Culture, Ethics and Compliance

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SETON HALL | LAW
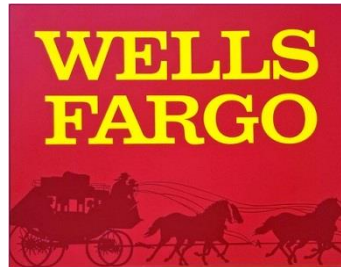*integrity loyalty engagement*
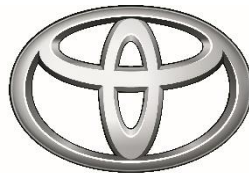
Code on Interactions with Healthcare Professionals

PhRMA

Timeline

PhRMA Code
July 2002

US OIG
Compliance
Guidance
Apr. 2003

AdvaMed
Code
Jan. 2004

- Belgium's
  MedicinesAct
  May 2006
- ABPI (UK) Code
  of Practices
  May 2006

Australian
Competition &
Consumer
Commission
Mar. 2007

JPMA (Japan)
Promotion
Code
May 2008

- Revised
  PhRMA Code
  Jan. 2009
- Revised
  AdvaMed Code
  July 2009

US Healthcare
Reform
Mar. 2010

Revised ABPI
Code of
Practices
Jan. 2011

- US Sunshine Act
  Feb. 2013
- French Sunshine Act
  May 2013
- EFPIA Disclosure
  Code June 2013
- French Sunshine Act
  Report Due Aug.
  2013

- Revised ABPI
  Code of
  Practices
  Jan.2014
- French
  Sunshine
  Act Report Due
  Feb. 2014
- First US
  Sunshine
  Report
  Due Mar. 2014

EFPIA Data
Collection
CY 2015

First EFPIA
Disclosure
Report 2016

2002 2003 2004 2005 2006 2007 2008 2009 2010 2011 2012 2013 2014 2015 2016

From pwc – EFPIA and Global Transparency Requirements Implementing an aggregate spend program in a global marketplace, February 2014

$ 31.3 Billion recovered by the US Government since January 2009 through the False Claims Act

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Dictionary

comply 🔊

verb | com·ply | \kəm-ˈplī\

: to conform, submit, or adapt (as to a regulation or to another's wishes) as required or requested • *comply* with federal law • the devices *comply* with industry standards

¹culture 🔊

noun | cul·ture | \ˈkəl-chər\

c : the set of shared attitudes, values, goals, and practices that characterizes an institution or organization • a corporate *culture* focused on the bottom line

ethic 🔊

noun | eth·ic | \ˈe-thik\

ethics *plural in form but singular or plural in construction* : the discipline dealing with what is good and bad and with moral duty and obligation

- It is more than elegantly written Codes of Conduct, Values Statements and Ethics Principles – it is the way things really work when conducting day-to-day business.

- It is a workplace that makes it easy to do the right thing and difficult to do the wrong thing.

- It is a workplace where people know what the right thing is and will do it even when no one is watching.

" Sometimes what is thought to be ethical in one time period, is deemed not to be so later on "

Dr. Myron Scholes
Nobel Prize Winner
Partner, Long Term Capital Management

Bayer's 'Heroin'. Between 1890 and 1910 heroin was sold as **a non-addictive substitute** for morphine. It was also used to treat children suffering with a strong cough.

Cocaine drops for toothache. Very popular for children in 1885.

The Katzenbach Center

strategy&
Formerly Booz & Company

CULTURE AND CHANGE
Why Culture Matters and How It Makes Change Stick

Cultural Outlook

84% believe culture is critical to business success

60% think culture is more important than strategy or operating model

51% think a major overhaul is currently needed in their culture

ONLY **35%** think their company's culture is effectively managed

Who's driving the change?

Who IS in charge of culture change?

Who SHOULD BE responsible for culture change?

59% claim the CEO and other top leaders are currently responsible for change

14% say all employees are currently responsible for change

43% say CEO and other top leaders

42% say all employees

2,200 respondents across seniority levels, countries and company size

CRITICAL

MORE IMPORTANT THAN STRATEGY

EFFECTIVELY MANAGED

EVERYONE IS RESPONSIBLE FOR CHANGE

From: pwc - 2013 culture and change management survey

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Words of Wisdom from Warren Buffett

"It takes 20 years to build a reputation and five minutes to lose it. Lose money for the firm and I will be understanding; lose a shred of reputation for the firm and I will be ruthless."

*"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**."*
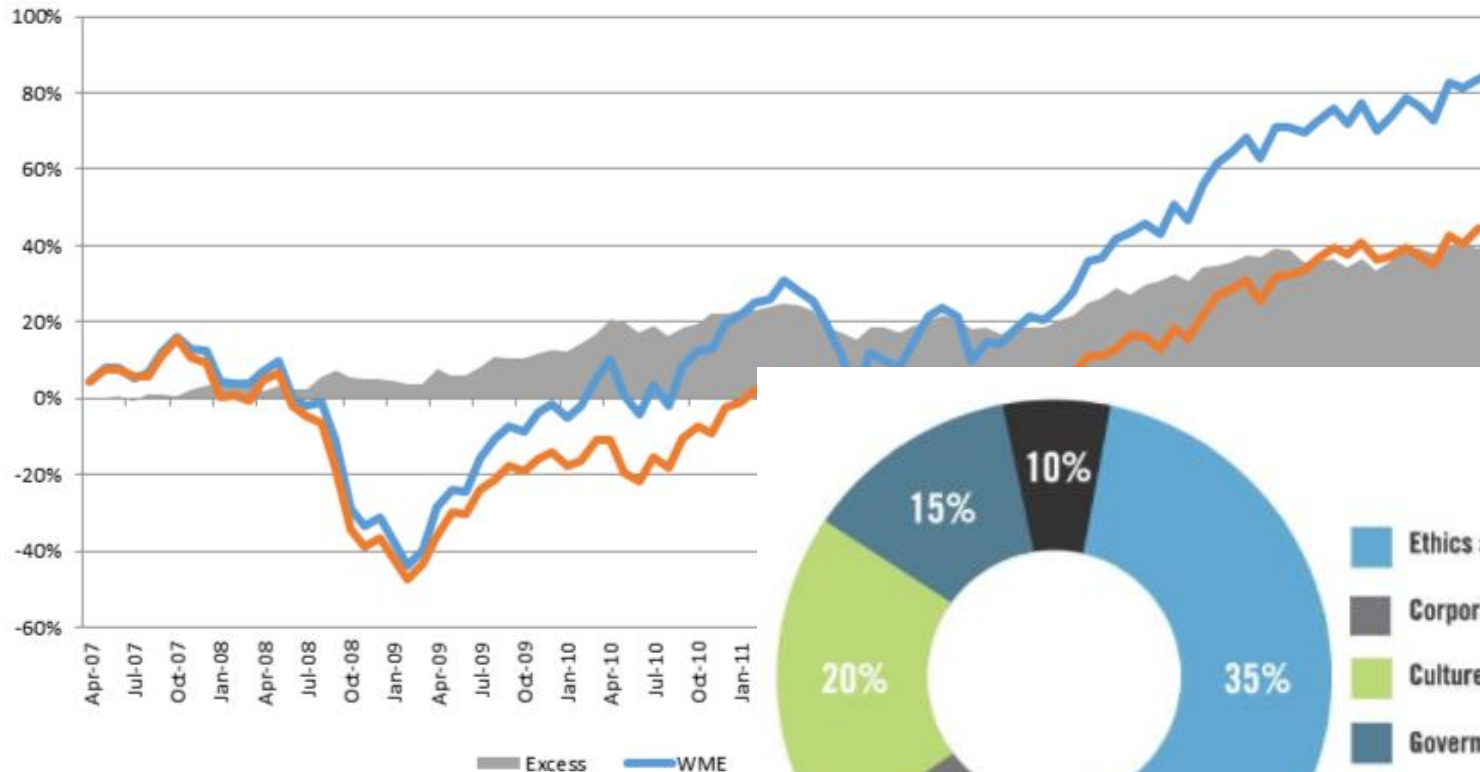
Sixty percent of a company's market value is based on its reputation
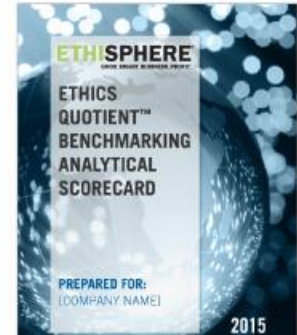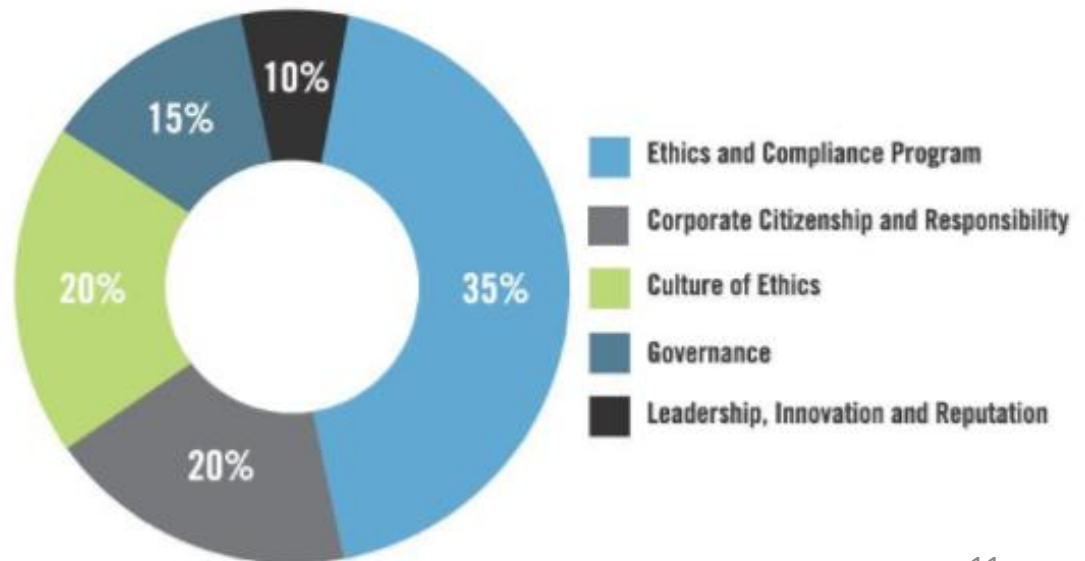
Weber Shandwick – November 2011

Fortune Magazine "100 best companies to work for" score 6% higher than the rest in the S&P 500 index

ETHISPHERE
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2017 WORLD'S MOST ETHICAL COMPANIES®
WWW.ETHISPHERE.COM

WME Index vs MSCI ACWI
Cumulative Performance
April 2007 - May 2015

Source: Ross Applied Investment

- Ethics and Compliance Program — 35%
- Corporate Citizenship and Responsibility — 20%
- Culture of Ethics — 20%
- Governance — 15%
- Leadership, Innovation and Reputation — 10%

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Positive Business Impact of an Ethical Culture

- Prevents non-compliance and fraud by communicating to employees that improper conduct is not tolerated.

- Counteracts government encouragement of employees to bypass internal reporting systems and go directly to them.

- Reduces costs related to litigation, fines, negative media impact and disruption to operations.

- Mitigates the exposure of Board members, Sr. Management and employees to criminal and civil liability.

- Increases attraction of best talent and employee retention by communicating the organization's commitment to ethical operations and standards.

- Solidifies the organization's credibility, which translates into an immensurable marketing benefit.

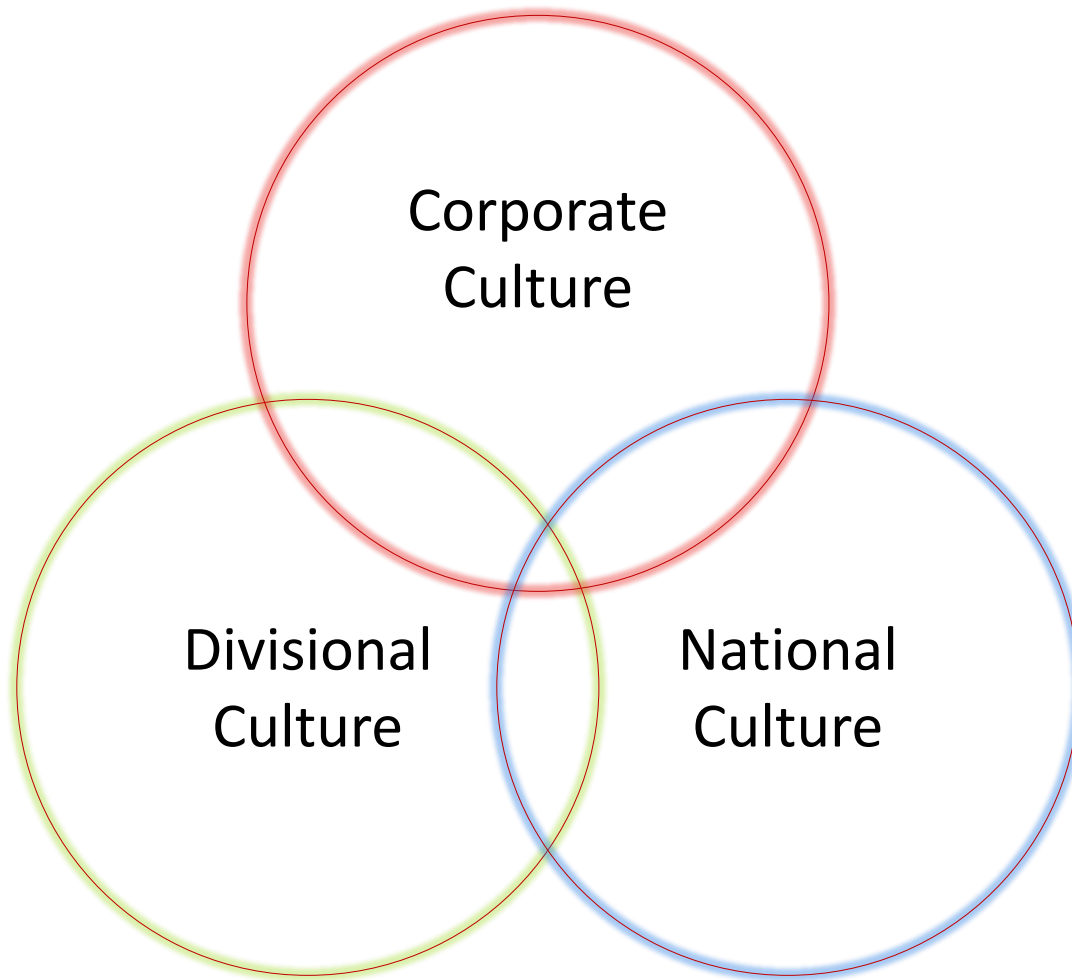**An Ethical Culture can no longer be a country-by-country approach**

- In a world of information, there are no more secrets and there is no place to hide.

- In today's world, news of a corporation's mishaps or missteps travel around the globe in a matter of hours, and the smallest local episode can have a global effect.

Corporate
Culture

Divisional
Culture

National
Culture

Even in a brand new
organization,
there is never a
cultural "clean slate" –
people bring their
cultural baggage
with them

Not all subsidiaries are
at the same level of
organizational maturity,
and have significant
differences in local
culture and regulations

Latin American Business Culture

- Even for subsidiaries of Global Companies, the LA business model is a hybrid between globalization and the region/country historic traditions.

- In the workplace and with customer interactions, there is a collective spirit where hierarchy, loyalty and personal relations are of absolute importance.

- The survival of the organization greatly depends on social networks and government relationships.

- Processes and control mechanisms not driven by local needs are very difficult to understand/accept.

European Union Business Culture

- Great progress made in creating a culture of compliance, to a large measure assisted by well-developed laws and the aggressive local enforcement

- General perception in the EU countries that following the rules is important <u>provided</u> they are local rules and cultural norms

- A big challenge for US companies with EU operations; a strong distrust and frustration with the messages coming from US (viewed as overtly paternalistic, simplistic and overreaching)

Russian and Non-EU Countries Business Culture

- Huge importance of relationships with local public officials and social networks; your business success depends on "who you know" and not the quality of your products

- Pervasive traditional culture of hospitality involving elaborate entertainment and hospitality (infused with large quantities of alcohol)

- Workplace model is based on hierarchy; for global companies with local operations, tone in the middle is frequently the only one that matters

- Arcane and complicated administrative and bureaucratic regulations create lack of clarity and give local government officials the opportunity to interpret those rules to the advantage of companies willing to pay bribes
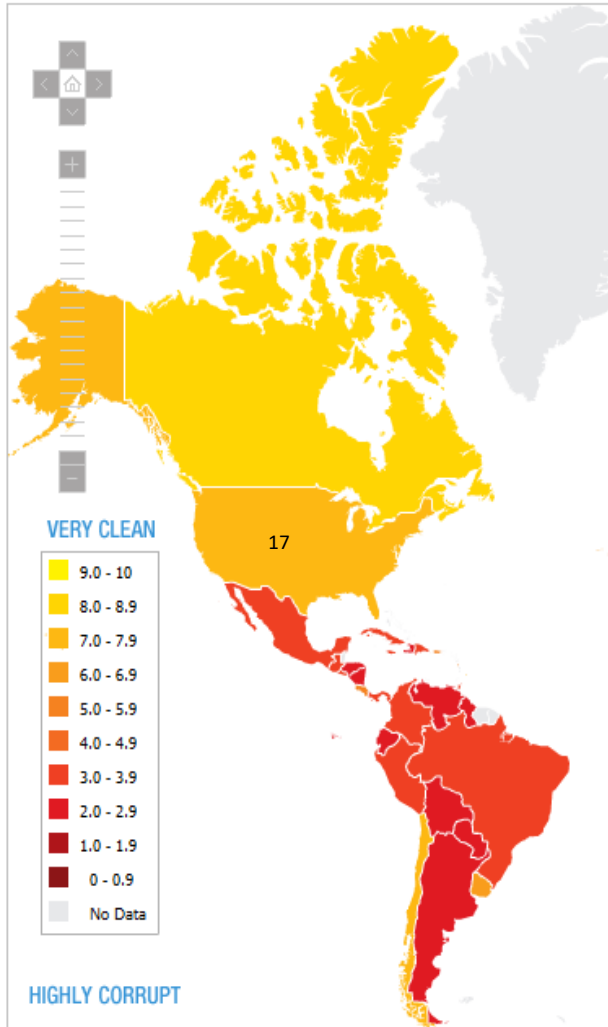
- Relationships are paramount, and loyalty to one's "network" or "family" usually trumps loyalty to company

- Cultural norms emphasize flexibility and working to solve a problem rather than blind adherence to rules imposed by outsiders

- Legal frameworks are often still developing in most jurisdictions, leaving significant discretion to government officials and thereby creating avenues for solicitation of bribes

- "Bribing opportunities" are exacerbated by the culture of deference to people in the position of official authority who often solicit for bribes

- Pervasive traditional culture of hospitality involving elaborate entertainment and consumption of exotic and rare dishes (the "puffer fish syndrome")

- Historical pervasiveness of corruption leads many to believe that corruption is inevitable or a necessary evil for doing business rather than immoral or unethical - the pragmatic justification for culture of bribes

Corruption Perceptions Index

Zheng Xiaoyu

VERY CLEAN

	9.0 – 10
	8.0 – 8.9
	7.0 – 7.9
	6.0 – 6.9
	5.0 – 5.9
	4.0 – 4.9
	3.0 – 3.9
	2.0 – 2.9
	1.0 – 1.9
	0 – 0.9
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HIGHLY CORRUPT

BUSINESS PRINCIPLES FOR PROMOTING INTEGRITY IN THE PHARMACEUTICAL SECTOR

A REGIONAL MULTI-STAKEHOLDER INITIATIVE FOR LATIN AMERICA LED BY TRANSPARENCY INTERNATIONAL UK'S PHARMACEUTICALS & HEALTHCARE PROGRAMME

If the world had 100 inhabitants, they would be distributed:

Asia	60
Europe	18
S. America	8
Africa	7
N. America	7

Half of the world's population is in China and India

Ethical Culture Danger Zones

Fear of Retaliation

The fear of payback for doing the right thing is a powerful cause of inaction in organizations.

Avoidance

When bad things go unpunished or are ignored, it can lead to even worse behavior.
It sends the message, "We don't care."

Rationalization

The *"everybody's doing it*" mindset can lead people into murky ethical waters. Using neutral terms to describe questionable actions (e.g., "creative accounting") is a subtle form of rationalization.

Thresholds Lowered

With each unethical decision, the next one becomes easier. It's a slippery slope.

A

Alignment and Accountability

- Increase transparency and personal accountability, particularly at the line management level.

- Preserve alignment between performance goals and business realities.

- Include ethical business goals in key performance metrics and personal performance evaluations that are simple enough to understand and don't stop at "*what*" but incorporate "*how*" and "*when*".

B

Beware the Unknown (Risk)

- Incorporate risk assessment methodology in all key projects and initiatives to better understand and manage sources of risk while encouraging prudent risk-taking.

- Reinforce training and certification on critical processes/activities for Company personnel & third parties.

- Establish the concept that the only alternative to risk management is "crisis management."

The ABC of Creating an Ethical Culture

- When cascading messages through management layers and geographies, take steps to ensure that the tone at the top is not diluted or "lost in translation."

- Balance messages for higher performance so they are not mistaken as tacit endorsements of excessive / improper risk-taking ("tolerate misconduct to reach goals").

- In times of change and uncertainty, be transparent and deliver a clear message to counteract low morale, poor engagement, and employees' shift to self-preservation.

For a Compliance Professional, competence and technical skills are necessary but by no means enough

A Compliance professional must have the social intelligence to understand the business, navigate relationships, listen, communicate, influence, persuade and collaborate
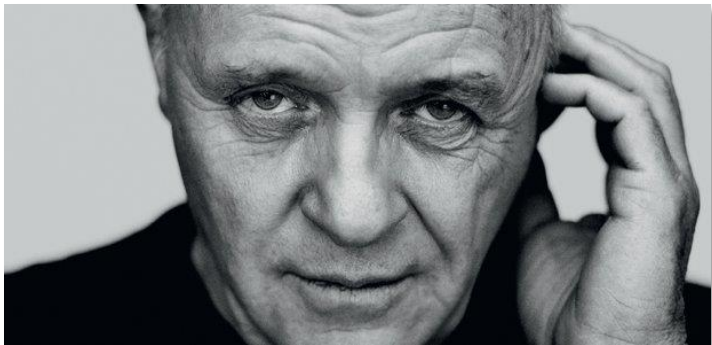
If you are not at the table ….
you are on the menu!

Thank You !

References

http://phrma-docs.phrma.org/sites/default/files/pdf/phrma_marketing_code_2008.pdf
https://www.strategyand.pwc.com/reports/cultures-and-change-infographic
https://ethisphere.com/ethisphere-announces-2017-worlds-most-ethical-companies/
https://www.transparency.org/news/feature/corruption_perceptions_index_2016
http://www.transparency.org.uk/publications/business-principles-pharma-sector/