Actuarial modeling of company's risk exposure
- User defined insurance program structures
- Multi-year projections of company's key financial metrics
- Projected financial impact of correlated events

The modeling tool produces meaningful outputs:

- Comparisons of commercial insurance rates and model simulated expected costs by insurance layer
- Simulated expected costs in layers near the in-force insurance attachment and limit
- Summary of unlimited and limited loss distribution
- Projected impact of events on company's key financial metrics, given various retention and limits levels

The modeling tool includes the following key features:

- Company's historical loss data, adverse uninsured events and insurance program structures
- Company's exposure profile defined by current and anticipated operations, Operations, growth, expansion, etc.
- User defined exposure and financial trends

Project Background

Company

- A leading global pharmaceutical manufacturer
- 2011 Revenue 18.9B USD; 29.7B USD Shr/Equity, 36.1B USD MktCap
- Active acquirer
- 2012 Self Insured Retention ~ 300m USD

Unique Loss Events

- Very low frequency, very high severity
- "Integrated Occurrence" insurance coverage
- Product liability claims subject to common insurance limit

Model Purposes

- **Practical**: Assess market premium quotes by insurance layer
- **Strategic**: Provides analytic rigor to insurance versus self insurance (captive)
- **Scenario Testing**: Projected outcomes at various confidence levels

Model Strengths

- **Simple technology**: Microsoft Access, SAS, intuitive menus
- **Easy to use and explain:** While sophisticated, the model is not a "black box"
- **Broad application:** Readily leveraged across industries and severity exposures

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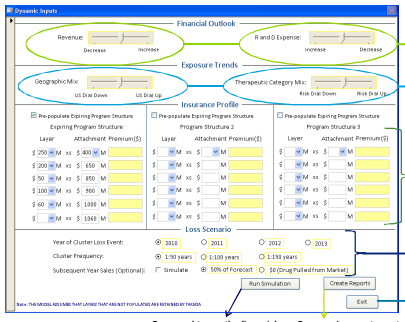
Risk Finance Model
User Inputs

User Inputs: Overview of the Dynamic Input Form



Financial outlook allows the user to adjust for economic conditions

Exposure trends allow the user to adjust future geographic and therapeutic concentrations

The user can enter up to 3 premium quotes and review the expiring program

Loss scenario selections allowthe user to model specific adverse events

Command to close the model

Command to run the financial simulation 200,000 times

Command generates outputs and only becomes active after the simulation is complete

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User Inputs: Financial and Exposure Scenarios

Financial Outlook

Financial inputs are combined with liability losses to create simulated net incomes. The model always utilizes a combination of Expected, Favorable, and Unfavorable results, but the user can change the percentages of these scenarios by dialing revenue and R&D expense up or down

- Revenue dial affects scenario percentages for Operating Revenue
- R&D Expense dial affects scenario percentages for the expense associated with Research and Development, which is expressed as a percentage of Operating Revenue

Exposure Trends

The Global Rx risk profile is incorporated into the industry batch distribution through modification factors. The user can then dial up or dial down this risk profile to adjust for future risk profile expectations

- Geographic Mix dial alters the sales outlooks for different regions, with US considered riskier than non-US
- Therapeutic Category Mix dial alters the sales outlooks for the 5 different categories of drugs where Category 1 (Lifestyle Obesity) is considered the most risky and Category 5 (Oncology) is considered the least risky

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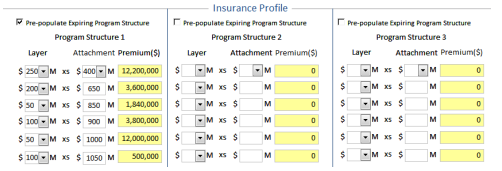
User Inputs: Insurance Profile



- The user defines the expiring or proposed insurance program structure
- If no structure is defined, the model defaults to the expiring program structure
- Additionally, up to two additionalinsurance program structures,including premium quotes, can be applied to compare the impact of the various structures
- The form requires anAttachment Point and a Premium for each Layer
- After the user enters the insurance program structures,the model generates 200,000 unlimitedbatch loss outcomes which are then adjusted/limited according tothe insurance program structure

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User Inputs: Loss Scenario

Loss Scenario

Year of Cluster Loss Event:	◉ 2011	○ 2012	○ 2013
Cluster Frequency:	○ 1:50 years	○ 1:100 years	◉ 1:150 years
Subsequent Year Sales (Optional):	☐ Simulate	◉ 50% of Forecast	○ $0 (Drug Pulled from Market)

The user must also specify parametersthat apply to the batch loss:

- § Year of Batch Loss Event is a requiredinput which assigns the specific adverse event to a year
- § Batch Frequency is a requiredinput which determines the severity of the Batch Loss
  - – Ex: a 1 in 50 year event would be less severethan a 1 in 150 year event
- § Subsequent Year Sales is an optional input that contemplates Global Rx's response to an event
  - – Operating Revenue isreduced by half or the full amount of expected sales depending on the scenario selected

Risk Finance Model Output Reports

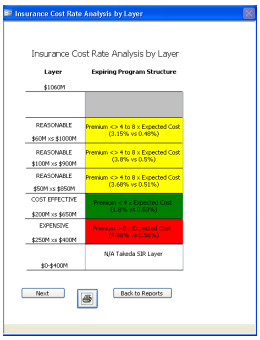
Output Reports: Insurance Cost Rate Analysis by Layer

The "Insurance CostRate by Layer Analysis" evaluatesthe in-force insurance premiums by layer against the projected product liability batch losses in the model

- § Applies to the insurance towers identified inthe dynamic inputs
- § Can compare up to 3 insurance towers
- § Require the user to input premium bylayer

The Risk Retention Model evaluatesthe value of each insurance layer

- § The model estimates the expected insurance costby layer ("Expected Cost")
- § The premium quote is compared to the Expected Cost
- § The layer is ranked (parameters defined byGlobal Rx)
  - – Expensive (red): premium is more then 8 times the Expected Cost
  - – Reasonable (yellow):premium is between 4 and 8 times the Expected Cost
  - – Cost Effective (green): premium isless than 4 times the Expected Cost



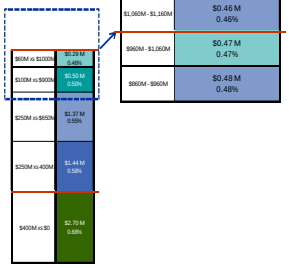
Output Reports: Marginal Layer Analysis

The "Marginal Insurance Layer Analysis" allows the user to evaluate the value of increasing or decreasing the insurance program structure attachment and limit.

- Compares expected costs to premium quotes around the expiring insurance tower limitand attachment points
- Incorporates four $100 million layers

Consider the 7/1/09 – 6/30/10 insurance tower

- Insurance limit:$1,060 million (see graph) Marginal Insurance Layer Analysis evaluates
  - $100 million xs $1,160 million
  - $100 million xs $1,060 million
  - $100 million xs $960 million
  - $100 million xs $860 million
- Insurance attachment:$400 million (not shown) Marginal Insurance Layer Analysis evaluates
  - $100 million xs $200 million
  - $100 million xs $300 million
  - $100 million xs $400 million
  - $100 million xs $500 million



Layer	Expected Loss (Millions) and Rate Per $100M Layer
$1,160M - $1,260M	$0.45 M 0.45%
$1,060M - $1,160M	$0.46 M 0.46%
$960M - $1,060M	$0.47 M 0.47%
$860M - $960M	$0.48 M 0.48%

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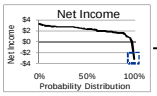
Output Reports: Loss Scenario Testing Analysis

The "Loss Scenario Testing Analysis" allows the user to define adverse batch loss events and investigate the impact on net income

- Select currency (US dollars and two additional currencies)
- Select a specific set of outcomes along the net income distribution
- Allows modification of future exposures (geographic and therapeutic mix), financial metrics (revenue and R&D), and insurance structure
- Displays results in an incremental fashion allowing the user to understand the impact of each input
- Quantifies the batch event, identifies the applicable insurance, and describes the batch event that would exhaust insurance

Output



Loss Scenarios	Net Income ($ millions)*					
Insurance (7/10 - 12/15): $600M xs $400M	2010	2011	2012	2013	2014	2015
Expected Scenario	$ 2,300	$ 1,983	$ 2,138	$ 2,565	$ 2,626	$ 2,949
1:150 Year Event (2011)	$ 2,300	$ 1,895	$ 2,091	$ 2,516	$ 2,575	$ 2,893
1:150 Year Event (2011) + Drug is Pulled from Market (2012)	$ 2,300	$ 1,895	$ 2,066	$ 2,490	$ 2,550	$ 2,865

Observations
1) 1:150 year cluster event in 2011 is $190 million loss
2) 1:213 year cluster event would exhaust the insurance limit

* Net Income figures are based on average of 200,000 model simulations

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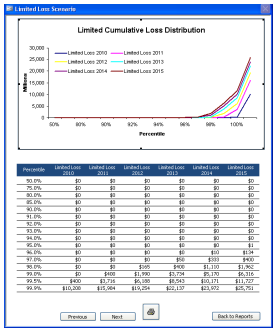
Output Reports: Cumulative Loss Distribution

The "Cumulative LossDistribution" displaysthe batch loss outcomes

- Allows the user to select the unlimited (beforeinsurance) or limited (after insurance) lossdistribution
- Displays the cumulative batch loss from 2010 to the evaluation age
  - 2010: batch event emerges during 2010
  - 2011: batch event emerges during 2010 or 2011



Percentile	Limited Loss 2010	Limited Loss 2011	Limited Loss 2012	Limited Loss 2013	Limited Loss 2014	Limited Loss 2015
50.0%	$0	$0	$0	$0	$0	$0
75.0%	$0	$0	$0	$0	$0	$0
80.0%	$0	$0	$0	$0	$0	$0
85.0%	$0	$0	$0	$0	$0	$0
90.0%	$0	$0	$0	$0	$0	$0
91.0%	$0	$0	$0	$0	$0	$0
92.0%	$0	$0	$0	$0	$0	$0
93.0%	$0	$0	$0	$0	$0	$0
94.0%	$0	$0	$0	$0	$0	$0
95.0%	$0	$0	$0	$0	$0	$1
96.0%	$0	$0	$0	$0	$10	$134
97.0%	$0	$0	$0	$90	$333	$965
98.0%	$0	$0	$165	$900	$1,110	$1,962
99.0%	$0	$400	$1,990	$3,274	$5,170	$6,316
99.5%	$400	$3,716	$6,186	$8,043	$10,171	$11,727
99.9%	$10,208	$15,064	$19,254	$22,137	$23,972	$25,751

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Risk Finance
Model Mechanics

Model Mechanics: Unlimited Loss Distribution

First, the model builds an unlimited product liability batch loss distribution by adjusting an industry loss distribution for Global Rx's product and risk profile

Develop Industry Batch Profile	Incorporate Global Rx Risk Profile	Incorporate Drug Variability	Simulate Unlimited Loss Outcomes
Build a pharmaceutical batch loss distribution	Modify industry distribution for Global Rx risk characteristics	Incorporate future uncertainty of sales and patient volume	Simulate 200,000 batch loss outcomes for 2010 - 2015
§ Historical batch events § Product liability trends – Judicial / tort – FDA approval rate	§ Primary consideration – Patient counts § Secondary considerations – Geography – Therapeutic category – Drug life cycle	§ Pipeline products – Launch success or failure § On market products – Sales / patient vary from expected levels	§ Order loss outcomes (lowest to highest) § Build unlimited loss distribution

Interim Output of Each Step

Industry Parameters	Global Rx Expected Parameters	Global Rx Parameters	Global Rx Unlimited Loss Distribution

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Batch Losses – Empirical Data

Batch Events included in model:

#	Pharmaceutical Company	Drug	Approved Use of Drug	Year	Total Projected Cost ("Ultimate")	Prior Model Projected Cost
1			Diet Pill	1997	$ 21,000,000,000	$ 18,573,280,000
2			Pain Medicine	2005	$ 7,950,000,000	$ 7,000,000,000
3			Diabetes	2007	$ 6,000,000,000	N/A
4			*Pain Medicine*	*2005*	*$ 3,194,000,000*	*N/A*
5			Schizophrenia	2004	$ 2,700,000,000	$ 1,225,000,000
6			Anti-depressant	2001	$ 2,000,000,000	$ 72,700,000
7			*Schizophrenia*	*2003*	*$ 1,916,000,000*	*N/A*
8			Cholesterol	2002	$ 1,393,000,000	$ 1,393,000,000
9			*Schizophrenia*	*2004*	*$ 1,000,000,000*	*N/A*
10			*Menopause*	*2003*	*$ 840,000,000*	*N/A*
11			Diabetes	2000	$ 750,000,000	$ 155,010,000
12			Narcotic	2002	$ 654,890,133	$ 1,390,133
13			*Birth Control*	*2001*	*$ 68,700,000*	*N/A*
14			*Acne*	*2003*	*$ 50,000,000*	*N/A*
			Average		$ 3,536,899,295	$ 4,060,054,305

6 out of the 7 new Batch Events have projected cost < prior average ($4.06B)

Batch Events excluded from model due to insufficient data:

#	Pharmaceutical Company	Drug	Approved Use of Drug	Year	Total Projected Cost ("Ultimate")	Prior Model Projected Cost
1			Diabetes	2011	$ -	$ -
2			Birth Control	2008	$ -	$ -

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Batch Losses – Fitting the Distributions

We model frequency and severity separately:

Frequency

Similar to Model 1.0, Batch Event frequency is represented using a Poisson distribution. Based upon goodness-of-fit tests we continue to believe this is an appropriate model.

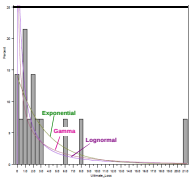
- The selected frequency is 0.875, compared to 0.889 in Model 1.0
- Including Yazand Actos would increase the frequency to 1.000

Year	# of Batch Claims Drug
1996	0
1997	1
1998	0
1999	0
2000	1
2001	2
2002	2
2003	3
2004	2
2005	2
2006	0
2007	1
2008	0
2009	0
2010	0
2011	0

Severity

Claim severity distribution estimates total projected cost ("ultimate") of an industry Batch Event.

- We considered three severity distributions:
  - Exponential
  - Gamma (Selected)
  - Lognormal
- The graph below displays the fitted curves compared to the industry data
- Statistical goodness-of-fit tests were performed to conclude that our estimated parameters are realistic



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Batch loss frequency is modeled based on adjusted industry experience and actual Global Rx experience

Industry Experience

Year	# of Batch Claims Drug
1996	0
1997	1
1998	0
1999	0
2000	1
2001	2
2002	2
2003	3
2004	2
2005	2
2006	0
2007	1
2008	0
2009	0
2010	0
2011	0

16 years of observed experience

14 Batch Claims occurred

Global Rx Experience

Confidential Product detail

1 claim in Global Rx's 230+ year history

Expected Number of Batch Claims = Average { **Industry Experience adjusted for Global Rx market share and Risk Loading Factor** } & **Global Rx Experience**

= Average { $\frac{14}{16}$ x 3.6% x Risk Loading Factor } & $\frac{1}{230}$

3.6% = Global Rx market share (pre 2011 acquisition

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The first step in calculating the Risk Loading Factor is to estimate the Individual Critical Loss Consideration Loading Factors

In this example sales by region are weighted by judgmentally selected relativities to estimate the overall CLC Loading Factor

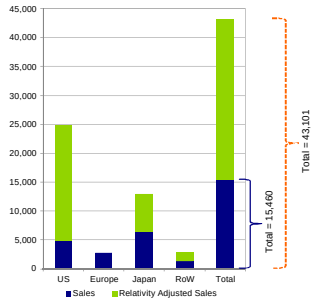
Geographic Region

Region	Sales
US	4,954
Europe	2,683
Japan	6,439
RoW	1,384

Region	Relativity
US	5.00
Europe	1.00
Japan	2.00
RoW	2.00

Region	Product
US	24,771
Europe	2,683
Japan	12,878
RoW	2,769

Loading Factor: 2.79 = $\frac{43,101}{15,460}$



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Next, an Aggregate CLC Loading Factor is calculated by multiplying the Individual CLC Loading Factors

Below is a detailed calculation for illustration purposes:

Geographic Region

Region	Sales
US	4,954
Europe	2,683
Japan	6,439
RoW	1,384

Region	Relativity
US	5.00
Europe	1.00
Japan	2.00
RoW	2.00

Region	Product
US	24,771
Europe	2,683
Japan	12,878
RoW	2,769

Loading Factor: 2.29

Patient Count

Patient Group	Sales
< 200K	3,648
200K - 1M	2,943
> 1M	8,870

Patient Group	Relativity
< 200K	0.25
200K - 1M	1.00
> 1M	1.25

Patient Group	Product
< 200K	912
200K - 1M	2,943
> 1M	11,088

Loading Factor: 0.97

Lifecycle Stage

Age	Sales
< 3 Years	1,565
3 - 5 Years	842
6 - 8 Years	1,899
> 8 Years	11,155

Age	Relativity
< 3 Years	1.75
3 - 5 Years	0.50
6 - 8 Years	1.00
> 8 Years	0.25

Age	Product
< 3 Years	2,739
3 - 5 Years	421
6 - 8 Years	1,899
> 8 Years	2,789

Loading Factor: 0.51

Therapeutic Category

Thera Cat	Sales
1	4,849
2	2,558
3	3,705
4	598
5	3,750

Thera Cat	Relativity
1	3.00
2	2.00
3	1.00
4	0.75
5	0.25

Thera Cat	Product
1	14,548
2	5,117
3	3,705
4	449
5	938

Loading Factor: 1.60

Aggregate CLC Loading Factor: 2.19

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Finally, the Aggregate CLC Loading Factor is compared against the max and min possible Aggregate CLC Loading Factors

Step 1: Min (least risky) and max (most risky) possible Risk Loading Factors are calculated by multiplying all the lowest RLFs to estimate the minimum and multiplying all the highest RLFs to estimate the maximum

Region	Relativity
US	5.00
Europe	1.00
Japan	2.00
RoW	2.00

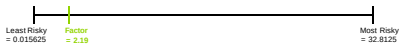
Patient Group	Relativity
< 200K	0.25
200K - 1M	1.00
> 1M	1.25

Age	Relativity
< 3 Years	1.75
3 - 5 Years	0.50
6 - 8 Years	1.00
> 8 Years	0.25

Thera Cat	Relativity
1	3.00
2	2.00
3	1.00
4	0.75
5	0.25

Least Risky = 1.00 x 0.25 x 0.25 x 0.25 = 0.015625
Most Risky = 5.00 x 1.25 x 1.75 x 3.00 = 32.8125

Step 2: The *Aggregate CLC Loading Factor* is compared against the least and most risky loading factors



$$\text{CLC Adjustment} = \frac{2.19 - 0.015625}{32.8125 - 0.015625} = 6.63\%$$

Step 3: The *CLC Adjustment* is added to the average expected *Frequency Adjustment* to determine the *Risk Loading Factor*, which measures Global Rx's risk profile compared to the industry average

$$\text{Expected Number of Batch Claims} = \text{Average}\left[\left\{\frac{14}{16} \times 3.6\% \times (50\% + 6.63\%)\right\}, \& \frac{1}{230}\right]$$

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The Model relies on two judgmental assumptions to simulate batch frequency

The chart below demonstrates how the average frequency for 2011 changes as model assumptions are adjusted with a Global Rx Market Share of 3.6%:

Industry Frequency: 1:1 Years
Global Rx Frequency @ 3.6% Market Share: 1:32 Years

Global Rx Risk Profile Relative to Industry	2011 Expected Frequency: Judgmentally Selected Global Rx Frequency 1/50	1/100	1/250	0
100%	1:37 Year	1:46 Year	1:52 Year	1:60 Year
90%	1:40 Year	1:49 Year	1:59 Year	1:65 Year
75%	1:44 Year	1:56 Year	1:69 Year	1:80 Year
50%	1:54 Year	1:73 Year	1:93 Year	1:109 Year

More Risky ↓ Less Risky

- The assumptions that were built into Model 1.0 generated an expected frequency of about 1:100 year event (circled above)
- As scenarios move from least to most risky, the simulated frequency increases by about 34% (37 / 109)

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The Model relies on two judgmental assumptions to simulate batch frequency

The chart below demonstrates how the average frequency for 2011 changes as model assumptions are adjusted with a Global Rx Market Share of 2.0%:

Industry Frequency: 1:1 Years
Global Rx Frequency @ 2.0% Market Share: 1:57 Years

Global Rx Risk Profile Relative to Industry	2011 Expected Frequency: Judgmentally Selected Global Rx Frequency 1/50	1/100	1/250	0
100%	1:52 Year	1:69 Year	1:89 Year	1:105 Year
90%	1:55 Year	1:72 Year	1:93 Year	1:118 Year
75%	1:58 Year	1:81 Year	1:108 Year	1:136 Year
50%	1:66 Year	1:97 Year	1:140 Year	1:196 Year

More Risky ↓ Less Risky

- By decreasing Global Rx's Market Share from 3.6% to 2.0%, the expected frequency decreases
- 75% risk assumption together with a 1/100 judgmental frequency assumption yields a composite average frequency of 1:81 years
- As scenarios move from least to most risky, the simulated frequency increases by about 27% (52/196)

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The shape of the limited loss distribution may also change depending on the frequency inputs

More Risky → Less Risky

Global Rx Risk Profile Relative to Industry	2011 Limited Loss at 99.0% Percentile: Judgmentally Selected Global Rx Frequency 1/50	1/100	1/250	0
100%	$ 526	$ 300	$ 16	$ -
90%	$ 449	$ 259	$ -	$ -
75%	$ 333	$ 98	$ -	$ -
50%	$ 300	$ 0	$ -	$ -

More Risky ↓ Less Risky

50% Risk, 0 Frequency

Percentile	Limited Loss 2011	Limited Loss 2012	Limited Loss 2013	Limited Loss 2014	Limited Loss 2015	Limited Loss 2016
50.0%	$ -	$ -	$ -	$ -	$ -	$ -
75.0%	$ -	$ -	$ -	$ -	$ -	$ -
80.0%	$ -	$ -	$ -	$ -	$ -	$ -
85.0%	$ -	$ -	$ -	$ -	$ -	$ -
90.0%	$ -	$ -	$ -	$ -	$ -	$ -
91.0%	$ -	$ -	$ -	$ -	$ -	$ -
92.0%	$ -	$ -	$ -	$ -	$ -	$ -
93.0%	$ -	$ -	$ -	$ -	$ -	$ -
94.0%	$ -	$ -	$ -	$ -	$ -	$ -
95.0%	$ -	$ -	$ -	$ -	$ -	$ -
96.0%	$ -	$ -	$ -	$ -	$ -	$ -
97.0%	$ -	$ -	$ -	$ -	$ -	$ 300
98.0%	$ -	$ -	$ -	$ 68	$ 300	$ 2,287
99.0%	$ -	$ -	$ 300	$ 642	$ 1,510	$ 4,728
99.5%	$ -	$ 623	$ 2,229	$ 3,578	$ 4,728	$ 5,776
99.9%	$ 4,911	$ 8,757	$ 10,997	$ 12,734	$ 14,622	$ 15,756

100% Risk, 1/50 Frequency

Percentile	Limited Loss 2011	Limited Loss 2012	Limited Loss 2013	Limited Loss 2014	Limited Loss 2015	Limited Loss 2016
50.0%	$ -	$ -	$ -	$ -	$ -	$ -
75.0%	$ -	$ -	$ -	$ -	$ -	$ -
80.0%	$ -	$ -	$ -	$ -	$ -	$ -
85.0%	$ -	$ -	$ -	$ -	$ -	$ -
90.0%	$ -	$ -	$ -	$ -	$ -	$ 16
91.0%	$ -	$ -	$ -	$ -	$ 1	$ 68
92.0%	$ -	$ -	$ -	$ -	$ 48	$ 260
93.0%	$ -	$ -	$ -	$ 6	$ 210	$ 300
94.0%	$ -	$ -	$ -	$ 120	$ 300	$ 541
95.0%	$ -	$ -	$ 35	$ 300	$ 559	$ 1,204
96.0%	$ -	$ -	$ 300	$ 590	$ 1,402	$ 2,206
97.0%	$ -	$ 138	$ 634	$ 1,732	$ 2,758	$ 3,712
98.0%	$ -	$ 613	$ 2,284	$ 3,774	$ 4,951	$ 5,936
99.0%	$ 526	$ 3,628	$ 5,959	$ 7,938	$ 9,392	$ 10,644
99.5%	$ 3,427	$ 7,795	$ 10,597	$ 12,783	$ 14,171	$ 15,336
99.9%	$ 13,742	$ 18,159	$ 21,490	$ 23,846	$ 25,462	$ 27,035

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Model Mechanics: Limited Loss Distribution

Second, the model applies the insurance structure to the unlimited product liability batch distribution resulting in Global Rx's limited batch loss distribution

Simulate Unlimited Loss Outcomes

Simulate 200,000 batch loss outcomes for 2010 - 2015

- § Order loss outcomes (lowest to highest)
- § Build unlimited loss distribution

Assign Product and Entity

Reflect Global Rx and recent acquisitions' insurance coverage

- § Assign each batch loss to specific product
  - – Incorporates individual product risk levels and expected sales

Assign Insurance Year

Select insurance policy year based on adverse event history

- § Adverse event assumptions
  - – Emergence patterns do not materially differ between US and non-US products
  - – Adverse events peak 2 - 3 years after approval
  - – Batch events emerge within 4 years after first reporting

Calculate Limited Loss Outcomes

Apply the insurance structure to the 200,000 unlimited batch loss outcomes

- § Incorporates insurance attachments and limits
  - – The user may define the insurance coverage
  - – If the user does not define an insurance structure, then the July 2009 – June 2010 coverage is applied
- § Order loss outcomes (lowest to highest)
- § Build limited loss distribution

Interim Output of Each Step

Global Rx Unlimited Loss Distribution | **Loss by Product and Entity** | **Loss by Year** | **Global Rx Limited Losses**

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Batch Events must be mapped to an Insurance Year to appropriately calculate the net loss

Key Model Assumptions:

- Batch Events are reported within four years
- Insurance coverage is based on the earliest report date

Batch Year	Insurance Year 2008	2009	2010	2011	2012	2013	2014	2015	2016
2016						24%	21%	26%	29%
2015					25%	22%	26%	26%	
2014				20%	24%	29%	28%		
2013			15%	14%	43%	29%			
2012		18%	19%	23%	40%				
2011	24%	19%	28%	29%					

24% probability that Insurance Year is 2008 given a Batch occurred in 2011

Probability of Insurance Year given a Batch occurred in 2011

The information above can also be represented in the following format:

Batch Year	Insurance Year 3 Yrs Ago	2 Yrs Ago	1 Yr Ago	Batch Year
2016	24%	21%	26%	29%
2015	25%	22%	26%	26%
2014	20%	24%	29%	28%
2013	15%	14%	43%	29%
2012	18%	19%	23%	40%
2011	24%	19%	28%	29%

For the 2011 Batch Year,
"3 Years Ago" = Insurance Year 2008
"2 Years Ago" = Insurance Year 2009
"1 Year Ago" = Insurance Year 2010
"Batch Year" = Insurance Year 2011

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Batch Events are mapped to Insurance Year through a multi-step process

Result: The *Batch Year to Insurance Year Probability* is calculated by taking Step 1 x Step 2

Batch Year	Insurance Year 3 Yrs Ago	2 Yrs Ago	1 Yr Ago	Batch Year
2016	24%	21%	26%	29%
2015	25%	22%	26%	26%
2014	20%	24%	29%	28%
2013	15%	14%	43%	29%
2012	18%	19%	23%	40%
2011	24%	19%	28%	29%

24% = A x B

Step 1: After a Batch Event is modeled, *Batch Year to Approval Year Probability* is estimated

Approval Year	2011	Batch Year 2012	2013	2014	2015	2016
Batch Year	1%	20%	0%	1%	2%	0%
1 Yr Ago	11%	3%	40%	3%	1%	4%
2 Yrs Ago	5%	14%	2%	21%	1%	1%
3 Yrs Ago	0%	9%	19%	3%	28%	4%
4 Yrs Ago	0%	0%	11%	21%	4%	27%
5+ Yrs Ago	82%	55%	28%	51%	64%	63%

A

When a Batch Event is simulated, it is first assigned to an Approval Year. This assignment is made using the percentages displayed in the table to the left. **The percentages are based on risk-weighted sales.**

Step 2: An *Approval Year to Insurance Year Pattern* is estimated

Approval Year	Insurance Year 3 Yrs Ago	2 Yrs Ago	1 Yr Ago	Batch Year
Batch Year	0%	0%	0%	100%
1 Yr Ago	0%	0%	66%	34%
2 Yrs Ago	0%	35%	43%	22%
3 Yrs Ago	23%	27%	33%	17%
4 Yrs Ago	20%	22%	26%	32%
5+ Yrs Ago	29%	21%	23%	27%

B

After assigned Batch Events to an Approval Year, they are then assigned to an Insurance Year. This assignment is made using the percentages displayed in the table to the left. **The estimated percentages are based on the SAE reporting pattern.**

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Model Mechanics: Net Income Distribution

Lastly, the limited product liability distribution becomes an input in the financial simulation, producing a net income distribution

Calculate Limited Loss Outcomes

Apply the insurance structure to the 200,000 unlimited batch loss outcomes

- § Incorporates insurance attachments and limits
  - – The user may define the insurance coverage
  - – If the user does not define an insurance structure, then the July 2009 – June 2010 coverage is applied
- § Order loss outcomes (lowest to highest)
- § Build limited loss distribution

Simulate Net Income

Combine financial inputs and product liability loss inputs to simulate net income

- § Simulate 5 financial variable values for 200,000 outcomes
  - – Expected, favorable, or unfavorable value
  - – Contemplates financial outlook dynamic inputs (revenue and R&D)
- § Adjust for PL losses
  - – Simulated limitedbatch losses
  - – Static non-batch expected loss

Incorporate Batch Correlation Impact

Adjust financial variables for correlated impact ofbatch loss

- § Simulate revenue reduction
  - – Select product that triggered the batch loss
  - – Simulate Global Rx's response
  - – Reduce subsequent year revenue for response
- § Simulate net asset reduction
  - – Follows a similar procedure as revenue reduction
  - – Contemplates operating expense

Calculate Net Income Outcomes

Aggregate financial inputsand adjustments

- § Order the net income outcomes
- § Build net income distribution
  - – Net income distribution shown in both U.S. dollars and additional currencies

Interim Output of Each Step

Global Rx Limited Losses | **Income outlooks adjusted for losses** | **Revenue and Assets reduced for losses** | **Global Rx Net Income**

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Net Income Distribution

Expected, Favorable and Unfavorable inputs are needed for:

- Operating Revenue
- Net Assets
- Foreign Exchange Rate
- Interest Rate (US and Japanese)
- R&D Expense

	($MM)	FY10	FY11	FY12	FY13	FY14	FY15
Expected	Revenue	14,080	12,916	13,115	13,371	13,555	14,197
Expected	Foreign Exchange Rate	100	100	100	100	100	100
Expected	Interest Rate	3%	3%	3%	3%	3%	3%
Expected	R&D Expense	2,816	2,583	2,623	2,674	2,712	2,839
Expected	Net Assets	22,997	22,976	23,341	24,135	25,054	26,330
Favorable	Revenue	14,080	14,208	14,427	14,708	14,911	15,617
Favorable	Foreign Exchange Rate	100	110	110	110	110	110
Favorable	Interest Rate	3%	5%	5%	5%	5%	5%
Favorable	R&D Expense	2,816	2,325	2,361	2,407	2,441	2,555
Favorable	Net Assets	22,997	25,274	25,675	26,549	27,559	28,963
Unfavorable	Revenue	14,080	11,624	11,804	10,028	10,166	10,648
Unfavorable	Foreign Exchange Rate	100	90	90	75	75	75
Unfavorable	Interest Rate	3%	1%	1%	1%	1%	1%
Unfavorable	R&D Expense	2,816	2,842	2,885	3,343	3,390	3,549
Unfavorable	Net Assets	22,997	20,678	21,007	18,101	18,791	19,748

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Net Income Distribution

Financial Inputs are combined to simulate Net Income:

	2012	Input Value Comment
Operating Income		
Operating Revenue	12,555,579,000	Operating Revenue: Financial forecast provided by Global Rx
Cost of Sales	(2,511,115,800)	Cost of Sales: 20% of Operating Revenue
Selling, General, and Administrative Expense	(3,766,673,700)	SG&A: 30% of Operating Revenue
R&D Expense	(2,887,783,170)	R&D Expense: 20% of Operating Revenue adjusted for financial dial
Product Liability Cluster Loss	0	Cluster Loss: Simulated by model
Product Liability Non-Cluster Loss	(1,483,174)	Non-Cluster Loss: inflation adjusted static Deloitte input
Operating Income	3,388,523,156	
Other Income		
Net Assets	231,731,737	Net Assets: Financial forecast provided by Global Rx
Expected Blended Interest Rate	1.25	Interest Rate: Combination of US and Japanese expected interest rates
Interest Income	115,865,869	Interest Income: Interest Rate x 40% of Net Assets
Interest Expense	0	
Other Income	115,865,869	
Operating + Other Income	3,504,389,025	
Income Tax	(1,331,667,829)	Income Tax: 38% of Operating + Other Income (based on 2008 ratio)
Static Adjustment	(689,197,691)	Static Adjustment: Used to ensure simulated mean net income is consistent with Global Rx's plan
Net Income ($)	1,483,523,504	
Expected Blended F/X Rate	XX	F/X: US portion of net income may be currency risk adjusted

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Net Income Distribution

Finally, financial variables are adjusted for Global Rx's response to batch losses:

Loss Scenario

Year of Cluster Loss Event: (•) 2011 ( ) 2012 ( ) 2013

Cluster Frequency: ( ) 1:50 years ( ) 1:100 years (•) 1:150 years

Subsequent Year Sales (Optional): [ ] Simulate (•) 50% of Forecast ( ) $0 (Drug Pulled from Market)

Event Happens Outside Year of Batch Loss

Global Rx's response is simulated by the model

- Drug pulled from market
  - 50% probability
  - Future revenue reduced by batch drug sales
  - Net assets reduced by 30% of batch drug sales
- Drug remains on market in restricted capacity
  - 50% probability
  - Future revenue reduced by 50% of batch drug sales
  - Net assets reduced by 15% of batch drug sales

Event Happens in Year of Batch Loss

Global Rx's response is dictated by the model inputs

- Drug pulled from market
  - 100% probability
- **Or** drug remains on market in restricted capacity
  - 100% probability
- **Or** drug response is simulated 50/50

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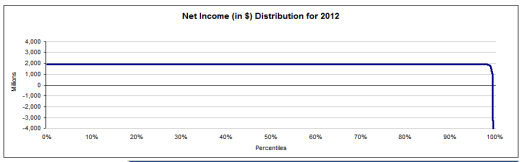
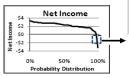
Net Income Distribution

The net income output report displays the potential deviation from target net income due to batch losses, up to a user-specified confidence level





Loss Scenarios	Net Income (in $Millions)*				
Insurance: $590M xs $300M	2012	2013	2014	2015	2016
Expected Senario	1,852	1,817	1,463	2,191	2,916
1:150 Year Event(2014)	1,852	1,817	1,131	2,141	2,856

*Based on 200,000 simulations with a 75% Risk Adjustment Factor and a 1 in 100 Year Company Frequency.

Observations:

1) 1:150 year batch loss event in 2014 is $951 million loss.

2) 1:149 year batch loss event would exhaust the expiring insurance structure.

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