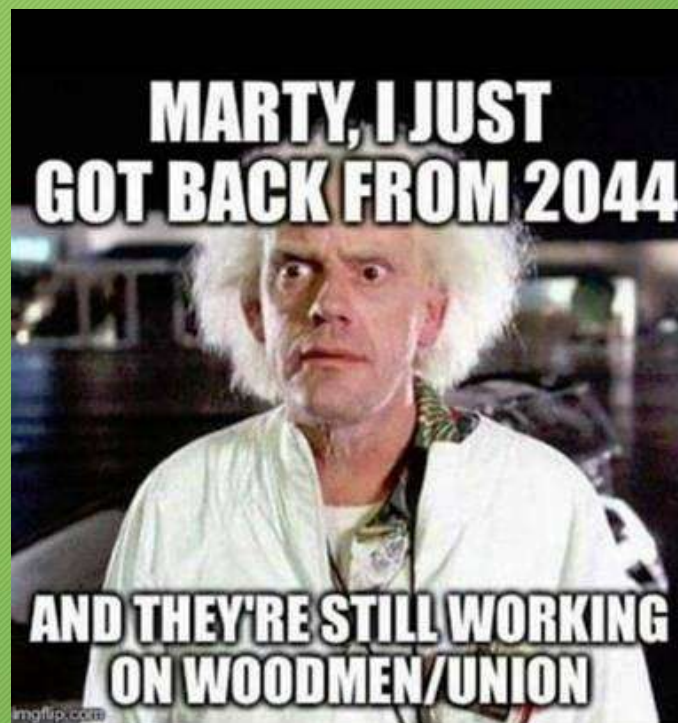


# THE FDA WEB ARCHITECTURE UPGRADE for the FDA

Dr. Dennis Lewis, PMP

No mercy for projects...





# The framework

- The project was quite a disaster in spite of meeting time, cost, and scope.
- The company will be keep anonymous
- to protect the innocent
- and the guilty.
- Comments are strictly those of the author.





# THE FDA

- Under the U.S. Department of Health & Human Services.
- Regulates more than \$1 trillion of consumer goods.
- FDA regulates about 25% of what you buy.
- About  $\frac{3}{4}$  of its budget comes from pharmaceutical companies under Prescription Drug User Fee Act.
- FDA budget at the time was about \$2.1 billion
- 3% requirement - \$63 million set aside for small business.
- White Oak Campus, Silver Spring, MD



# FDA protects public health



**Food,  
except meat  
from livestock,  
poultry and some  
egg products -USDA**



**Electronic  
product  
radiation**



**Cosmetics**



**Dietary  
supplements**



**Tobacco  
products**

**At that time the project supported –  
Centers for Disease Control and Prevention**

**Advancing the public health by helping to speed product  
innovations**

# Topics

Groupthink

Decision-  
making

Cognitive  
illusions

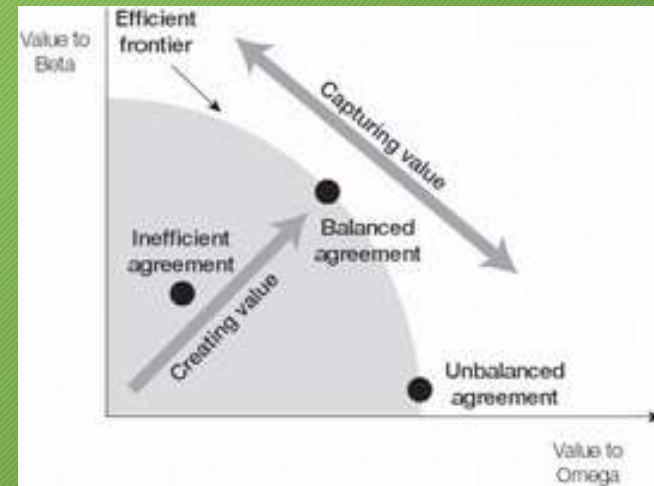
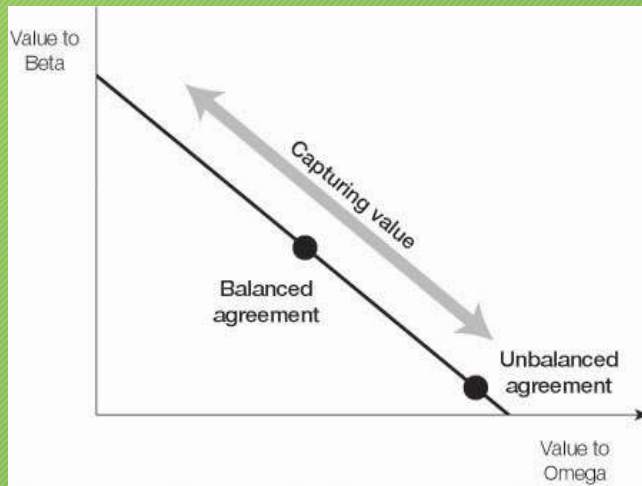


# Groupthink

- Term derived from George Orwell's "1984"
- 1971- Janis researched
  - 1941 Pearl harbor
  - 1961 Bay of Pigs
  - 1964-67 Handling the Vietnam War
- More recent studies
  - NASA and Challenger
  - Mount Everest team that failed
  - Project decision making



# Dividing a Fixed Pie or Enlarging the Pie



Type I: Overestimations of the group — its power and morality

1. *Illusions of invulnerability* creating excessive optimism and encouraging risk taking.
2. *Unquestioned belief* in the morality of the group, causing members to ignore the consequences of their actions.



# The Prime tried to “warn” the FDA about the Sub

- The Prime stereotyped the Sub as incompetent and immoral.
- The kick-off meeting set the tone for the relationship.
- One of the executives tries to warn the FDA about the sub’s character towards the end of year 2.
- The sub had successfully served the FDA for several years.
- The contracting officers listened, but mentioned how the sub was liked by the FDA.
- The FDA cancelled the contract after year 2 of a 5 year (-\$15 million).

## Type II: Closed-mindedness

1. Rationalizing warnings that might challenge the group's assumptions.
2. Stereotyping those who are opposed to the group as weak, evil, biased, spiteful, impotent, or stupid.



# No risks or issues

- Monthly report contained a section for risks and issues
- FDA Contracting Officer's Technical Representative
  - Failure is not an option
  - We have no risks or issues
- I tracked internal to the company; however as an experienced PM, I did slip up a couple of times and put risks and issues on the monthly FDA report...
- Type III: Pressures toward uniformity
  - 1. Self-censorship of ideas that deviate from the apparent group consensus.
  - 2. Illusions of unanimity among group members, silence is viewed as agreement.
  - 3. Direct pressure to conform placed on any member who questions the group, couched in terms of "disloyalty"
  - 4. **Mindguards**— self-appointed members who shield the group from dissenting information.



# Recommendations for preventing groupthink

- The leader sets an open, safe environment.
- Adopt an impartial stance instead of stating preferences and expectations at the beginning.
- Bring in outside expert(s) on a staggered basis.
- Appoint a “devil’s advocate” functioning as a good lawyer.
- When dealing with rival organizations, develop alternative scenarios.
- Time permitting, hold a “second chance” meeting to express doubts and rethink the entire issue before making the final decision.

# Behavioral models

Rational

“Logical”

Intuitive

“Gut”

Bounded  
rationality

“Satisfactory  
versus optimal  
decision”

When I reached 15 team members. Hire a tactical PM or IT lead?

Rational - IT lead

Intuitive - Tactical PM

Bounded rationality - IT lead



# Bounded rationality

- Generally, people are rational and fill in the gaps with irrational decision-making.
- Our limitations for making the decision
  - Manageability of the problem - complex?
  - Cognitive capability - memory?
  - Time available - how time sensitive?
- Organizations minimize this effect with
  - Routinization
  - Specialization
  - Training
  - Standard Procedures
  - Etc.





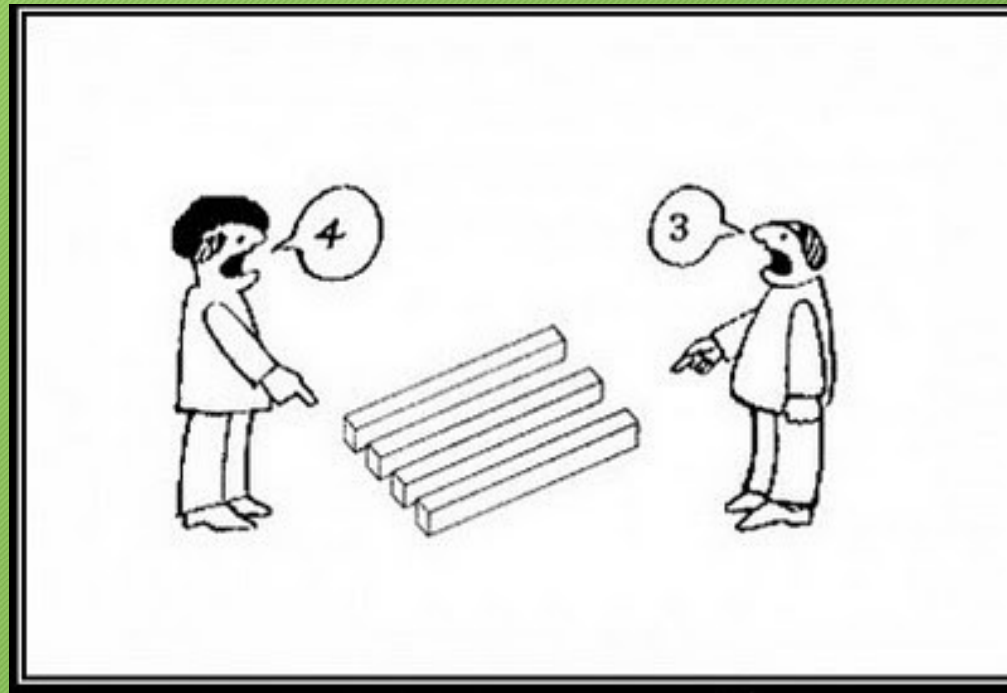
# Behavioral patterns

- Which is more likely to happen to you overseas – a terrorist attack or a car accident?
- People Survey says... terrorist attack. Statistics say...car accident
- Are there more words in the English language that start with the letter ‘k’ or those words that have the letter “k” in the third position?
- People Survey says...first letter. Actual dictionary says...third letter
- The risk of cognitive illusions
- “an impression that you get at the intuitive, but not necessarily emotional, level that is wrong or misleading.”





# Cognitive illusions - a matter of perspective



# Cognitive illusions

- The list is overwhelming - a few examples
- Fortune telling - presuming to know the future
- The company was sure it would continue the contract
- Mind reading - presuming to know what someone else is thinking
- My IT lead thought he knew the FDA
- Optimism bias in cost estimation
- Typically in technology and innovation projects



# How to overcome cognitive illusions

- Is intuition bad?
- Most of the time our intuition is correct.
- What is human nature and what is the role and power of the situation?
- Debiasing our perceptions.
- Training and education helps.
- Building in rational models of decision-making.
- Monitoring and reinforcing the decision making process(es).