



**LRN**

# Regulation, Compliance, Culture Or All of the Above?

*FDA Regulatory and Compliance Symposium  
August 24, 2006*



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# Speakers

- Ann Beasley Bacon
  - Compliance Counsel, Boehringer Ingelheim Pharmaceuticals, Inc.
- Gary Giampetruzzi
  - Deputy Compliance Officer, Pfizer Inc
- Heather Powell
  - Compliance Counsel, Cephalon
- Adam Turteltaub
  - Corporate Relations Executive, LRN

# LRN

- LRN's legacy began over 10 years ago, providing customers with legal research at a fixed fee via a global network of over 1,000 legal experts.
- In 1998 began educating workers to identify and avoid legal and ethical risk.
- Today, over 11 million course completions by our customers' employees



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# Boehringer Ingelheim Corporation

- Boehringer Ingelheim is a research-driven group of companies dedicated to researching, developing, manufacturing and marketing pharmaceuticals that improve health and quality of life.
- Our business consists largely of Prescription Medicines, Consumer Health Care, Biopharmaceuticals and Animal Health. We focus on the production of innovative drugs and treatments that represent major therapeutic advances.
- Excellence in innovation and technology guides our actions in all areas. Our products have long been highly successful in the treatment of respiratory, cardiovascular, central nervous system, urological and virological disorders. In addition we have intensified our research into the immune system, metabolic diseases and cancer.

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# Boehringer Ingelheim Corporation

- Boehringer Ingelheim, which currently has almost 37,500 employees, has 143 affiliated companies spread around the globe. We have research facilities in nine countries and production plants in more than 20. Our pharmaceuticals research and development spending corresponds to about 18 percent of net sales in Prescription Medicines.
- Our global headquarters is in Ingelheim, the German town where the company was founded in 1885.
- Headquartered in Ridgefield, Connecticut, Boehringer Ingelheim Corporation is the parent of six American subsidiaries that employ nearly 6,400 people. Our US business includes operations in human pharmaceuticals, human generic pharmaceuticals, veterinarian pharmaceuticals, OTC products and chemicals.

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# Cephalon

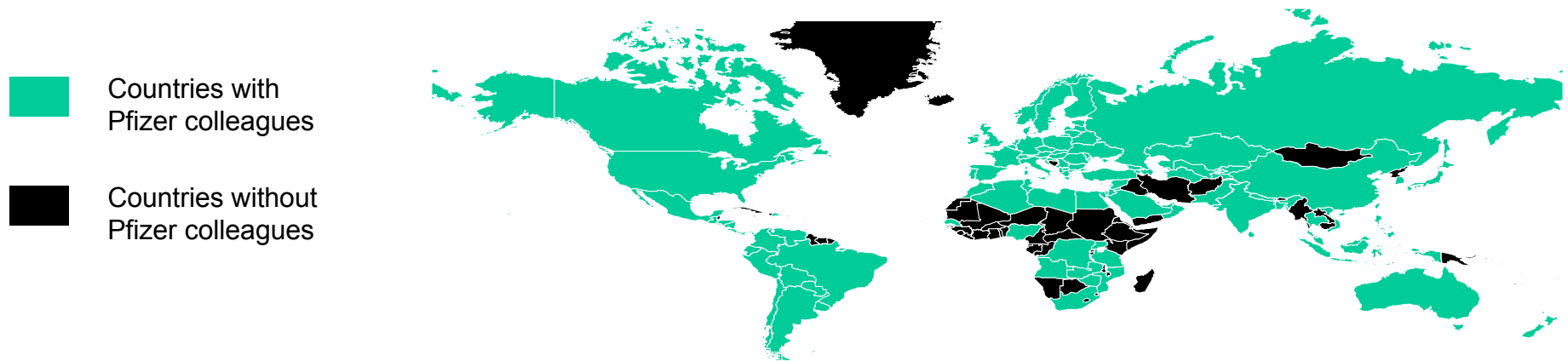
- Based in Frazer, PA with 2500 employees worldwide.
  - Manufacturing facilities in Minnesota, Utah and Europe.
- Five marketed products: Provigil, Actiq, Gabitril, Trisenox, Vivitrol.
- Compliance Officer Eric Siegel hired in 2004.
  - Two compliance attorneys hired since: 2005 and 2006
- Continually enhancing compliance program.
  - Live training
  - Web-based training via LRN
  - 24/7/365 Ethics and Compliance HelpLine
  - Global Code of Conduct revision in 2006

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# Pfizer Inc

- Largest pharmaceutical company in the world
  - Founded in 1849
  - Headquartered in New York City, NY
- Core areas of business
  - Approximately 11,500 U.S. sales representatives
  - Tens of thousands of sales representatives across other countries
  - PGRD - research and discovery; PGM - manufacturing operations
  - Animal Health, Capsugel, Consumer Healthcare (recent sale)
- The two in four factor
  - Two acquisitions in four years greatly increased employee base
  - From approximately 40,000 to 120,000 colleagues today
- Compliance, Ethics, Values and Leadership Behaviors
  - Pfizer Global Compliance Program: Every Colleague, Every Day

# Global Operations: Global Compliance, Ethics, Values and Leadership Behaviors



Our Global Mission:  
Compliance Brings Value



"We will become the world's most valued company to patients, customers, colleagues, investors, business partners, and the communities where we work and live."



# The Role of Rules

- Rules have worked in many areas
- But they reflect vulnerabilities, not strengths
- Designed to proscribe, reign in and constrain, rather than encourage and inspire
- Subject to interpretation and deliberate misinterpretation (loopholes)
- Are by their very nature over and under-inclusive

**“America’s greatest invention: the loophole” – Conrad Black**



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# A New Era of Values

“Can Chuck Prince  
Clean Up Citi?”

**“Beyond fine words,  
Prince has to transplant  
that culture of probity into  
the DNA of thousands of  
employees worldwide.”**

*—Business Week, October 4, 2004*

The Boeing Conundrum

**“... the CEO must set the  
standard for unimpeachable  
professional and personal  
behavior.”**

**-- Former Boeing Chairman Lou Platt**

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# Fundamental Shifts

- From rules to standards
- From back-end controls to front end
- From defense to offense— from viewing ethics as a burden or cost to viewing ethics as essential for success
- From what you produce to how you produce it
- From evaluating conduct on plausible deniability to expecting absolute honesty
- From the rule of law to law + ethics – “can” and “should” considered together
- From programs to culture

# Regulators Have Zeroed In On Culture



## Federal Sentencing Guidelines

“... undertake an appropriate assessment of corporate efforts to create an **organizational culture** that encourages a commitment to compliance with the law and ethical conduct.”



## National Association of Corporate Directors

“...Implement new board and committee practices...and establish an **ethical corporate culture**”



## U.S. Air Force

“Companies must have values-based ethics programs.”

# Culture & Regulators



## The Department of Justice

“... A corporation is directed by its management and management is responsible for a **corporate culture** in which criminal conduct is either discouraged or tacitly encouraged.”



## The Securities and Exchange Commission

“[K]eep up your vigilance, avoid complacency, and remain steadfast in your efforts to maintain strong compliance programs, built on the foundation of **a culture in which investor interests are placed first**. Let your business and compliance decisions always be guided by that principle.”

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# CEOs Care About Culture

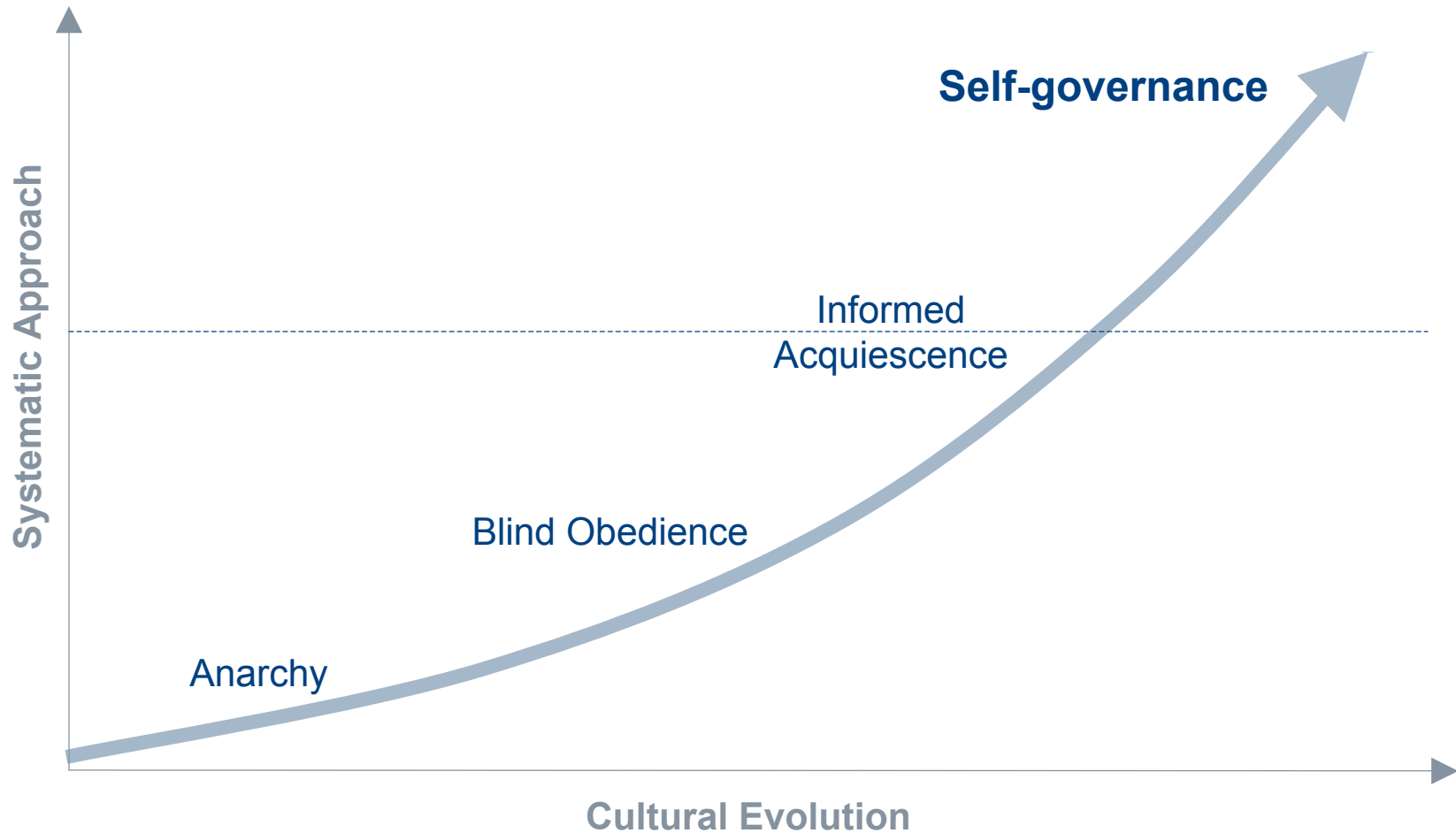
- “I came to see, in my time at IBM, that **culture** isn't just one aspect of the game; it is the game.” Lou Gerstner, IBM
- “Our values are a declaration of our core beliefs and the defining features of a **culture** that breeds achievement.” Hank McKinnell, Pfizer.
- “No matter how good the numbers look, **culture matters** as much as financial profile.” Jack Welch, GE

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# A Working Definition of Culture

- Culture is a system of beliefs, norms, practices, habits, values that are passed from one generation to the next relating to how to act, make decisions and govern our affairs
  - It is at once the greatest controller and greatest determiner of success
  - Only culture can create the predictability, consistency, reliability and certainty necessary for enduring success
- Rule of law / compliance alone is not sufficient

# Corporate Culture





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# Discussion