

Ethics and the Biotech Industry

- What is Bioethics?
- Study of ethical principles and values that ought guide behavior and policy in biomedicine

What ethics is not

- Personal beliefs
- What polls and surveys reveal
- The law
- Religious beliefs

What ethics is

- Justified principles and values
 - Convincing argument
 - Pragmatic payoff
- Values that have appeal outside your own group or nation
- Character and virtues that produce trust

Why ethics matters

- Ethics leads the law
- Ethics sometimes is all there is
- Ethics is what people care about when it comes to medicine and biotechnology!
 - Duty to protect patients and public health
 - Economic incentives are not enough and may well be mistrusted
 - Those who pursue health have a higher moral standard to meet

The 21st century will be the
century of biology and the life
sciences

BUT WE ARE NOT READY TO RESPOND
TO THE ETHICAL CONCERNS PEOPLE
IN THE USA AND WORLDWIDE HAVE
ABOUT THIS FACT

Ethical failure can kill biotech

- Fetal tissue research
- Gene therapy
- Stem cell research
- GMO foods
- Norplant
- Research in the third world

Current Dangers: marketing

- Conflicts of Interest
- Gifts
- Intellectual Property

Current Dangers: Advertising

- DTC
- Celebrities
- Internet
- Free trade and importing
- Failure to Manage Ethics

Models for managing ethics and biotech

- Proactive product management
- Hacking
- Fire fighting (smoke jumpers)
- Policy/Code formulation
- Audit and educate

Managing ethics: case studies: proactive

- Pfizer and Viagra
 - Recognition that a capability had medical value
 - Fear of entering a controversial market
 - Concern about unknown risk

Ethical challenges of Viagra

- What is the disease
- Just a quality of life issue
- What about adverse events/deaths
- What about misuse
 - sexual crime, teenagers, illicit sex, sexually transmitted diseases, nursing homes
- How to get the drug
- Advertising

Managing ethics: Hacker model

- Genomics collaborative
 - Needs to obtain cells and tissues for biobanking
 - Payment to pathologists and surgeons
 - Consent for subjects
 - Property rights and ownership

Managing ethics: fire fighting

- Framingham Genomics
- NHLBI, BU, Harvard, private investors
- Link data in Framingham study to genetic makeup of study subjects
- Community uncertainty and study concerns about altruism

Managing Ethics: Policies and Codes

- Dupont and GMO
 - Fix legacy of Monsanto
 - Deal with worldwide distrust of GMO
 - Problems are not just safety!
 - Engineering nature
 - Fears of genetics
 - Losing biodiversity and culturally significant plants
 - Pollution
 - Informed consent about what people eat
 - Preserving ways of life

Managing ethics: auditing/educating

- Monitoring Dupont Biotech Code
- Gene therapy
- AstraZeneca

Is ethics going away anytime soon?

- Stem cell research
- Transgenic animals
- Cloning for medicines and food
- Artificial organs
- Germ line manipulation
- Brain revolution
- diagnosis
- treatments
- enhancement
- Anti-aging

What must investors, CEOs, Boards and auditors do?

- Due Diligence
- Understand bioethics
- Prepare clients to cope
- Enter public policy debates over ethics