

Business-Ethics Issues in the Healthcare Industry in the U.S.

(Ethics of the Business of
Medicine)



Overview

- Creighton and Gustafson
- Sources of Business Ethics for Healthcare
- Healthcare Business in the U.S.
- The Cost vs Care conflict
- Stakeholder Concerns for Healthcare
- Pharmaceutical Sales Ethics

Creighton University

- Creighton is a Jesuit university, rooted in the Catholic tradition. At Creighton we live this mission and are guided by our identity.



Religiously-Rooted University and Hospital



Center for Healthcare Policy and Ethics

- <http://chpe.creighton.edu/default.htm>





Sources of Ethical Direction

- Religious values
- Legal Framework/Government Policy
- Philosophical
 - Utilitarian (interest of the majority)
 - Kantian (Duty/intention-based Universal rule)
 - Social Contract
 - Natural Law
 - Others...



Healthcare is a unique Business

- Must balance the obligation to care for others with the necessity of making a profit as a business.



Healthcare Business in the U.S.





Healthcare is big business in U.S.

- Total U.S. health care expenditures were projected to increase from \$2.26 trillion in 2007 to \$2.77 trillion in 2010, with annual increases averaging about 7%
- Health spending in the U.S., at about 16.2% of Gross Domestic Product (GDP) in 2007

(Plunkett Research LTD.)



Market Distribution

- Hospital care (about \$697.5 billion)
 - 5,756 hospital properties
 - 946,997 beds
 - 37 million patients.
- Physician & clinical services (\$474.2 billion)
- Prescription drugs (\$229.5 billion)
- Nursing home and home health (\$190.0 billion)
- Other items totaling \$668.8 billion.

(Plunkett Research LTD.)



Government Spending on Healthcare

- **Medicare**, the U.S. federal government's health care program for Americans 65 years or older, provided coverage to 43.3 million seniors in 2007.
- Total state and federal spending on **Medicaid** during 2006 was \$304.2 billion. The cost in California alone was \$34.2 billion.
- Together, Medicare and Medicaid represented 19.2% of the entire 2006 federal budget that was about \$2.65 trillion.



Ethical Concerns

**Conflict between
Profit/Efficiency
and Patient Care**




Non-Profit Hospitals Under Fire

- Dr. Herbert Pardes, the president of NewYork-Presbyterian Hospital,, received more than \$4.3 million in compensation in 2004, plus \$1.2 million in contributions to his employee benefit plan.
- Dr. Spencer Foreman, president of Montefiore Medical Center in the Bronx, received \$1.1 million in compensation and \$712,000 in benefits.



What is profitable to Businesses in the Healthcare industry:

- Selling Pharmaceuticals
- Selling Medical Supplies
 - Hospital equipment
 - Lab equipment
- Selling Medical Services
 - Patient care
 - Nursing home care
 - In home care



What is not as directly profitable: **Prevention**

“An ounce of prevention is worth a pound of cure”

- But companies can't make much money preventing diseases through education.



Public Cost of Poor Health

- 109 million Americans suffered from one or more of the most common, chronic diseases, including cancer, diabetes, heart disease, pulmonary conditions, mental disorders, stroke or hypertension. (1/3 of All Americans)
- One year's cost of treatment of these conditions at \$277 billion, but estimated lost economic productivity to be vastly higher at \$1 trillion.
- Lost work and lost output due to these illnesses is reducing the nation's GDP by about 10%.
 - (2003 Milliken Institute Study)



Resulting Problem:

- A Market-Driven healthcare system which profits from new technologies to treat health problems has less incentive to prevent healthcare problems, since treating those problems is what provides profit.



High Cost High Risk Market

- Case in Point: Pfizer's Torcetrapib
- In the 15,000-patient trial, there were 82 deaths for the torcetrapib combo (T + L) vs. 51 for Lipitor. FDA rejected Torcetrapib.
- The failure cost Pfizer \$800 million in research costs, \$20 billion in market capitalization and 15 years of research.



Upside of Market Driven Care

- Incentive for innovation
- Incentive for efficiency
- Less government intervention



Market-Driven Care in the U.S.:

Quality vs Cost

Potential Negative Effects of Market forces:

- alienate physicians
- undermine patient trust of physicians
- hurt academic medical centers and the research establishment
- More patients without health care coverage.



How Managed Healthcare Cuts costs

- recruit the healthiest patients
- excluding the sickest
- rationing care by making it inconvenient to obtain
- denying care by a variety of mechanisms.

Quality Care vs Cost Control

- Physicians are caught between the desire for quality care and the desire for cost control on the part of payors, including HMOs, Medicare and Medicaid.





Two Conflicting Goals of Doctors: Give Care vs Market Efficiency

As Caregiver:

- provide a wide range of services, recommend the best treatments
- improve patients' quality of life

As Efficiently keeping expenses to a minimum:

- limit the use of services
- increase efficiency
- shorten the time spent with each patient
- use specialists sparingly.



Managed healthcare plans

Good of Patient vs

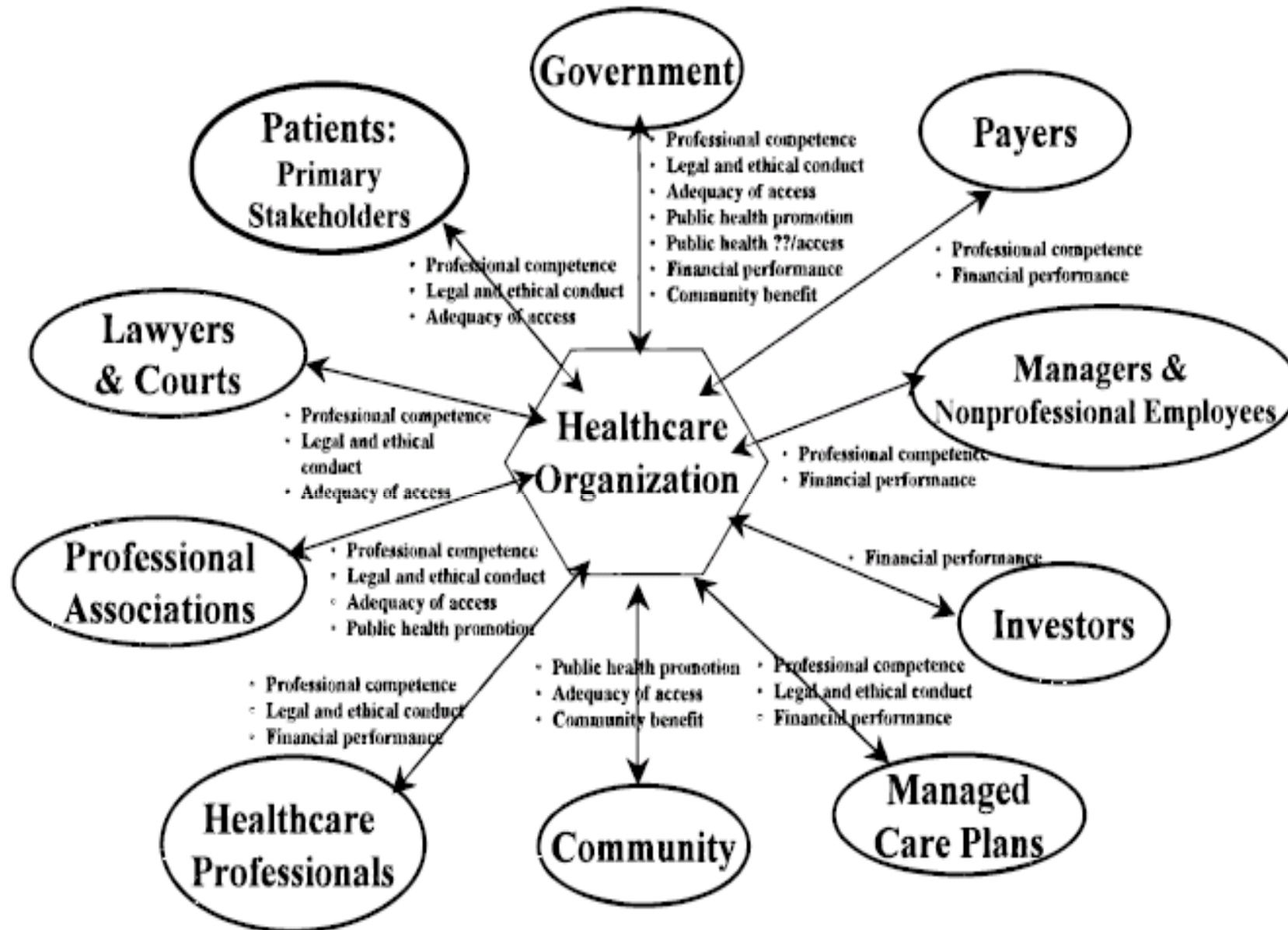
- (1) the good of all the other patients served by the plan
- (2) the good of the plan and the organization themselves
- **(3)** the self-interest of the physician.

from Edmund Pellegrino



Stakeholder Theory:

Who are the Stakeholders
for a Healthcare
Organization?



From Pat Werhane: "Business Ethics, Stakeholder Theory, and the Ethics of Healthcare in Organizations"



Physician's Concerned Stakeholders:

- Patients: Fiduciary Relationship
- Hospital
- Pharm Reps



Insurance/HMO concerned stakeholders:

- Stockholders/ Participants (Costs)
- Patients (care)
- Healthcare industry (Doctors & Hospitals)
(good working relationship)

An example: Pharmaceutical Related Ethics





Types of promotional materials

Type	Number	Companies associated with promotional material
Updates on drugs or treatments	Six	GlaxoSmithKline (twice in same month for Avandia), Pfizer, AstraZeneca, Novo Nordisk
Pens	Ten	Pfizer (2 different products), MerckSharpeDohme, Boehringer Ingelheim, Bayer, Abbott Nutrition
Notepads/notebooks	Nine	Pfizer, Janssen-Cilag, MerckSharpeDohme, Sanofi-Aventis
Brochures/pamphlets	Twenty four types	Pfizer (2 different products), Bayer (2 different products), Boehringer Ingelheim, MerckSharpeDohme, Sanofi-Aventis
Clinical manuals/booklets	Two	Pfizer, MerckSharpeDohme
Plush toys	One	Abbott Nutrition
Product samples	Multiple packs for two different drugs	Sanofi-Aventis, GlaxoSmithKline
Articles/abstracts	Three	Sanofi-Aventis, MerckSharpeDohme, Bayer
Plastic folders	Four	Pfizer, MerckSharpeDohme, Sanofi-Aventis (2 different products)
Event sponsorships and dinners	Five	Sanofi-Aventis (2 different products), Novartis, Bayer (included dinner), Abbott Nutrition (included dinner)
Small gifts like tissue boxes, soap, mouse pads and bags	Five	Bayer, Pfizer, Sanofi-Aventis, Boehringer Ingelheim, Abbott Nutrition
Screening programs (bone density, etc)	One	Sanofi-Aventis



Lack of Regulation Worldwide

In 2004, the World Health Organization established that **less than one-sixth** of countries had a well-developed system of drug regulation, and one-third had little to no regulatory capacity.⁶



Success: China's Response

- A stark example comes from a leading industry report that attributed China's considerably **slowed growth rate in the sector (from 20.5% in 2005 to 12.3% in 2006)** to a government anti-corruption campaign. The campaign was introduced during the second quarter of 2006 to set limits on physician directed promotion, and according to the report, served to dampen sales in the region.¹⁵



Consequences of Poor Marketing Information:

It is estimated that up to 50% of medicines in developing countries are inappropriately prescribed, dispensed or sold.



Irrational Drugs

- In 2005, the Indian National Commission on Macroeconomics and Health labeled 10 out of 25 top selling brands of medicines in the country as being either “irrational or non-essential or hazardous.”²⁷



Non-Essential Drugs

Table 2: Top selling irrational, non-essential or hazardous drugs in India (2005)²⁸

Rank	Brand	Producer	Headquarters
1	Becosules	Pfizer	USA
3	Corex	Pfizer	USA
9	Liv-52	Himalaya	India
11	Dexorange	Franco-Indian	India/France
12	Digene	Abbott	USA
17	Combiflam	Aventis	France
20	Polybion	E. Merck	Germany
21	Glucon-D	Heinz	USA
22	Evion	E. Merck	Germany
25	Revital	Ranbaxy	India



New Drugs??

- A survey in April 2005 by the French journal *La Revue Prescrire* concluded that 68 per cent of the 3,096 new products approved in France between 1981 and 2004 brought “nothing new” to existing treatments.



Are new Drugs Necessary??

- A breakdown of more than 1,000 new drugs approved by the US Food and Drug Administration between 1989 and 2000 revealed that more than three-quarters had no therapeutic benefit over existing products.³⁰



\$\$ Pharmaceuticals \$\$

- The pharmaceutical industry in 2006 was worth US\$ 643 billion.
- Total pharmaceutical sales from the top 10 companies accounted for more than 40% of the total market (see table).

Top corporations by global pharma sales: 2006

Rank	2006 Global sales		% Constant US\$ growth	
	US\$Bn	%Global sales	2006	CAGR 01-05
01 Pfizer	46.1	7.6	-0.7	4.8
02 GlaxoSmithKline	37.0	6.1	5.5	5.0
03 Novartis	31.6	5.2	6.1	14.1
04 Sanofi-Aventis	31.1	5.1	1.4	11.2
05 Johnson & Johnson	27.3	4.5	1.2	9.2
06 AstraZeneca	26.7	4.4	11.2	7.0
07 Merck & Co.	25.0	4.1	4.9	4.1
08 Roche	23.5	3.9	16.1	13.5
09 Abbott	17.6	2.9	6.4	10.7
10 Amgen	16.1	2.7	20.6	30.2
Total top 10 corporations	\$282.1	46.4%	5.7%	8.8%

Source: IMS Health, MIDAS, MAT Dec 2006



Pressures on Pharm Companies

It is estimated that:

- More than 90% of the pharmaceutical industry's total pharmaceutical revenues came from medicines that have been on the market for more than five years, i.e. not new drugs.
- By 2009, a dozen of today's top 35 branded prescription drugs will lose patent protection.
- Expiring patents expose an estimated \$157 billion worth of sales (measured in 2005 terms) to generic erosion.
- The leading pharmaceutical companies will lose between 14% and 41% of their existing revenues as a result of patent expiries.
- The industry's growth rate is now at 7% compared to 14.5% 1999 (see table).

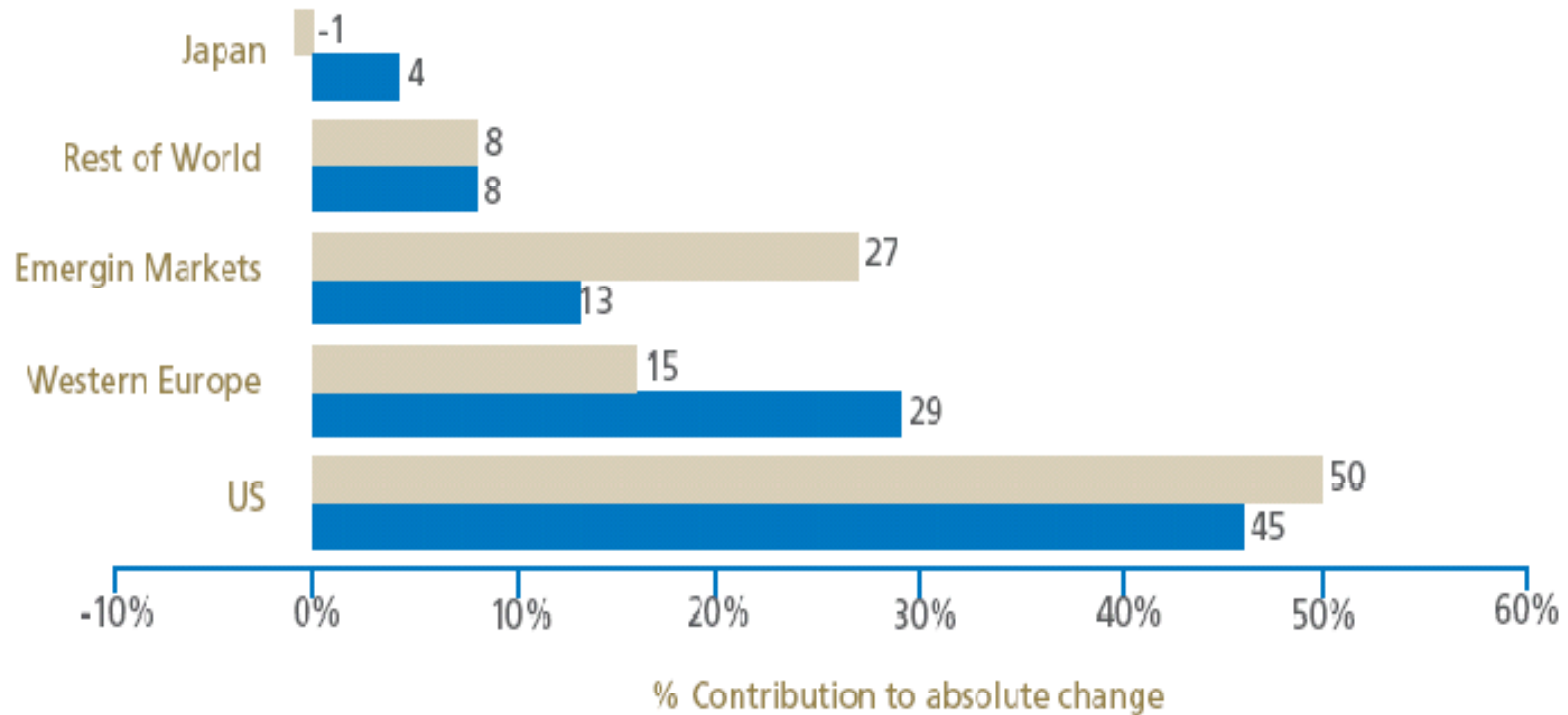


Industry growth rate 1999-2006

Global sales US\$BN	1999	2000	2001	2002	2003	2004	2005	2006
Total world market (US\$)	334	362	387	427	498	559	601	643
%Constant US\$ growth	14.5	11.7	11.8	10.6	10,4	8.0	6.8	7.0

Source: IMS Health, IMS Market Prognosis International, Feb 2007

Industry Growth Rate



■ 2001 ■ 2006
2001: AC = \$45.5 Billion 2006: AC = \$42.4 Billion

Source: IMS Health, IMS Market Prognosis International, Feb 2007



Fast Growth!

- For example, India was one of the fastest growing markets in 2006, with pharmaceutical sales increasing 17.5 percent to \$7.3 billion.



Drug Promotion

1. **Increasing the perceived frequency** and/or severity of the indications.
2. **Widening the indications** to include more people.
3. Increasing the **perceived** likelihood and magnitude of **benefits**.
4. Decreasing the **perceived** likelihood and magnitude of **harms**.
5. Increasing the use of the drug for **longer durations**.



Pharmaceutical Gifts in Pakistan

- **Low cost:** pens/pads/diaries/calendars.
- **Medium cost:** stethoscope/books/briefcases.
- **High cost:** air conditioners/laptops/desktop computers/club membership.
- **The latest practice is:** For writing 200 prescriptions of the company's high priced drug, a doctor is rewarded with the down payment on a brand new car.



Advertising with Incomplete Information

- 2005 study of Psychobiology of the Paulista Medical School of the Federal University of São Paulo Brazil
- Analysed 24 Brazilian advertisements for the same psychoactive drugs as advertised in American and/or British publications from the same period.
- Observed that “Brazilian advertisements omitted information on usage restrictions, such as contraindications, adverse reactions, interactions, warnings and precautions, and that such information was present in American and British advertisements.”



Doctors' Biased Behavior

Evidence shows that biased doctors are more likely to:

- Prescribe a drug if they had recently attended a sponsored event by the manufacturer.
- Prescribe a drug that is not clinically indicated.
- Have a drug placed on a hospital formulary.


Health expenditure in developing countries

Country	Per capita spending on health in USD (\$) ⁷⁶	Total health expenditure as % of GDP ⁷⁷
Bangladesh	\$ 14	3.1
Pakistan	\$ 18	3.2
India	\$ 23	6.1
China	\$ 45	5.8
Brazil	\$ 267	7.9
Mexico	\$ 311	6.1
Compared to USA	\$4,499	14.6



*Governments' Key Recommendations:

1. **Implement, improve and monitor legislation** in line with the WHO Resolution on the Rational Use of Medicines and the WHO Ethical Criteria for Medicinal Drug Promotion.
2. Support the provision of **independent information** on drugs for consumers and health professionals.
3. Implement and enforce a **ban on gifts to doctors**.
4. **Enforce strict sanctions** that will deter poor corporate practice in drug promotion.
5. Take measures to improve the transparency of drug companies' marketing activities and seriously address the conflict of interest encountered in drug companies' funding of medical education.



****Key Recommendations at the Company Level:**

- 1. Stop the practice of gifts to doctors**
- 2. Implement rigorous policies** on vetting of drug promotion materials and adherence to existing codes of conduct
- 3. Provide transparent and verifiable information** on the precise nature of relationships and associated funding for all stakeholder groups, including health professionals, pharmacists, students, journalists, clinical research organisations and patient groups.



****Industry-Wide Level:**

1. **Ensure codes of conduct** on drug promotion extend to interactions with health professionals AND consumers.
2. **Invest in innovative partnerships with government and civil society organisations** so that corporate funding of disease awareness campaigns, and CME may be channelled via blind trusts in line with specific health priorities of consumers at a community or national level.



Bibliography

- Drugs, Doctors and Dinners: How drug companies influence health in the developing world
- **Managed Care and the Morality of the Marketplace**
(NEJM, 333:50-52, 7/6, 1995)



■ Establishing Ethics in Your Workplace



Gallup Organization Findings Tone at the Top

VALUES

One of the
Seven Demands of Leadership



Gallup Research Based Findings

During nearly forty years of research and tens of thousands of interviews, Gallup has determined the
Seven Demands of Leadership.

These are behaviors of individuals who are perceived as leaders within their organizations, communities and nations.



How to Manage Organizational Ethics?

1. Create a formal program w/resources
2. Put someone in charge of it
 - General Counsel
 - HR director
 - Internal auditor



Support for Managing Organizational Ethics Programs

Ethics and Compliance Officer Association

<http://www.theecoa.org/>

Compliance
with Laws

***SWEET
SPOT***

Ethical
Behavior

Compliance and Ethics Program



Compliance Organization





Responsibilities



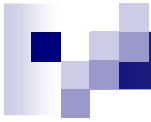
1. **Provide Guidance and Answer Questions**
 - *Create and Assist in Creating Policy & Procedure*
 - *Develop and Deliver Training*
 - *Foster Awareness & Encourage Ethical Behaviors*
2. **Respond to Auditors and Regulators**
3. **Respond to Complaints (Receive/Investigate/Document/Resolve)**
4. **Liaison with the Board of Directors**
 - *Listen*
 - *Report*
5. **Keep Current on and Facilitate Compliance with Laws and Regulations**



Communication & Training

Getting the right message out





What is communicated?

Ethics Materials:

- Mission
- Values
- Code of conduct/ethics
- Policies
- Decision methods
- Your culture

Ethics program:

Who is the Ethics Officer? How to make contact?

Senior Management Commitment to Ethics:

Why organizational ethics matters?



Ways to Communicate

- Website
- Email
- Brochures
- Meetings – Formal & Informal
- Orientation sessions
- Newsletters
- Manuals

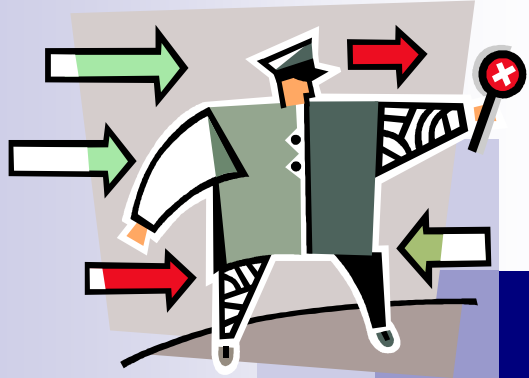


Ethics Training

Design for individual groups

Groups:

- new recruits
- existing employees
- top management
- local management



Enforcement

Ensuring Observance

Putting into practice

Making it happen



Types of Enforcement

The best policy is to *prevent* wrongdoing

1. Getting Compliance (preventative)
 - Training and Education ('I didn't know')
 - Review: Audit for compliance and quality
 - Incentives: compensation and recognition
 - Model: Leadership talks, and walks the talk

2. Punishment (responsive)
 - Clear Sanctions in place
 - Ethics Committee (method in place)
 - Someone with oversight responsibility



Implementing Enforcement

- Consistency is Important across Firm
 - Cross-check from HR for termination issues
- Codified Policy is helpful
- Yet, Flexibility is important also
- Realize Firing is sometimes correct action for sake of firm.
- Unions usually have process/expectations



Conclusion: We Face many issues

- Sources of Business Ethics for Healthcare
 - Religious or philosophical or governmental?
- Healthcare Business in U.S. is huge which leads to unique temptations/problems
- Cost vs Care conflict is always with us
- Stakeholder Concerns for Healthcare are multifaceted and complicated
- Pharmaceutical Sales Ethics: we can do something



www.andygustafson.net

- “Business Ethics Resources”
- “Powerpoints”
- [Business Ethics in Healthcare](#) (Tehran 4/2008)



Business Ethics in Healthcare

- <http://www.slu.edu/bander.xml>
- <http://www.scu.edu/ethics/>