



# Implementation of DA Projects

## THREE FABLES

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# Three Fables

- A Rash Decision
- When all else fails,  
buy the company!
- Are we going to Europe?

# Fable I



# A Rash Decision

## Setting

- Compound A is a top selling drug.
- Produces rash and must be dosed slowly.
- It has a major market share and will be going off patent in the next few years.
- Currently, searching for a follow-up without rash characteristics.

# A Rash Decision

## Alternative 1

- Compound B was a follow-up. Very promising and no rash problem.
- Phase II clinical trials: demonstrated an unforeseen tox problem. Reformulation may correct problem.
- Delay would be costly.

# A Rash Decision

## Alternative 2

- Compound C was the same class of drug.
- Had failed Proof-of-Concept for unrelated indication.
- Demonstrated rash tendencies, but not for sure, and clearly not as bad as Drug A.
- Was far along in development process and delay would not be significant.

# A Rash Decision

## Decision Analysis

Determine if we should try to “fix” compound B and/or do further testing of compound C.

# A Rash Decision

## Decision Analysis

- Project team created and decision board was apprised of the work.
- Good decision was to try to “fix” compound B.
- Better decision was to also run a small, but significant, test for rash of compound C.



# A Rash Decision

## Implementation Results

Decision Board agreed to trying to “fix” compound B which was begun immediately.

For compound C, the concept of the Value of Information was explained. An analogy was used.



# A Rash Decision

## Implementation Results

You're running from a bandit and see up ahead both a possible "get away" road as well as a cliff.

Take the road, you can keep running and, maybe, eventually get away.

But if you first take a peek over the cliff, you may find a ledge. The ledge guarantees immediate get away. If no ledge, your run down the road will be a bit harder.

# A Rash Decision

## Implementation Results

Decision Board agreed to spend the extra money to see if compound C would really produce rash.

A week later it was vetoed by an executive VP who had not been a member of the Decision Board.

## Fable II

When all else fails, buy the company!



# When all else fails, buy the company!

## Setting

- A marketed compound was fast becoming a blockbuster.
- New additional indications could make it the biggest blockbuster of all time.
- But it was also fast approaching its patent expiration.
- Was there a way to significantly extend its patent life?

# When all else fails, buy the company!

## Alternative Courses-of-Action

- Pursue a compound in development for a related disorder that had a similar mechanism of action.
- Develop a metabolite though it would be years behind.
- Reformulate for once-a-day.
- Joint venture with a company that had the technology for a once-a-day formulation.

# When all else fails, buy the company!

## Decision Analysis

Revealed that even the best strategy had a poor chance of success.

Additional ideas were generated, but were just variations on the same themes.

# When all else fails, buy the company!

## Decision Analysis

The “value of control” showed that working out an arrangement with the company with the technology would be the best thing to do.

The problem was that we had an unpleasant history with them and it was unlikely they’d agree to anything.



# When all else fails, buy the company!

## Implementation Results

The team decided that **NO COURSE OF ACTION WAS WORTH PURSUING.**

There was no possibility of working out an arrangement with the company with the once-a-day technology.

# When all else fails, buy the company!

## Epilogue

Three years later (one year after the GW and SB merger) a “technology partnership” was announced where GSK had a significant investment in our old enemy!

# Fable III



Are we going to Europe?



# Are we going to Europe?

## Setting

- A US product was selling beyond expectations and into blockbuster range.
- Years before, because of safety concerns, the product had not received EU regulatory approval.
- But years had passed and there was no evidence of safety problems.
- So it seemed logical to try again for Europe.

# Are we going to Europe?

## Decision Analysis

This was a straightforward 'yes' or 'no' decision where safety was believed to be the essential issue.

However, there were 27 uncertainties and a huge amount of contention as to what to do.

# Are we going to Europe?

## Decision Analysis

However, the two major factors turned out to be a surprise – efficacy and dosing.

- In Europe, the bar had been raised. It was almost 100% assured that efficacy could not be proven.
- Also, studies would likely demonstrate that dosing could be reduced to get the current effects.

# Are we going to Europe?

## Implementation Results

The decision was made to not attempt to enter EU as we would probably not get approval and could lose a significant portion of the US market.

Three years later, a new project team has been established to determine if we should introduce this blockbuster into Europe.

The moral to each story is...



# A Rash Decision

The highest level executive that is not involved in the DA will also veto its implementation.

When all else fails, buy the company.

Good ideas that are not implemented may persist.  
They're just waiting for someone else to get the credit!

# Are we going to Europe?

It doesn't pay to worry or rejoice about implementation of a DA. Corporate memory is exceedingly short.

# The Real Challenges

The answer is right in front of us.