

Ethics, Business, Innovation

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ASSOCIATION

Collective Aims

- Promote innovation
 - New drugs
 - New devices



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- Promote innovation
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- Patient safety
 - Provide a benefit
 - Do no harm



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Collective Aims

- Promote innovation
 - New drugs
 - New devices
- Patient safety
 - Provide a benefit
 - Do no harm
- Keep the trust
 - of patients
 - of community



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Specific Objectives

- Companies
 - Need profits
 - Answerable to shareholders
 - Need clinical outcomes
 - Need doctors to prescribe



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- Companies
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- Doctors
 - Need patients
 - Want good outcomes



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 - Need doctors to prescribe
- Doctors
 - Need patients
 - Want good outcomes
 - **Want good incomes**



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Specific Objectives

- Governments
 - Provide health care
 - Encourage business
 - Regulate industry
 - Safety
 - Transparency
 - Control costs



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Company Perspective

- New product
- Needs safety
 - Preclinical testing
 - Regulatory approval



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- Need sales



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Company Perspective

- New product
- Needs safety
 - Preclinical testing
 - Regulatory approval
 - Clinical trials
 - Clinical papers
- Need sales
- Target doctors



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Doctors' Perspective

- Well trained and skeptical
- Treat patients
- Enjoy trust in the community
- Believes in the New



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- Well trained and skeptical
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 - Better
 - Quicker
 - Safer



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Doctors' Perspective

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



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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

- Unusual business model
 - Company markets the product
 - Doctors choose the product
 - Governments pay for the product
- Educated players
 - Sophisticated industry
 - Highly trained doctors
 - Specialized government departments



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Ethical Problems

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



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Lack Science

Use Testimonials



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Better Way

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



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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



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Registries

- Other registries
 - Anterior Cruciate Ligament
 - Cardiac stents
 - Breast implants, etc.



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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



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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)



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International Code

- Global trade
 - Same pathology
 - Converging medical practice
- Companies
 - Multinationals have legal departments
 - Smaller companies need help
- Governments
 - Lobby for business



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 - Lobby for business
 - Lobby for patients and for ethical practice



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Thank you.