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• Not withdrawn until 2010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

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

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
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Scientific ethics
- Transparency
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- Limited choice of providers
- Cutting corners on safety
- “Me-too” drugs
- Price-gouging
- Selective publication
- Marketing spin
- 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

- Internal Priority
- Regulatory
- Transparency
- Supply Chain
- External Accreditation
Achieving Corporate Sustainability

Internal Priority

- Regulatory
- Transparency
- Supply Chain
- External Accreditation
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
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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

- Internal Priority
- Transparency
- Regulatory
- Supply Chain
- External Accreditation
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

Transparency: Dx Industry Example

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

Achieving Corporate Sustainability

Internal Priority

Regulatory

Supply Chain

Transparency

External Accreditation
Walmart Suspends a Fish Supplier

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
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Regulatory
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