Business Ethics and Legal Compliance 201

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This Week's Program
Three Broad Areas

1) **Understanding the Law**
- Specific Legal Regimes
- Enforcement (Types and Sanctions)
- Application issues

2) **Developing Compliance Structures and Practices**
- Specific Methods and Internal Controls
- Tools for Reducing Noncompliance Risks and Avoiding Pitfalls
- Utilizing what you have learned

3) **Fostering an Ethical Business Culture**

Why Focus on Business Ethics?

1. Compliance is values driven -- doing what is right is an end in itself
2. Enforcement agencies expect it
3. When something goes wrong, enforcement officials will look behind policies and procedures
4. Employees prefer to work for ethical companies
5. *Compliance rules and processes are insufficient alone – compliance depends on culture*

Framing the Conversation

- This presentation is *not* about a particular conception of business ethics or morality
- Business ethics is *not* a substitute for law
- There is understandable skepticism about whether business ethics codes and programs further compliance
- <u>This presentation is about what works</u>

  - Why fostering an ethical business culture is essential
  - How to build and maintain such culture
  - Drawing on literature and your experiences

Why Does an Ethical Business Culture Promote Compliance?

Company

Employee

Society

Overlapping and Conflicting Interests
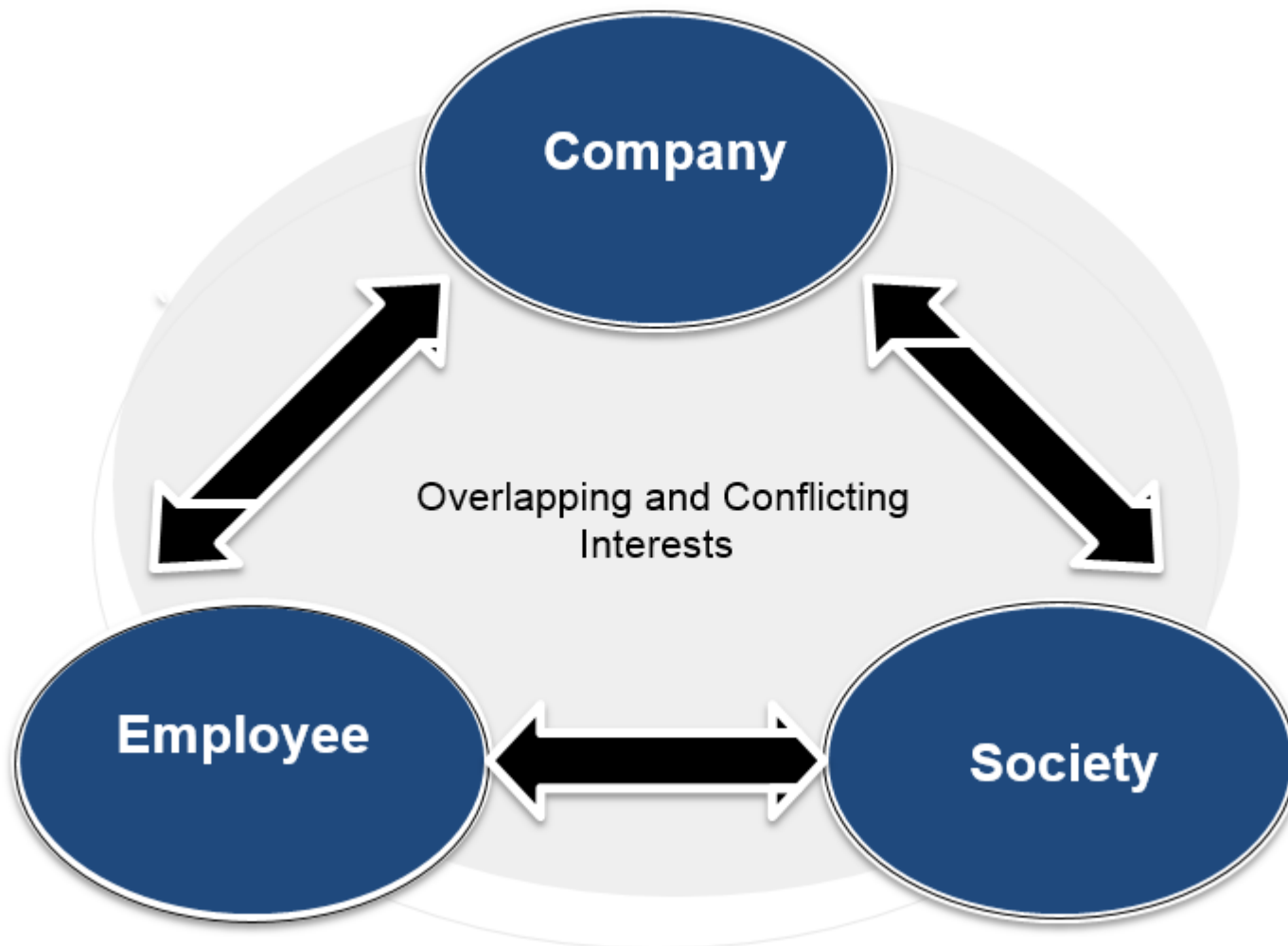
The Theory Translated

A Focus on Ethics . . .

1. Inspires in a way rules do not
2. Gives you opportunities to involve other employees
3. Builds trust and loyalty
4. Removes clearly ethically and legally suspect choices from consideration
5. Assists managers and employees in navigating legal gray areas
6. Prompts employees to question the ethical (and therefore legal) dimensions of their actions

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OR

?

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7. Makes employees comfortable reporting and discussing ethical (and therefore legal) concerns
8. **Eliminates norms that can undercut legal compliance efforts**
9. **Establishes norms and behaviors that are more powerful than policies, rules, and procedures**

Warren Buffett, 2010

- "…We now employ more than 250,000 people and the chances of that number getting through the day without any bad behavior occurring is nil. But we can have a huge effect in minimizing such activities by jumping on anything immediately when there is the slightest odor of impropriety. Your attitude on such matters, expressed by behavior as well as words, will be the most important factor in how the culture of your business develops. **Culture, more than rule books, determines how an organization behaves**."

Volkswagen's new CEO must tackle the 'culture of arrogance'

VW's ability to rebound from this cheating scandal hinges on the company's willingness to address the culture that enabled it. . . .

Even Bernd Osterloh, VW's top labor executive and a member of the supervisory board, conceded at Friday's press conference in Wolfsburg, Germany that "Volkswagen needs a fundamental cultural change."

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How to Establish and Maintain an Ethical Business Culture

Principles/Values in Corporate Codes

- *Honesty*
- *Patient welfare and access*
- *Ethical research practices*
- Personal responsibility/accountability
- Loyalty
- Compliance with legal mandates
- Fairness to other stakeholders and interests
  - employees, agents, communities, environment
- Nondiscrimination
- Other (e.g., confidentiality)
- *Fair profits for shareholders*

I. Standard Principles/Values in Corporate Codes

- *Honesty*
- *Patient welfare and access*
- *Ethical research practices*

  - First principles should be universal but not carved in stone

  - Principles should be subject to periodic review

 - All subsidiary principles and rules should flow from these

II.   Ethical Leadership at the Top

- **THE EASY PART**
  - All agree tone at the top is key
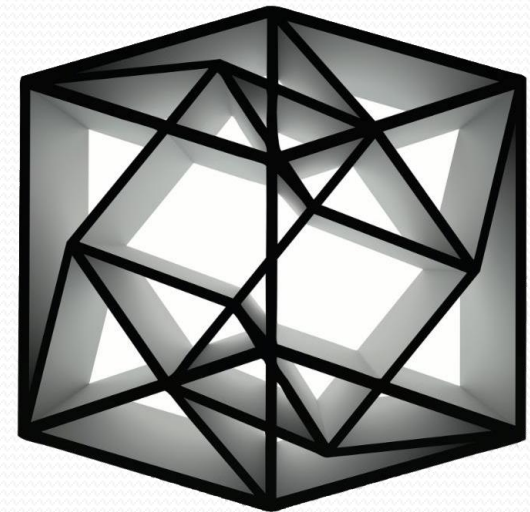 - By now, most leaders want to set an ethical tone

- **THE REALLY HARD PART(S)**
  - Consistency is essential
    - Leadership messages, behaviors, practices, strategic planning
  - Employees and others view leadership through their own experiences
    - Through their interactions with their managers and co-workers
    - Through their perception of other messages, policies, and practices
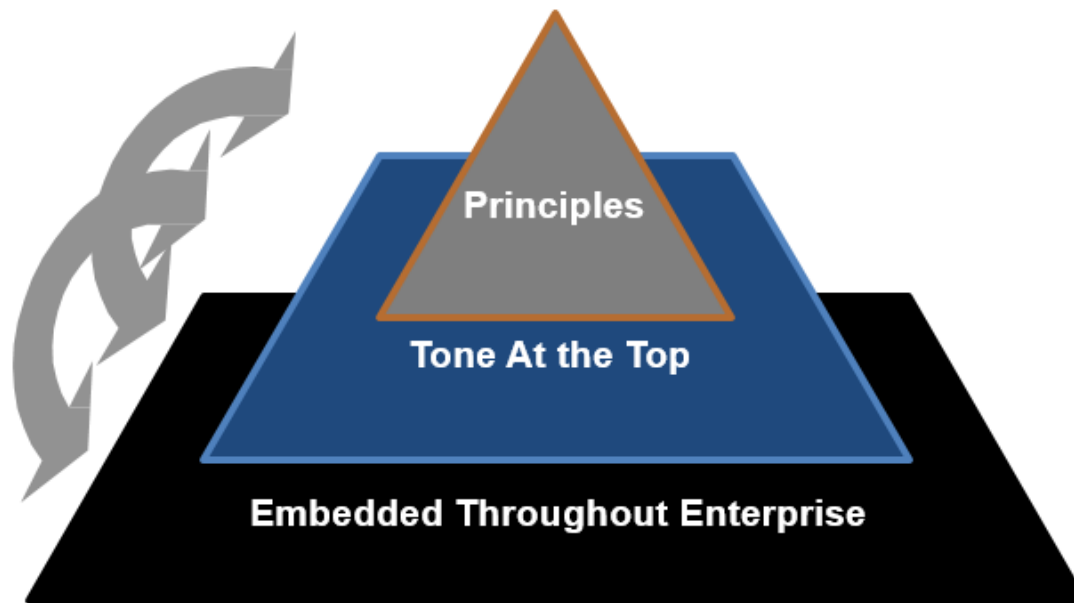
III. Embedding Ethics Throughout the Enterprise

- No single policy, procedure, or action is enough
- Culture must be consciously constructed and maintained
- A comprehensive, multi-dimensional strategy is required
  - Top to bottom
  - Internally and externally
  - Across departments and functions
  - Formal and informal
  - Beginning to end of processes
  - *Internalization far from your office*

Entry Points for Misbehavior

PHASE II	PHASE III	SUBMISSION	LAUNCH	LIFE CYCLE MANAGEMENT
Site Selection	Registration Batch Production	Pre-Approval Inspection	Product to Market	Cold-chain Management
Technical Transfer	Scale-up/ Validation	Final Package	Production Efficiency Studies	Supply/Distribution
Process Development	CMC Preparation			Drug Delivery Expansion
Clinical Manufacturing				

Embedding Ethics Throughout the Enterprise: Seven Components

- Communications
- Company Structure
- Decision-Making Practices
- Participation and Collaboration
- Full Integration into Processes
- Rewards and Punishments
- Symbols, Rituals, and other Reminders

Through Communications . . .

- **Akin to a Branding and Marketing Strategy**
  - Develop your brand of ethics
    - Use a simple slogan to capture ethical principles
    - Promote this brand everywhere

Through Communications . . .

- **Akin to a Branding and Marketing Strategy**
  - **Develop your brand of ethics**
    - Use a simple slogan to capture ethical principles
    - Promote this brand everywhere
  - **Ensure consistency throughout the company**
    - Insist all company communications reflect values
    - Audit and refashion existing communications and policies
    - Tailor articulation to meet the needs of the audience
  - **Send the messages through others**
    - Top and mid-level leadership, and co-workers
    - Find your champions
  - **Reinforce the message during challenging times**

Through the Company's Structure . . .

- **At the Very Top**
  - Ethics must be apparent at the board level and in board decision-making
  - Top executives must personify the values
  - Top ethics officer must have direct access to the board
  - Titles
- **Across all Divisions/Subsidiaries**
  - Common governing values with localized variations
  - Growth and international challenges
- **Extended to Third-Party Agents and Vendors**

Through Decision-Making Practices . . .

- Ensure principles guide strategic/business planning
- Develop decisional frameworks that embody principles
  - Build into every decisional process
  - Can utilize defaults, presumptions
- Remind employees of business and personal ethics
- Avoid resorting to pure economics or numbers
- Produce rules that reflect first principles
- Make the ethical choice easy

Through Participation and Collaboration . . .

- Build trust and ownership by involving employees in policy drafting
  - Develop principles, decisional frameworks, and resulting rules
- Help them make the connection between ethical principles and their work
- Engage them with trainings that are entertaining and interactive
  - Use video, games, and case studies
 - Connect discussions to real examples and scenarios

Through Full Integration into Processes. . . .
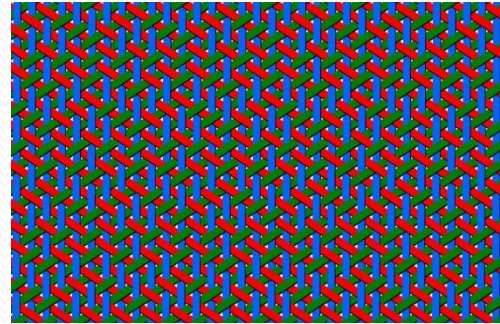
- Weave ethics into all practices and processes
  - Build ethics into hiring
  - Integrate ethics into *all* training
  - Tie promotion and advancement to principles
- Ensure ethical principles govern at every stage
  - e.g., strategic planning, research and development, production, marketing, sales
- Think quality control -- avoid leaving ethical considerations until late in any process
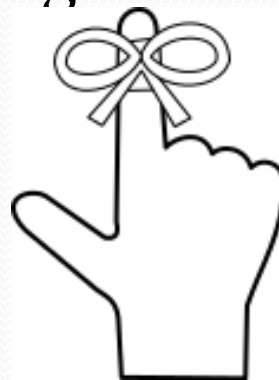- Create systems that will withstand personnel and organizational change

Through Rewards and Punishments . . .

- Ensure rewards and expectations do not undercut principles
  - Compensation systems
  - Performance benchmarks and metrics
- Bolster trust and legitimacy through appropriate punishments
  - Consequences must appear consistent
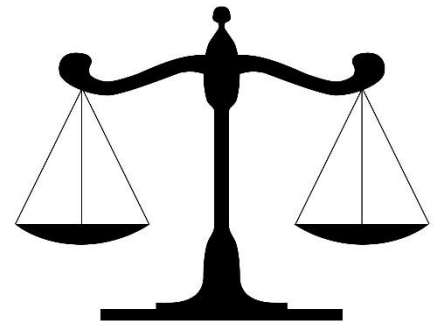
Through Symbols, Rituals, and Other Reminders . . .

- Set milestones and measures, and celebrate the small accomplishments
- Find examples to highlight formally and informally
- Tap employee enthusiasm
- Take advantage of all forms of direct and indirect communication
- Use tchotchkes, posters, and images to remind (consciously or unconsciously)

Your ideas . . .