A PASSION FOR INTEGRITY

Harmonising Compliance Challenges
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

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

Value Based

Rules Shaped

Value Based
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

Intent

Or the importance of Why?
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.

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
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
<table>
<thead>
<tr>
<th>Acceptable</th>
<th>Questionable</th>
<th>Beyond</th>
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<tbody>
<tr>
<td>• In line with your values</td>
<td>• What you can’t explain</td>
<td>• What puts the patient at risk</td>
</tr>
<tr>
<td>• legal</td>
<td>• What you can’t defend</td>
<td>• Wrong intent</td>
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<tr>
<td>• Legitimate business need</td>
<td>• What is not or poorly regulated</td>
<td>• Illegal</td>
</tr>
<tr>
<td>• Modest</td>
<td>• Common practice, not in line with values or codes</td>
<td>• Against your values</td>
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<tr>
<td>• Appropriate</td>
<td>• Common practice due to lack of enforcement</td>
<td>• Not in line with industry code or regulations</td>
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<tr>
<td>• Fair market value</td>
<td>• Complex activity with all of the above</td>
<td>• Extravagant</td>
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<td>• Patient benefit</td>
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<td>• Perceived to be acceptable</td>
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<td>• ..........................</td>
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To be .. or not to be .....Right!

The multinationals’ nightmare!
Cross border challenges

• Multiple rules in addition to IFPMA, EFPIA, EUCLIMED 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

Investigator meeting:
Participants from countries A, B, C, D, E held in country X

Regulations and codes from host country X

Company codes from countries A, B, C, D, E ... and host country X

Global company Standards

Organizing country code (in Europe)

Regulations and codes from countries A, B, C, D, E
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 !!