Ethics, Business, Innovation

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Collective Aims

• Promote innovation
  – New drugs
  – New devices
Collective Aims

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  – New drugs
  – New devices

• Patient safety
  – Provide a benefit
  – Do no harm
Collective Aims

• Promote innovation
  – New drugs
  – New devices

• Patient safety
  – Provide a benefit
  – Do no harm

• Keep the trust
  – of patients
  – of community
Specific Objectives

• Companies
  – Need profits
  – Answerable to shareholders
  – Need clinical outcomes
  – Need doctors to prescribe
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• Doctors
  – Need patients
  – Want good outcomes
Specific Objectives

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  – Need profits
  – Answerable to shareholders
  – Need clinical outcomes
  – Need doctors to prescribe

• Doctors
  – Need patients
  – Want good outcomes
  – Want good incomes
Specific Objectives

• Governments
  – Provide health care
  – Encourage business
  – Regulate industry
    • Safety
    • Transparency
  – Control costs
Company Perspective

• New product
• Needs safety
  – Preclinical testing
  – Regulatory approval
Company Perspective

• New product
• Needs safety
  – Preclinical testing
  – Regulatory approval
  – Clinical trials
  – Clinical papers
Company Perspective

• New product
• Needs safety
  – Preclinical testing
  – Regulatory approval
  – Clinical trials
  – Clinical papers
• Need sales
Company Perspective

• New product
• Needs safety
  – Preclinical testing
  – Regulatory approval
  – Clinical trials
  – Clinical papers
• Need sales
• Target doctors
Doctors’ Perspective

• Well trained and skeptical
• Treat patients
• Enjoy trust in the community
• Believes in the New
Doctors’ Perspective

• Well trained and skeptical
• Treat patients
• Enjoy trust in the community
• Believes in the New (Techno Optimism)
Doctors’ Perspective

• Well trained and skeptical
• Treat patients
• Enjoy trust in the community
• Believes in the New (Techno Optimism)
  – Better
  – Quicker
  – Safer
Doctors’ Perspective

• Well trained and skeptical
• Treat patients
• Enjoy trust in the community
• Believes in the New (Techno Optimism)
  – Better
  – Quicker
  – Safer
  – But unproven
Incentives

• Direct payments
• Royalties and consultancies
• Educational support
• Overseas trips
• Wining and dining
• Tickets to rugby games
Three Parties

• Unusual business model
  – Company markets the product
  – Doctors choose the product
  – Governments pay for the product
Three Parties

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  – Company markets the product
  – Doctors choose the product
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• Educated players
  – Sophisticated industry
  – Highly trained doctors
  – Specialized government departments
Ethical Problems

- Drugs or devices untested
- Informed consent with hope
- Payments undisclosed
- Cost of the New is usually high
- Advertisements overstated
Ethical Problems

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Lack Science
Use Testimonials
Better Way

• Company approaches institution
• No direct payments to doctors
• Randomized Controlled Trial
• Minimum 2 year follow up
• Independent assessment
• Peer reviewed publication
Registries

• AOA National Joint Replacement Registry
  – Captures all hip and knee replacements
  – Cooperation of surgeons, hospitals, industry
  – Government funded
  – Surgeon owned
  – Post market surveillance
  – Long term outcomes
Registries

• Other registries
  – Anterior Cruciate Ligament
  – Cardiac stents
  – Breast implants, etc.
Codes of Conduct

- Australian Orthopaedic Association
  - Position Statement on Interaction with Medical Industry
- Royal Australasian College of Surgeons
- Australian Medical Association
- Medical Board of Australia
- Medical Technology Association Australia
- State and National Legislation
Interaction with Industry

- AOA Position Statement spells out:
  - To act in the patients best interest
  - To avoid commercial persuasion
  - To disclose financial interests
  - To acknowledge sponsorship
  - To refuse gifts
Interaction with Industry

• MTAA Code stipulates
  – What companies can and cannot do
  – How to interact with surgeons

• AOA requires MTAA compliance
• Regular discussion and cooperation
• Arms length funding of projects
Legislation

- Illegal under Medical Board
  - To create unrealistic expectation
  - To use testimonials

- Corporations Act
  - Directors to act honestly

- Crimes Act
  - Offence to bribe a public official
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(The Brown Paper Bag)
International Code

• Global trade
  – Same pathology
  – Converging medical practice

• Companies
  – Multinational have legal departments
  – Smaller companies need help

• Governments
  – Lobby for business
International Code

• Global trade
  – Same pathology
  – Converging medical practice

• Companies
  – Multinationals have legal departments
  – Smaller companies need help

• Governments
  – Lobby for business
  – Lobby for patients and for ethical practice
Thank you.