

# Can Ethics Save Pharma?

Arthur L. Caplan

Chair

Department of Medical Ethics

University of Pennsylvania

School of Medicine



# Demonization of Pharma

- Spate of Recent Books and Exposés
  - Angell
  - Kassirer
  - Avorn

# Why Demonization?

- Ludicrous campaign against Canadian imports
- Ridiculous ad campaigns
- Prices skyrocketing

# Ethical scandals in 2004-2005

- SSRIs and Suicide in children, Glaxo, Lilly
- Warner Lambert/Pfizer off label promotion of Neurontin (430 million fine)
- SEC Boston --selective disclosure of data
- Merck and Vioxx, Pfizer Celebrex
- Rapid approval and withdrawal of Tysabri by An Biogen
- Amgen GDNF withdrawal/Parkinsonism
- NIH and consulting fees
- FDA, David Graham and censorship

# Demonized

- 13% of Americans think pharmaceutically companies are “generally honest and trustworthy” (Harris Poll, 2004)
- Public confidence has plunged faster for pharma than any other industry in recent years including managed care, tobacco and oil

# But--Pharma is not Tobacco

- Pharmaceutical Industry provides invaluable medicines that relieve pain, save lives, and cure patients
- Thousands of dedicated and talented employees
- Prospects for targeted medicines and genomic and proteomically driven breakthroughs are strong
- Key sector in American economy

# Exorcizing Demons

- Pharma could undertake a huge PR campaign
- Pharma could redouble lobbying efforts **OR**
- Pharma could commit to scientific foundation for the industry
- Pharma could recommit to ethical guidance for how it does its research, marketing, sales
- Pharma could simply stop its worst practices--
  - DTC, freebies and handouts

# Adverse Events Present Opportunities

- Time for Leadership
- Time to reduce liability
- Time to make health care safer
- Time to live up to self-proclaimed ethics of the industry (ethical pharmaceuticals)



# DSMBs, CROs and IRBs

- Sending a clear message about what is expected
- Making sure that composition of these groups reflects public interest and public good
- Follow up and study of performance

# Creating Registries

- The social contract with every subject in medical research
  - Promise to learn and to advance research
  - If data is not public it is a betrayal of a promise
- The duty to disseminate knowledge
- The means to disseminate knowledge

# Dealing with bad news

- Aggressively pursuing information
- Epidemiology must trump marketing
- Legal liability is minimized by watching for signs of trouble
- When in doubt convene the experts
- Call for FDA to toughen phase four monitoring

# Registries

- Need standardization
- Compulsory participation
- Auditing
- Updating

# Selling drugs

- The end of blockbusters?
- The era of targeted or personalized medicines

# The end of Efficacy

## Efficacy versus Effectiveness

- Large randomized controlled trials--are they sufficient?
- What about testing in the real world?
- Comparator trials

# The end of Efficacy

Taking Genomics seriously

Targeted medicines

variable responses in ethnic groups

Iressa and Asians, women, etc.

How much risk should a patient be allowed to take? Vioxx???

Comparator Trials long, long overdue

# Current Frenzy is Masking Emerging Ethical Challenges

- Aims of medicine--cure vs. quality
- Strategy for selling drugs
- The end of efficacy
- Rethinking marketing
- Accountability
- Availability of information
- Dealing with the poor and the elderly



# Marketing in Crisis

- DTC
- An admitted failure and a source of shame for the industry
- Why not a truce on DTC and strong voluntary guidelines?
- Detailing an admitted waste of resources but no one wants to disarm first or unilaterally!

# Demands of the Poor: here and abroad

- The ethics of doing research in poor nations
  - Informed consent?
  - Oversight of research
  - Whose rules, whose values?
- Meeting demands and needs--research targets--what are priorities?
- What about the poor?

# What needs to be done

- Defend quality of life
- End unethical marketing
- Make all data available in standard format
- Reform oversight system
- Insure compensation for all injured subjects
- Shift to effectiveness not efficacy
- Take needs of the poor seriously