

A Hippocratic Oath for the Diagnostics Industry

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**“Corporations are
people, my friend.”**

Mitt Romney, Iowa, August 2011

Rights of Corporations

Responsibilities of Corporations

Key Questions

- Why do healthcare corporations need to be held accountable to medical and scientific ethics?
- How can this be done?
- How would this apply to the diagnostics industry?



Do healthcare corporations face ethical challenges?

Merck and Vioxx

- Hugely profitable analgesic (\$2.5B in 2003 alone)
- 2000: Large study showed serious cardiac risks
 - Merck apparently suppressed some of the data.
 - Curfman et al. NEJM 2005; 353:2813-2814
 - Merck continued to heavily market the drug
- 2004: New study confirmed original results
 - Voluntary withdrawal from market September 2004
- Estimated 27,000 MI's and sudden cardiac death

J&J and the DePuy Hip Devices

- Metal-on-metal artificial hips
- High failure rates reported by surgeons to DePuy
- Australian registry showed high failure rates by 2008
- Not withdrawn until 2010
- 93,000 patients, estimated 13% failure rate

– Barry Meier, New York Times March 9, 2010

Health Management Associates (71 hospitals in Southeast)

- ED doctor report cards



= admit at least half of patients over 65yrs



= close



= too few admissions

- Doctors fired for “red” report cards

- Source: Creswell J, Abelson R. New York Times Jan 23, 2014.
<http://www.nytimes.com/2014/01/24/business/hospital-chain-said-to-scheme-to-inflate-bills.html>

Patents on DNA Sequences

- Numerous commercial laboratories
- Hurt patients through inflated prices, restricted availability
- Hurt science through limitations on research, data sharing
- Hopefully less of a problem in the future (?)

How much impact do corporations have on health care?

Then



Now



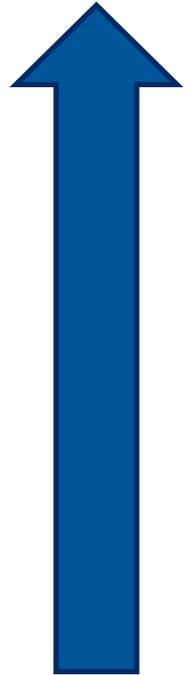
Then

Quality of care
determined by
doctors' behavior

Now

Quality of care
determined by
corporations'
behavior

Consolidation in Healthcare



Size of Hospital Systems

Size of Physician Groups

Size of Health Insurers

Size of Pharma

Size of Medical Device Companies

The Challenge

- We hold doctors and scientists accountable to medical ethics
- Do we hold healthcare corporations accountable to those same ethics?

Values in Healthcare

Medical ethics

- Autonomy
- Non-maleficence
- Beneficence
- Justice

Scientific ethics

- Transparency
- Objectivity
- Advancement of knowledge

How do Healthcare Co's Violate These?

Medical ethics

- Autonomy → Limited choice of providers
- Non-maleficence → Cutting corners on safety
- Beneficence → "Me-too" drugs
- Justice → Price-gouging

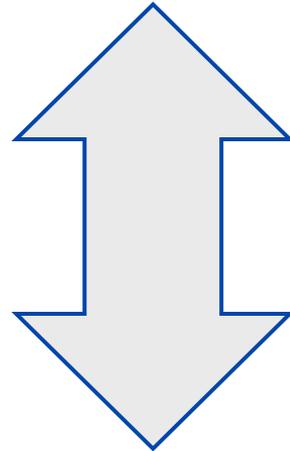
Scientific ethics

- Transparency → Selective publication
- Objectivity → Marketing spin
- Advancement of knowledge → Aggressive IP practices

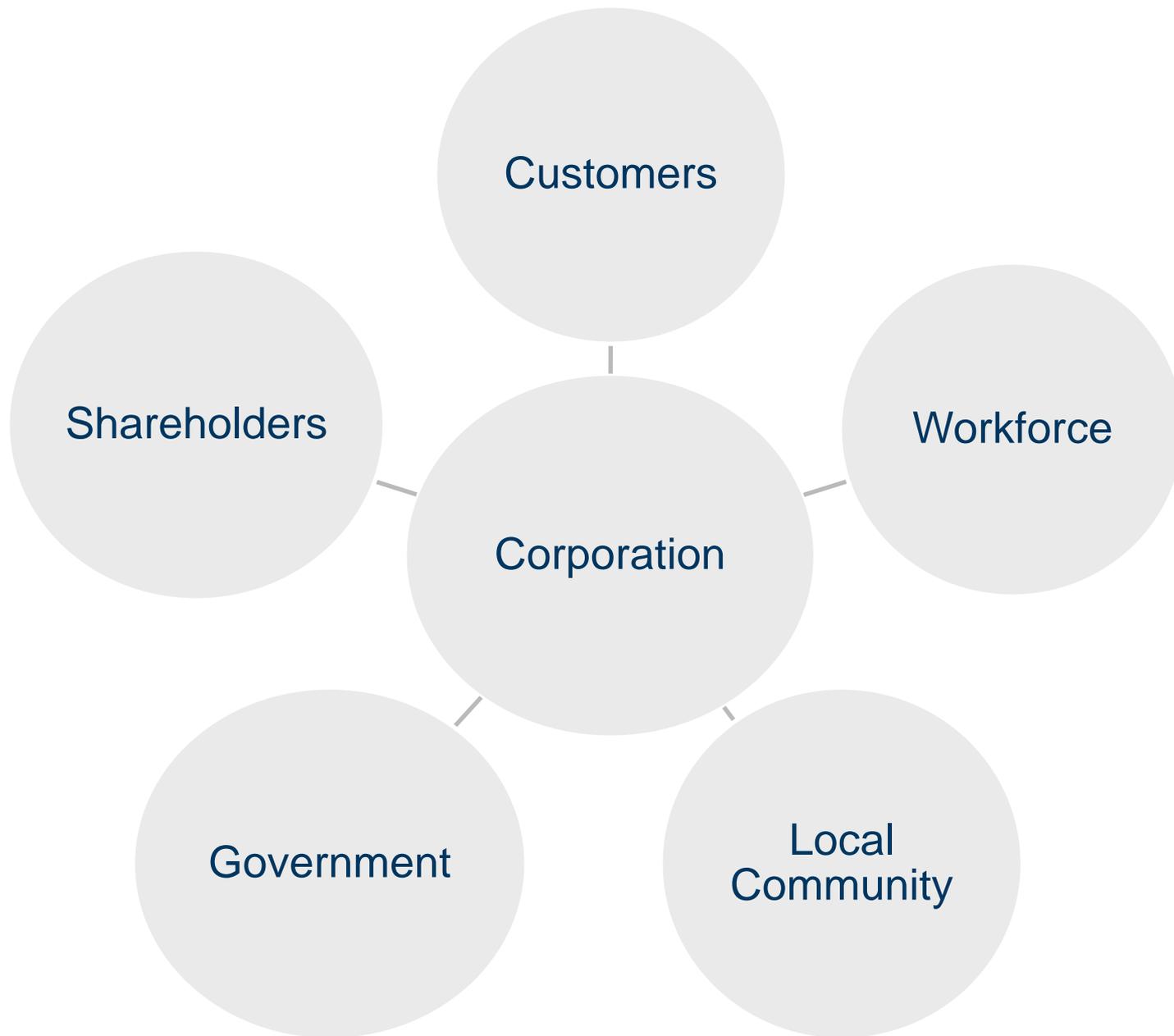
So how can we fix this?

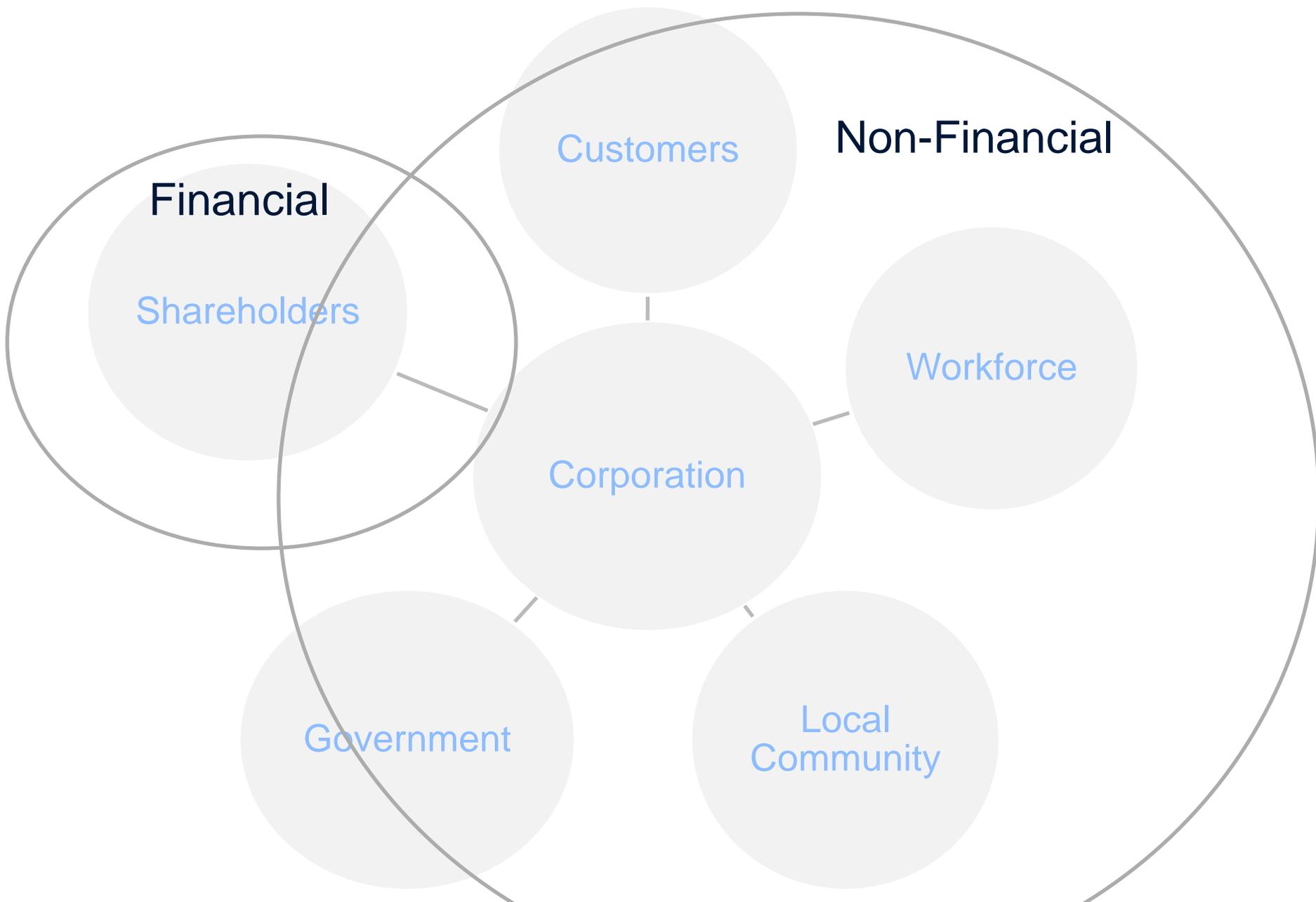
**Why would a for-profit company
care about anything other than
short-term profits?**

Long-term Sustainability

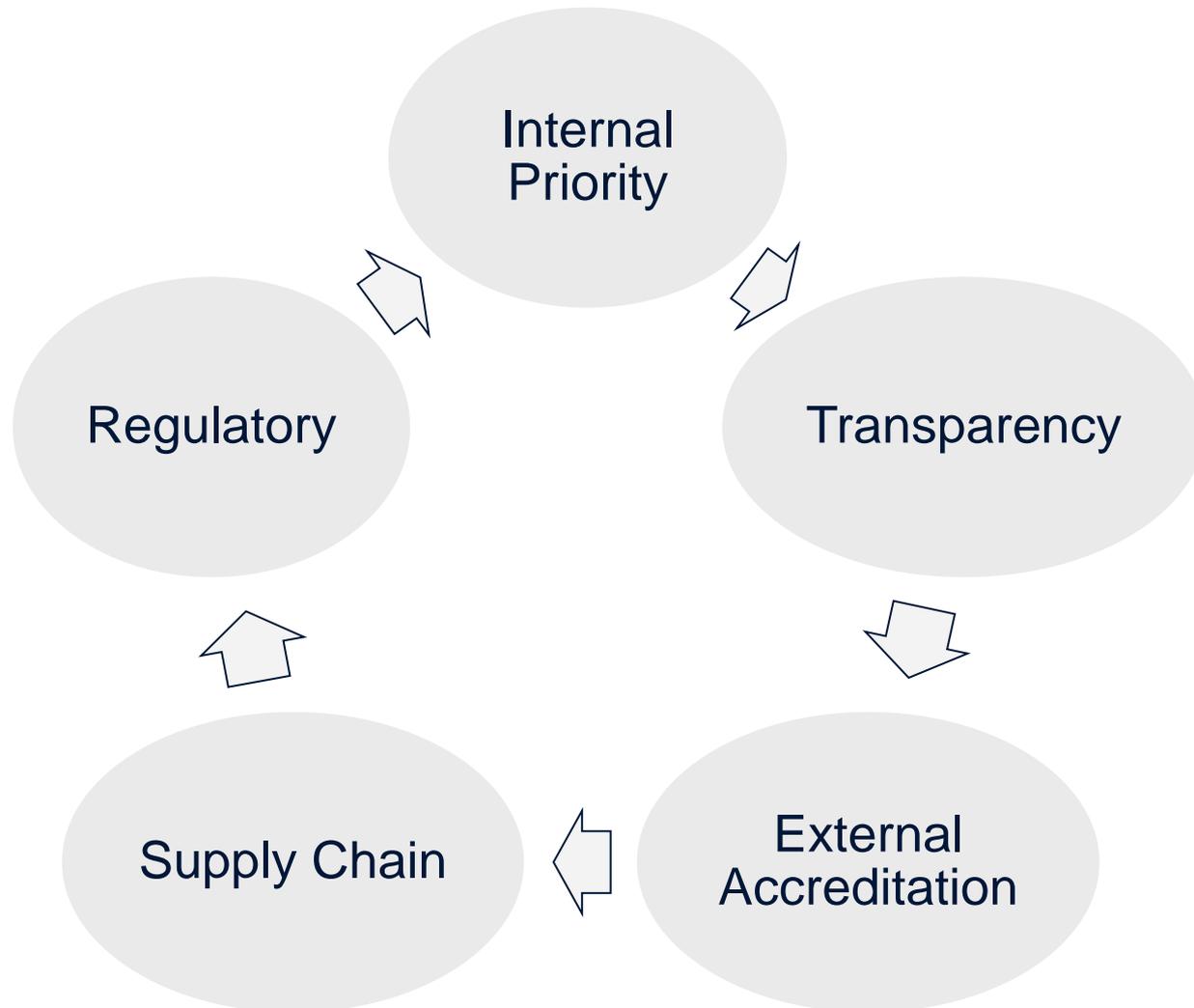


Stakeholder Partnerships

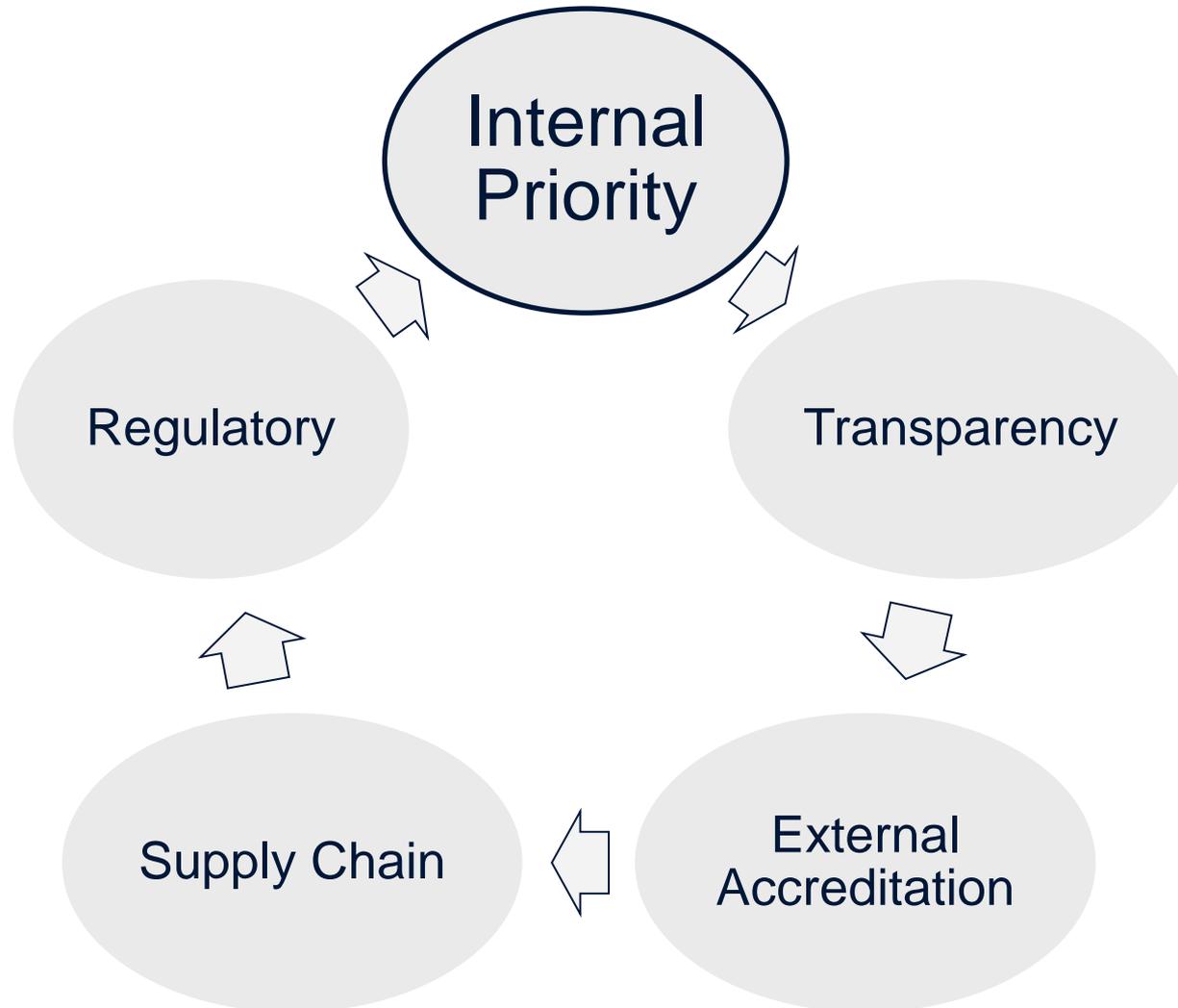




Accountability for Ethical Behavior



Achieving Corporate Sustainability





Board of Directors

- Corporate Responsibility and Sustainability Committee

Responsible Care[®] Global Charter

Responsible Care is the global chemical industry's unifying commitment to the safe management of chemicals throughout their life cycle, while promoting their role in improving quality of life and contributing to sustainable development.

As a signatory to the Responsible Care Global Charter my company will actively strengthen the Responsible Care initiative worldwide and is committed to:

- 1 A Corporate Leadership Culture** that proactively supports safe chemicals management through the global Responsible Care initiative
- 2 Safeguarding People and the Environment** by continuously improving our environmental, health and safety performance; the security of our facilities, processes and technologies; and by driving continuous improvement in chemical product safety and stewardship throughout the supply chain
- 3 Strengthening Chemicals Management Systems** by participating in the development and implementation of lifecycle-oriented, sound-science and risk-based chemical safety legislation and best practices
- 4 Influencing Business Partners** to promote the safe management of chemicals within their own operations
- 5 Engaging Stakeholders**, understanding and responding to their concerns and expectations for safer operations and products and communicating openly on our performance and products
- 6 Contributing to Sustainability** through improved performance, expanded economic opportunities and the development of innovative technologies and other solutions to societal challenges

Company

CEO Signature

Date



1

A Corporate Leadership Culture that proactively supports safe chemicals management through the global Responsible Care initiative

2

Safeguarding People and the Environment by continuously improving our environmental, health and safety performance; the security of our facilities, processes and technologies; and by driving continuous improvement in chemical product safety and stewardship throughout the supply chain

3

Strengthening Chemicals Management Systems by participating in the development and implementation of lifecycle-oriented, sound-science and risk-based chemical safety legislation and best practices

4

Influencing Business Partners to promote the safe management of chemicals within their own operations

5

Engaging Stakeholders, understanding and responding to their concerns and expectations for safer operations and products and communicating openly on our performance and products

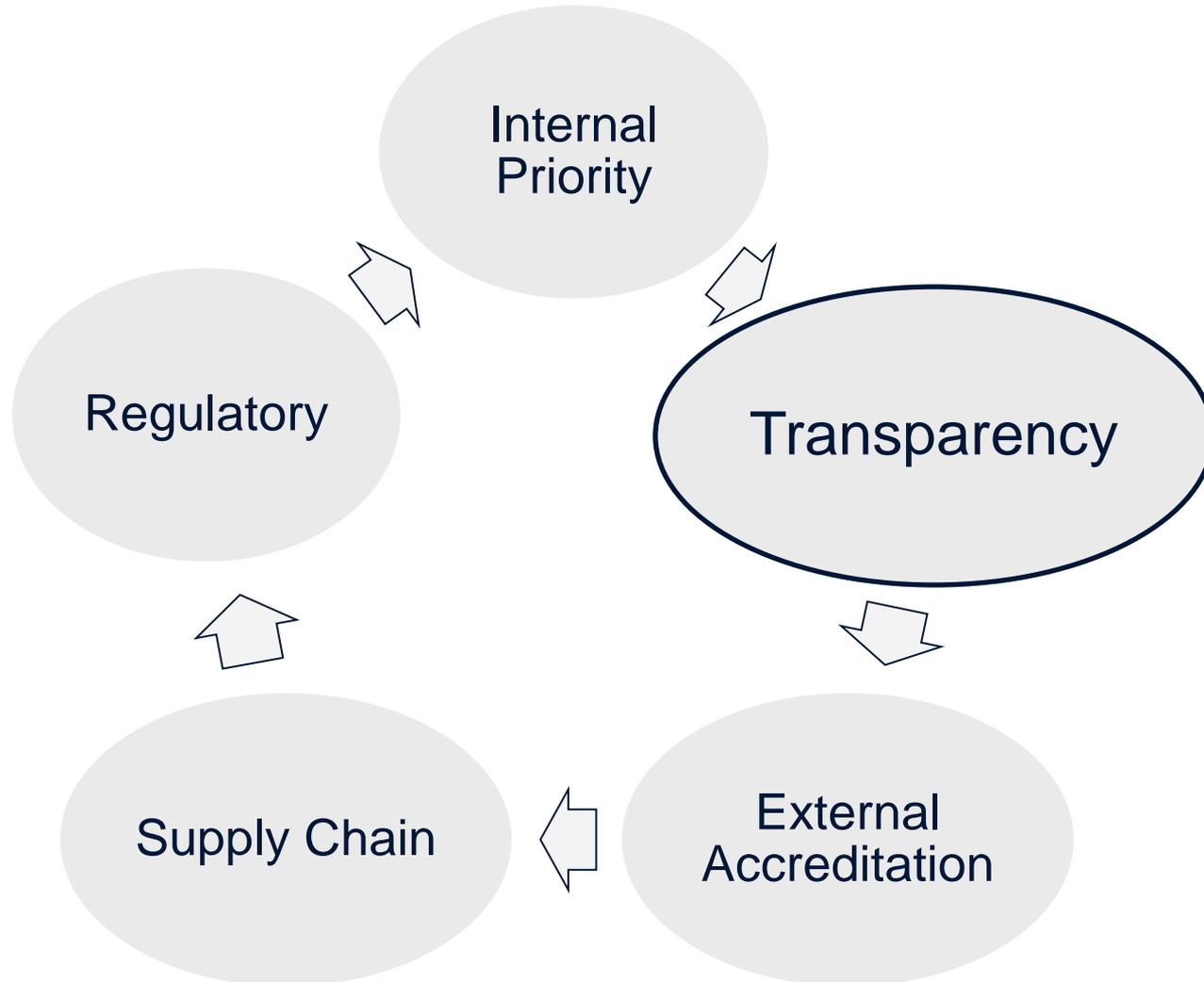
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Contributing to Sustainability through improved performance, expanded economic opportunities and the development of innovative technologies and other solutions to societal challenges

Lab Example: ARUP 5 Pillars

- I. Excellent Patient Care
- II. Good Working Environment
- III. Do the Right Thing
- IV. Improve Continuously
- V. Act Responsibly

Achieving Corporate Sustainability



Dignity Health Social Responsibility Report

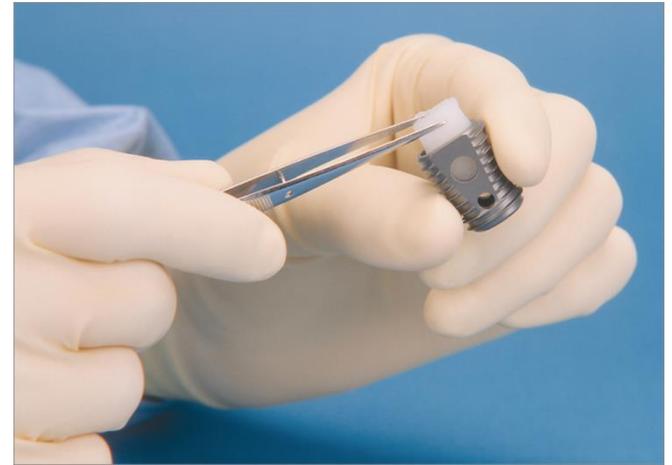
- 2013 highlights included:
 - 14% reduction in carbon emissions since 2010
 - Reprocessed 271,000 pounds of medical devices
 - Expanded employee diversity
 - 97% Composite Score in Hospital Quality Reporting Index
- Source: dignityhealth.org/

Sustainability Accounting Standards Board

- Analogous to FASB (accounting standards)
- Standardized reporting of sustainability data
- Allow investors to make informed investment decisions



Transparency Example: Infuse Bone Graft



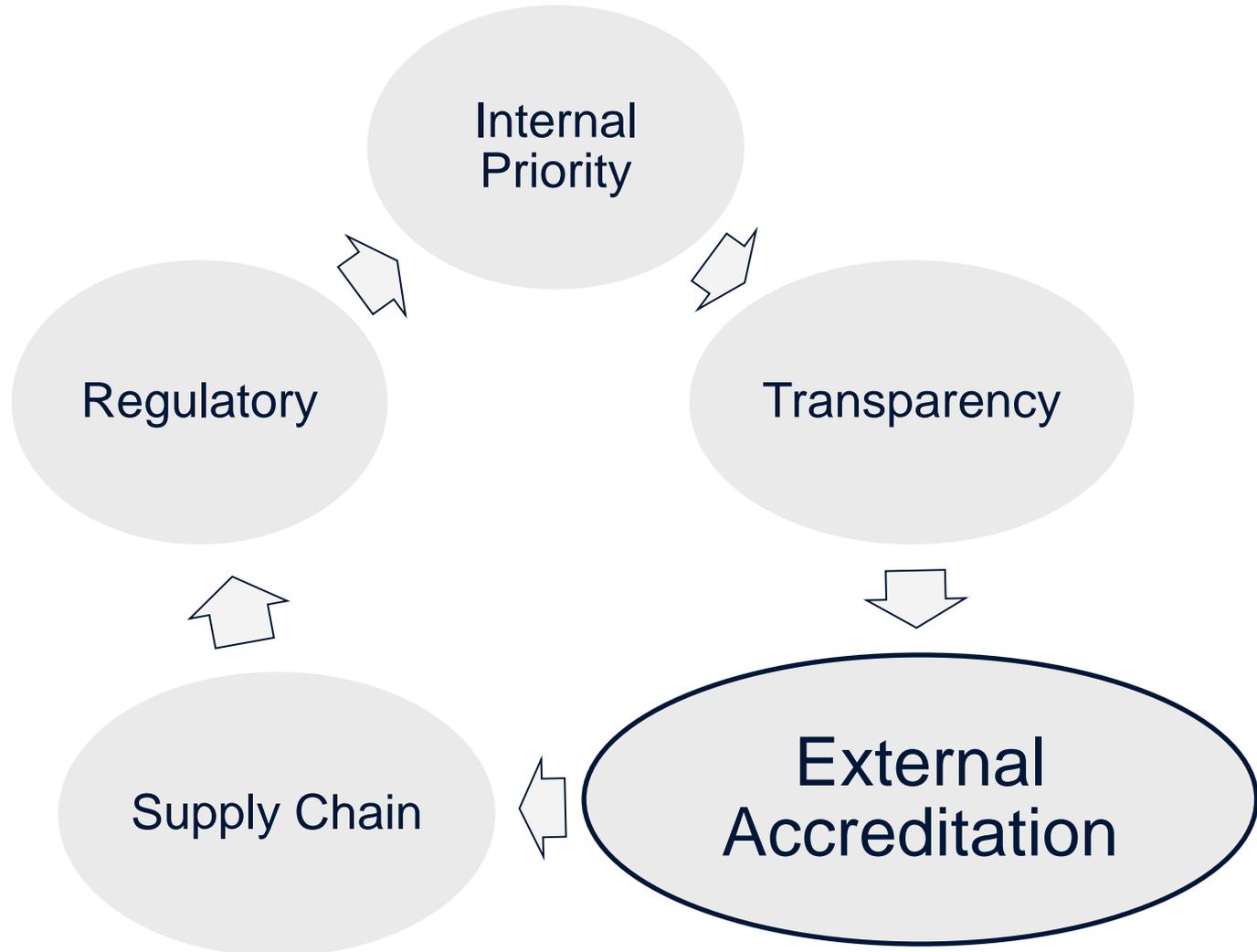
- Initial studies: rhBMP-2 better than bone grafting
 - \$1B/year in sales
 - Questions raised by spine surgery researchers
- Medtronic agreed to share raw data with U. of York, OHSU
- New analyses showed no benefit versus traditional grafting

JAMA. 2013;310(4):359-360. doi:10.1001/jama.2013.8485

Transparency: Dx Industry Example

- How do reagent vendors treat lot-to-lot variation?
 - Open sharing of internal data?
 - Or deny problems where possible?

Achieving Corporate Sustainability



Accreditation: Dx Industry Examples

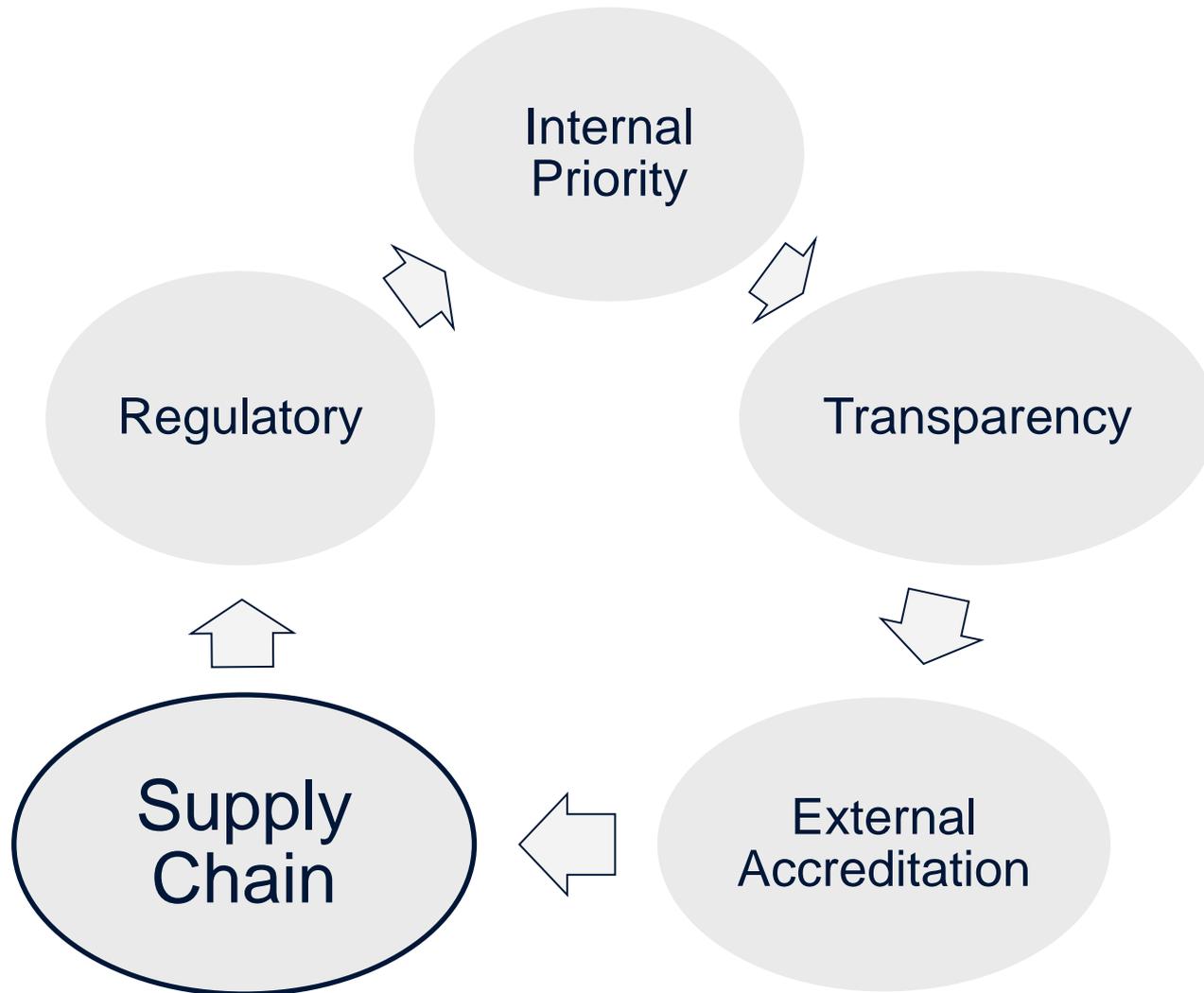
CLIA-approved accrediting organizations:

- AABB
- American Association for Laboratory Accreditation
- American Osteopathic Association
- American Society for Histocompatibility and Immunogenetics
- COLA
- CAP
- Joint Commission

ISO-14001 Environmental Mgmt Standard

- Requires periodic independent monitoring
- From 1991-2003, adopters of ISO-14001 reduced toxic emissions more than non-adopters
 - Toffel MW. Resolving information asymmetries in markets: the role of certified management programs. Harvard Business School Working Paper Feb 1, 2006

Achieving Corporate Sustainability



Walmart Suspends a Fish Supplier



Tim Mueller for The New York Times

Steven Greenhouse, New York Times June 29, 2012

Kaiser Permanente Sustainability Scorecard

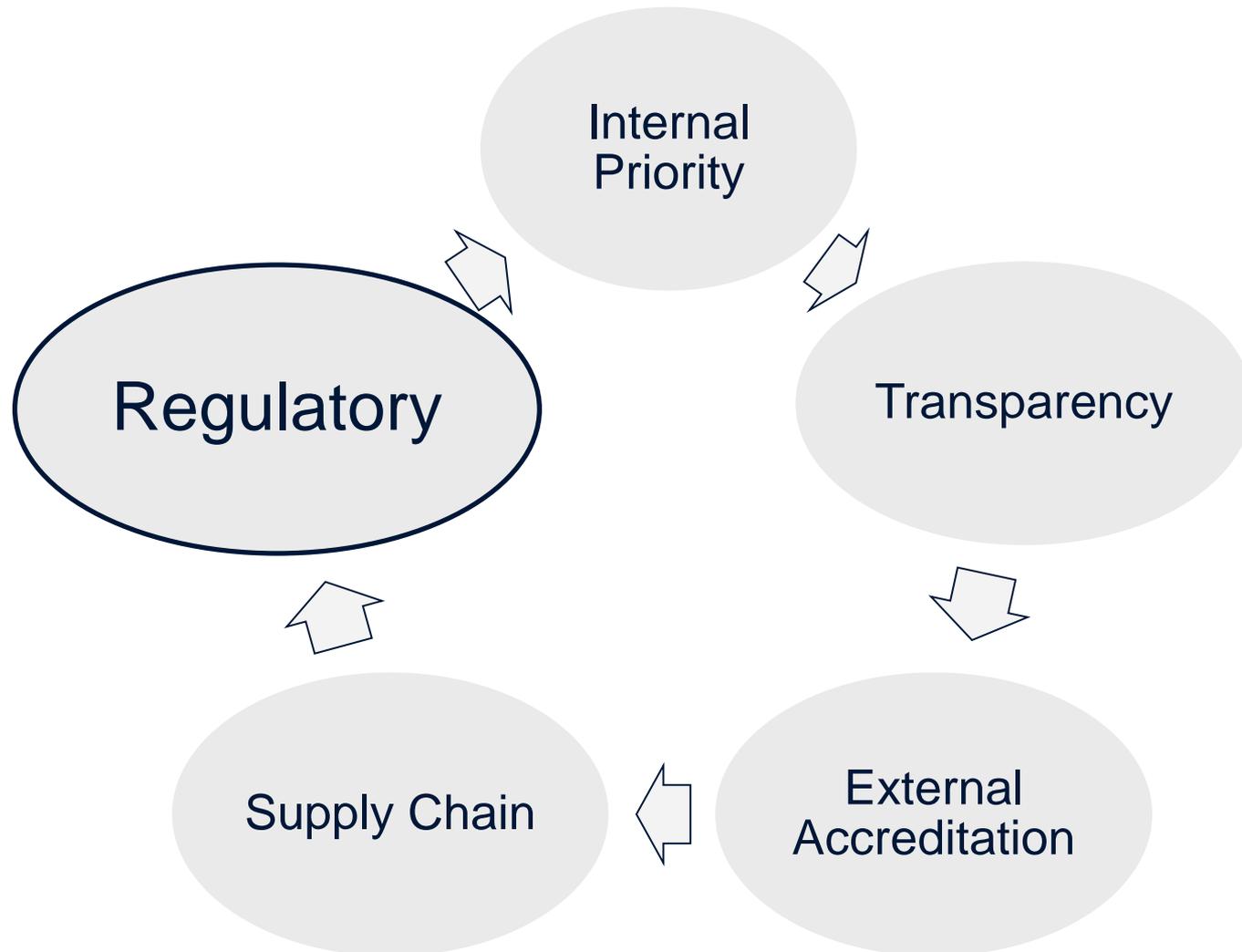
- KP purchases \$1B/year of medical products
- Suppliers required to submit information on environmental impact

Supply Chain: Lab Industry Examples

What if:

- Clinical laboratories refused to send out tests for “megapanel”
- Hospital systems required boutique laboratories to provide data on clinical effectiveness
- Hospital systems established data transparency standards for IVD reagent suppliers

Achieving Corporate Sustainability



Role of Regulatory Agencies

- Complementary to voluntary and industry efforts
 - Mandate accreditation
 - Mandate transparency
 - Prevent monopolies

Key Ideas for Laboratories

- Internal code of ethics
- Full transparency
 - Method validation
 - Clinical studies
- Work to strengthen accreditation systems
- Supply chain: what do we expect from our vendors?

Conclusions

1. Healthcare corporations must be held accountable to medical and scientific ethics
2. Successful models exist for:
 - Environmental impact
 - Labor
3. Time to adapt and apply these to the diagnostics industry