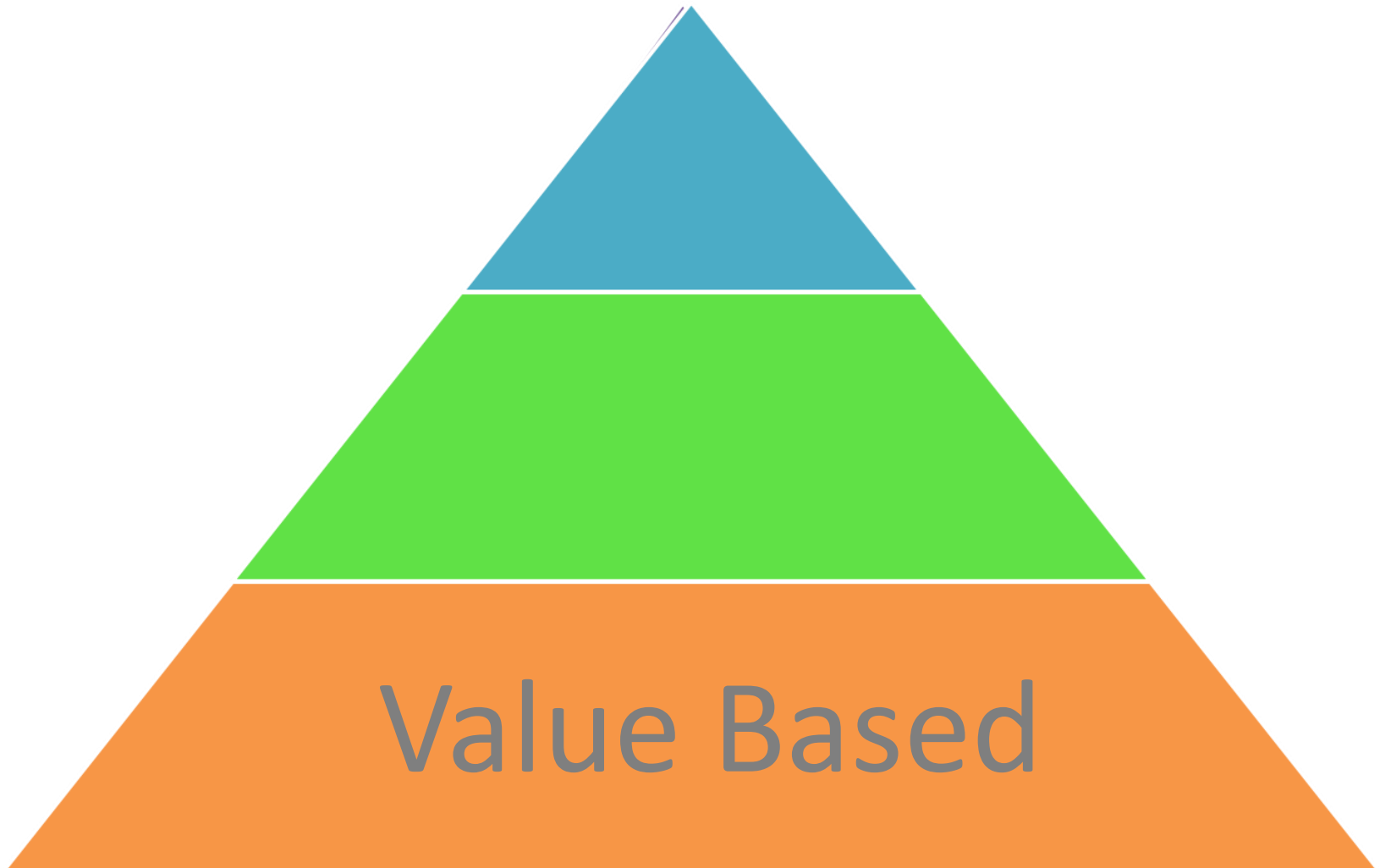




# A **PASSION** FOR INTEGRITY

*Harmonising Compliance Challenges*

# Values, Rules & Perception



# Values before Rules



## Our Credo

We believe our first responsibility is to the doctors, nurses and patients,  
to mothers and fathers and all others who use our products and services.

In meeting their needs everything we do must be of high quality.

We must constantly strive to reduce our costs  
in order to maintain reasonable prices.

Customers' orders must be serviced promptly and accurately.

Our suppliers and distributors must have an opportunity  
to make a fair profit.

We are responsible to our employees,  
the men and women who work with us throughout the world.  
Everyone must be considered as an individual.

We must respect their dignity and recognize their merit.

They must have a sense of security in their jobs.

Compensation must be fair and adequate,  
and working conditions clean, orderly and safe.

We must be mindful of ways to help our employees fulfill  
their family responsibilities.

Employees must feel free to make suggestions and complaints.

There must be equal opportunity for employment, development  
and advancement for those qualified.

We must provide competent management,  
and their actions must be just and ethical.

We are responsible to the communities in which we live and work  
and to the world community as well.

We must be good citizens — support good works and charities  
and bear our fair share of taxes.

We must encourage civic improvements and better health and education.

We must maintain in good order  
the property we are privileged to use,  
protecting the environment and natural resources.

Our final responsibility is to our stockholders.

Business must make a sound profit.

We must experiment with new ideas.

Research must be carried on, innovative programs developed  
and mistakes paid for.

New equipment must be purchased, new facilities provided  
and new products launched.

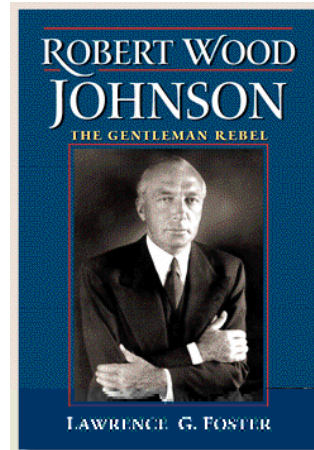
Reserves must be created to provide for adverse times.

When we operate according to these principles,  
the stockholders should realize a fair return.

- 1-pager document
- over 60 years “young” & alive
- we are responsible towards
  1. our customers, their families
  2. our employees
  3. the community
  4. our stockholders

*Johnson & Johnson*

*General Robert Wood Johnson*  
*former CEO*  
*Writer of Our Credo*

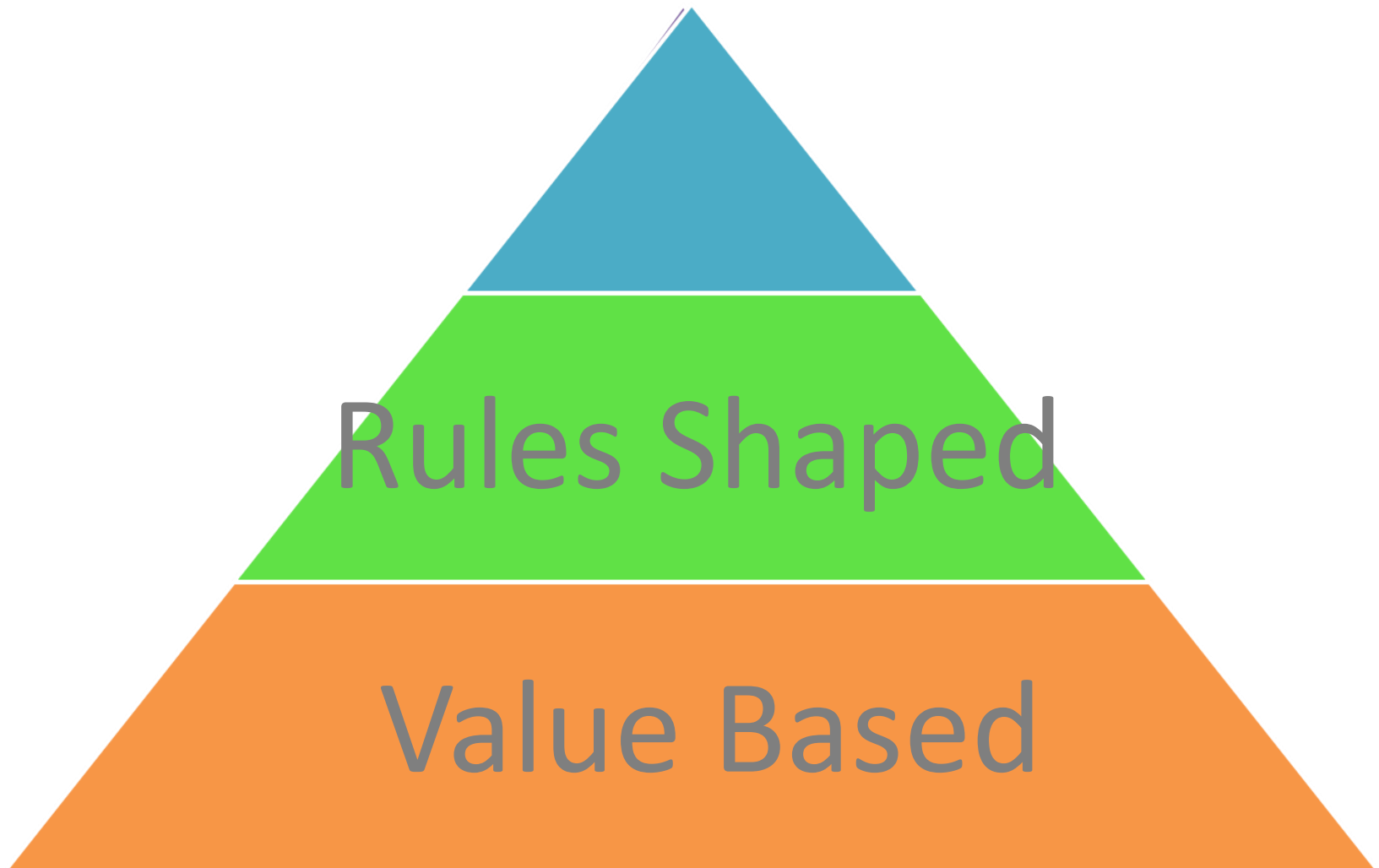


# Values before Rules



- 
- Value based Compliance : Empowerment, Effectiveness, Sustainability
  - General guide for every employee
  - Assuring the mindset
  - Cultural differences impact on ‘the Right Thing’
  - Moral Compass versus Complexity

# Values, Rules & Perception



# Rules before chaos



- Ability to Specify
- Provide more Clarity
- Add more Detail where needed
- Assure Consistency
- Provide Structure
- Allow for better Verification
- Set the basis for Enforcement

# Rules before chaos



- **Policy on Business Conduct**
  - HCBI Guide and Framework
  - **Applicability & Scope**
  - **Compliance at Johnson & Johnson**
  - **Johnson & Johnson Compliance Committee**
  - **Anti-corruption Policies and procedures**
  - **Interactions with Health Care Professionals**
  - **Exceptions Policy**
  - **Training and Certification**
  - **Financial Controls**
  - **Employment Actions**
  - **Hotlines and Whistleblower Protection**
  - **Continuing Improvement of Policies and Procedures**

# Values, Rules & Perception



Perception Optimized

Rules Shaped

Value Based



# Perception is reality

**Corruption:**  
Abuse of entrusted power for private gain  
Transparency International

RIGHT

GREY ZONE

WRONG



Intent  
Or the importance of  
Why ?

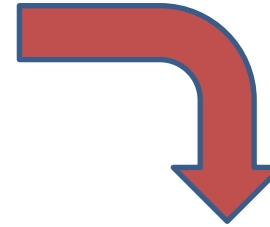
# Perception is reality

## Top Psychiatric Researcher Dr. Biederman Caught Lying about \$1.6 Million in Drug Money;

by Mike Adams, the Health Ranger, NaturalNews Editor

(NaturalNews) Harvard University's Dr. Joseph Biederman has been a loyal soldier in the battleground for chemical control over children's minds. A highly-influential researcher at Harvard University, Dr. Biederman spearheaded a 4000% increase in the diagnosis of pediatric *bipolar disorder* from 1994 to 2003, resulting in billions of dollars in revenues for drug companies and millions of children being put on mind-altering medications. Now, thanks to an investigation by the office of Sen. Charles Grassley and a damning report published in the *New York Times*, it has been revealed that Dr. Biederman lied about the amount of money he received from drug companies -- a figure that may exceed \$1.6 million.

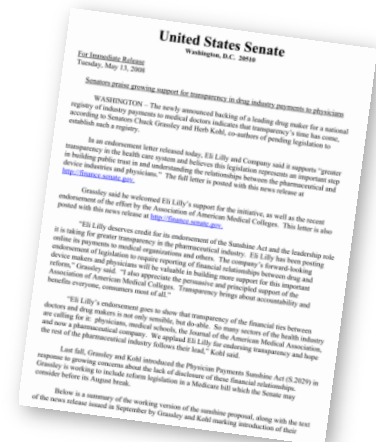
In the conflict-of-interest documents submitted to Harvard Medical School, Dr. Biederman vastly underreported funds received from multiple drug companies. In one instance, he reported a payment from Johnson & Johnson of just \$3,500 when, in reality, company records show J&J paid him \$58,169 in one year alone (2001). Before this story went public, Dr. Biederman sought to modify his conflict-of-interest records, and when pressed by Sen. Grassley's investigators, he made retroactive changes showing an additional \$1.6 he had previously failed to disclose. These disclosure might never have happened if Sen. Grassley's investigators had not started asking questions about the financial links between drug companies and Dr. Biederman.



Transparency the only answer

## Sunshine Act

Introduced by  
Sen. Grassley



Requirement to report & make publically available online any payments to physicians by Pharma

# The Health Care Challenge



- Government controlled social security
- FCPA
- OECD
- Number of possible GO interactions
- Number of staff involved

# The Health Care Challenge



## Who is who? Complex Stakeholders Interactions...

- Physicians are to the industry :
  - Customers (in their prescribing role)
  - Service providers (as Speakers, Experts, Researchers...)
  - Decision Makers (as Pricing Committee Members, Expert etc.)
- Who else is a customer ?
  - Wholesalers, Distributors, Pharmacists, Retail Chains, Hospitals, Clinics ....
  - The Sick Funds, the Managed Care Organizations
  - The Ministry of health (through Public Hospitals etc..)
  - The patient as co-payer and as the one who receives the treatment

# Medical Devices : Is it Different ?



- A very similar Tool Box :
  - Sales Representatives calls
  - CME through Educational Grants, Congresses, Symposia and Stands
  - Consulting / fee for service activities
  - Company and Investigators initiated studies

# Medical Devices : Is it Different ?



- But some differences :
  - Partly because of the offer (wide range of segments & products)
  - The HCP is a more 'direct' end user than in Pharma
  - Presence in the Operating Room
  - Relevance of On-label Off-label, need for MSLS
  - Product Training
  - Placement of equipments: trial, financial leasing and other rentals
  - Product development and IP : more widespread /every day interactions

# Medical Devices : Is it Different ?



- Most Applicable rules are generally the same :
  - HCPs are governed by the same rules :
    - Legal
    - Deontological
  - Processes are governed by the same rules : Fee for Service, Education
  - Public tendering legislations apply, Competition rules
  - FCPA
  - Product regulatory framework (partly)
  - Self regulation has strong similarities (Eucomed)
- No need for different rules but may be for some additional ad hoc rules to cover some of the differences

# To be or Not to be .... Right !



## Acceptable

- In line with your values
- legal
- Legitimate business need
- Modest
- Appropriate
- Fair market value
- Patient benefit
- Perceived to be acceptable
- .....

## Questionable

- What you can't explain
- What you can't defend
- What is not or poorly regulated
- Common practice, not in line with values or codes
- Common practice due to lack of enforcement
- Complex activity with all of the above

## Beyond

- What puts the patient at risk
- Wrong intent
- Illegal
- Against your values
- Not in line with industry code or regulations
- Extravagant

RIGHT

GREY ZONE

WRONG



**To be .. or not to be .....Right !**



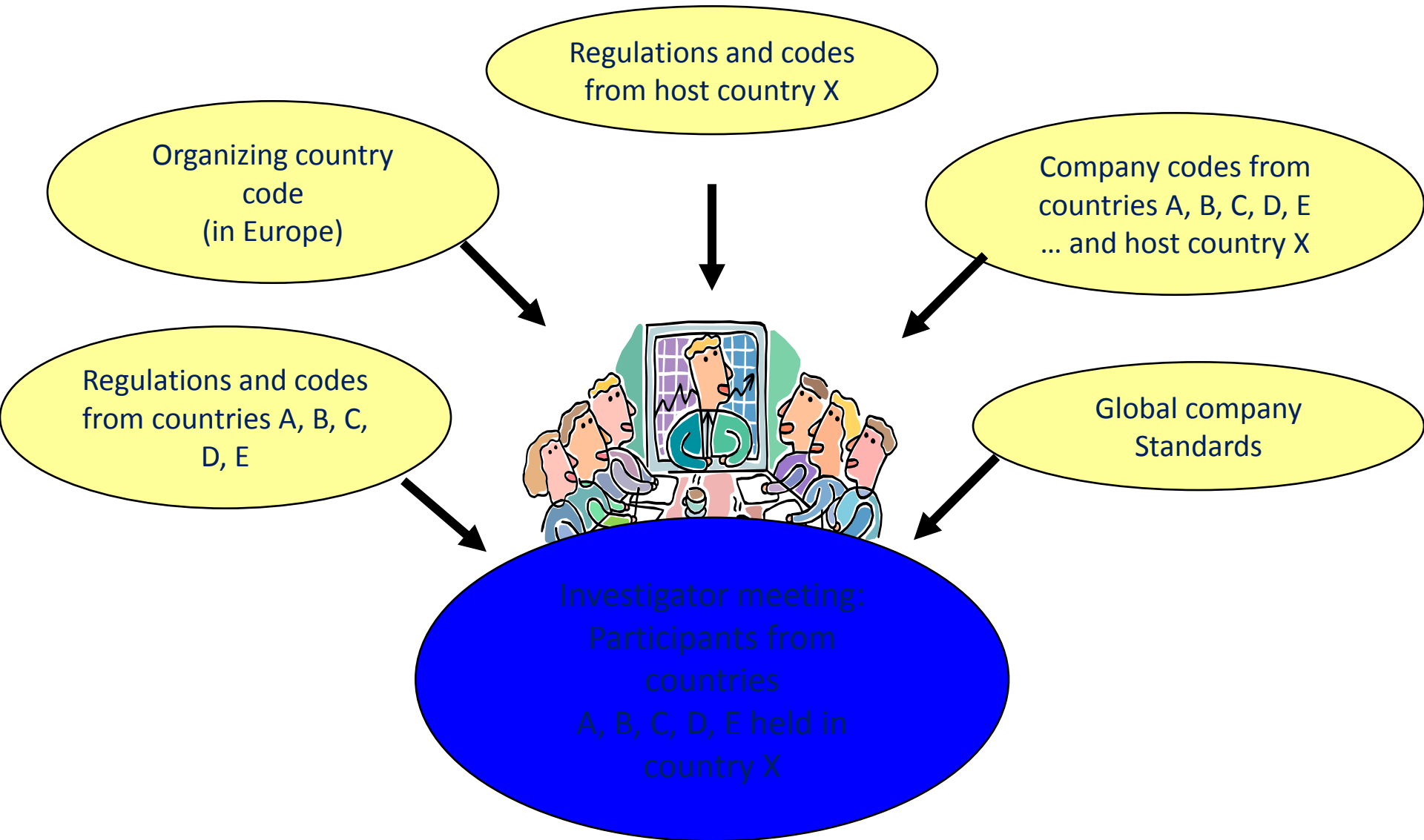
**The multinationals' nightmare !**

# Cross border challenges



- Multiple rules in addition to IFPMA, EFPIA, EUCOMED and national codes
  - Local legislations, tax regulations
  - Regulatory bodies, court actions, health professional codes, HCP employers rules, etc. etc.
- International Meetings involve multiple codes and laws
- Impossible to have one stand alone global training programme and materials

# Multi-country events: Which limits apply

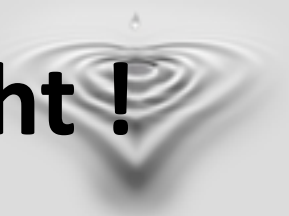




# J&J's response to the challenge

- One independent structure
- Reporting to the office of the Chairman
- Matrix Regions ↔ Sectors
- Strong local presence
- Standardised policy and process design
- Room for local tailoring
- Centralised testing
- Independent audits

**To be ... or Not to be ... Right !**



**It all depends !!!**



**Thanks For Your Attention !!**