

Lecture 29 Regulation of Science

Lecture 23 Regulation of Science

1. Public support for science
2. Public concern about integrity of science
3. Growth of research regulation

1. Public Support

☛ National Income (2002)

- Income tax + social security = 83%
- Corporate tax = 10%

National expenditures (2002)

☛ 65% = non-discretionary

☛ 35% = discretionary

- 19% non-military
- 16% military

Public commitment to research (2002)

☛ \$264B total

- Industry
- Federal government
- Other sources

☛ Types

- Basic
- Applied
- Development

☛ Public commitment

- \$1 in \$4 (discretionary)

Types of research

☛ Basic primarily at universities

☛ Development primarily in industry

Charts

☛ U.S. R&D funding, by source

☛ Total R&D as a percentage of GDP

☛ Federal R&D by budget function

☛ Current priorities

2. Public Concerns

☛ Humane use of animals in research

- Anti-vivisection begin in 19th century

- ☑ Gains support in US, 1950s
- ☑ 1965, Animal Welfare Act
- ☑ Remains controversial with groups such as PETA (People for the Ethical Treatment of Animals)

Human experiments

☛ Tuskegee syphilis study

- ☑ 1932, long-term effects of syphilis
- ☑ 1943-44, penicillin
- ☑ 1940s continue research .
- ☑ 1950s, withhold treatment
- ☑ 1972, widely reported .
- ☑ 1997, Clinton apology for Nation

Radiation studies

- ☛ post WW II, exposed troops to bomb blasts
- ☛ clinical studies on effects of radiation
- ☛ 1978 human subjects protection regulation,

Research Misconduct, 1970s

☛ Summerline case, 1974

- ☑ Faked experiments

☛ V.J. Soman

- ☑ Plagiarized over 50 articles

☛ John Darsee

- ☑ Faked experiments

☛ 1980s, David Baltimore & Robert Gallo

- ☑ Accused of misconduct but not convicted

Misleading scientific discoveries

☛ Cold fusion, 1989

- ☑ Fleishman and Ponds, Utah,
- ☑ experiment

- *palladium electrodes in heavy water*
- *run electric current through*
- *get out more energy than put in*
- *H collects on electrode, is packed so tightly together, fuses, gives off energy*

- ☑ replication proved very difficult

☛ “Discovery” of life on Mars

Research regulation

☛ Funding comes with strings:

- ☑ Research priorities
- ☑ Spending rules

- Appropriate & inappropriate behavior
- ☛ **Rules are complicated**
- ☛ **Researchers sometimes unaware of rules**

Use of animals

- ☛ **1963 *Guide for Care & Use***
- ☛ **1966 Animal Welfare Act**
- ☛ **1985 Health Research ...Act**
- ☛ **Rules:**
 - Institutional Animal Care & Use Committee (IACUC)
 - Humane care
 - *Replace*
 - *Reduce*
 - *Refine*

Use of Humans

- ☛ **Unethical research during WW II**
 - Nuremberg Code (1947)
 - Declaration of Helsinki (1967)
- ☛ **Unethical research in US**
 - Tuskegee experiment - syphilis study begun in 1930s*
 - Willowbrook experiment*
 - Radiation testing*
- ☛ **Minimum government rules, late 1960s**
- ☛ **1974, Congressional mandate for reform**

Government action

- ☛ **1974 National Research Act (Congress)**
 - National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research
 - Issues Report: *Belmont Report (1979)*
- ☛ **Recommendations turned into rules:**
 - Common Rule (45 CFR 46) (1981)*

Rules for HS research:

- ☛ **Proper review**
 - Institutional Review Board (IRB)
- ☛ **Follow basic principles**
 - Beneficence
 - Respect
 - Justice
- ☛ **Informed consent**
- ☛ **Ca. 18,000,000 research subjects in US?**
- ☛ **Protections?????**

Research Misconduct

- ☛ 1981, government hearings
- ☛ 1985, Congress now mandates actions
- ☛ 1987, NSF set up investigative proceedings under Inspector General, reports to Director of NSF
- ☛ PHS put in interim policies and procedures in 1989, immediately challenged in court
- ☛ 1990, set up an advisory committee on misconduct in research

Consequences

- ☛ **Rules and Procedures required:**
 - ☑ Definitions of misconduct
 - *Fabrication*
 - *Falsification*
 - *Plagiarism*
 - ☑ Procedures for investigation
 - ☑ Offices to handle
 - ☑ Misconduct officers & committees

Other R & R

- ☛ Data management
- ☛ Conflict of interest
- ☛ Authorship
- ☛ Peer review
- ☛ Collaboration
- ☛ Mentoring
- ☛ and . . .

Research as an activity

- ☛ Done by individuals or teams
- ☛ Usually requires financial support
- ☛ Part of larger institutions
 - ☑ Universities
 - ☑ Industry
 - ☑ Government laboratories
 - ☑ Private laboratories
- ☛ Plays important roles in society
 - ☑ Crucial to decision making

Steps to becoming a scientist

- ☛ undergraduate science major
- ☛ graduate level Ph.D. or professional degree

- ☛ post-doc researcher
- ☛ untenured faculty
- ☛ tenured faculty,
- ☛ laboratory director
- ☛ program, department head
- ☛ national committees

Major laboratory

- ☛ lab assistants and technicians
- ☛ post docs
- ☛ junior researchers
- ☛ senior researchers
- ☛ laboratory head or director

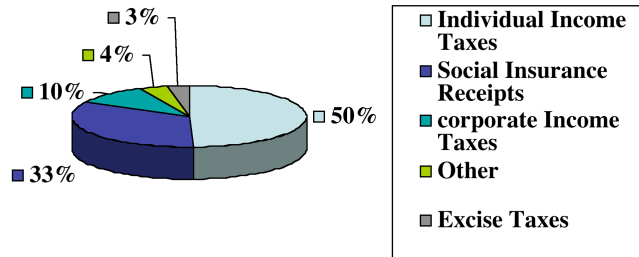
State of integrity in research in 2003

1. Public Support

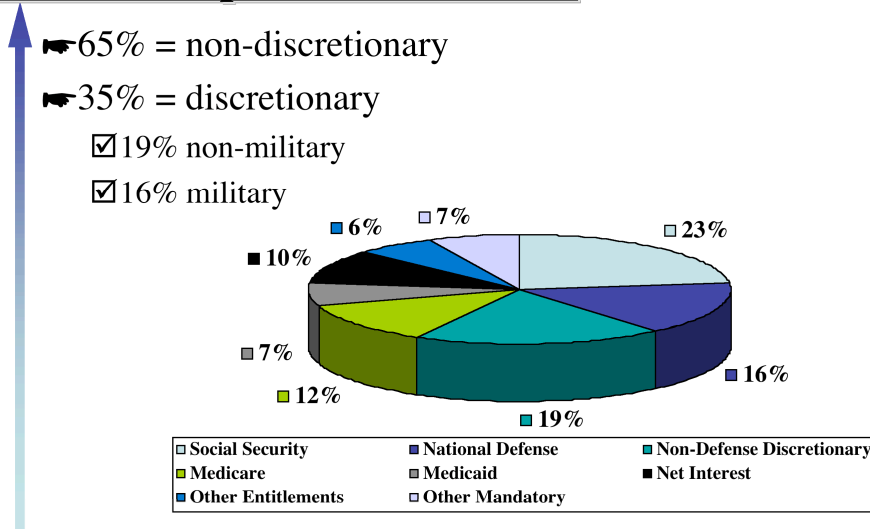
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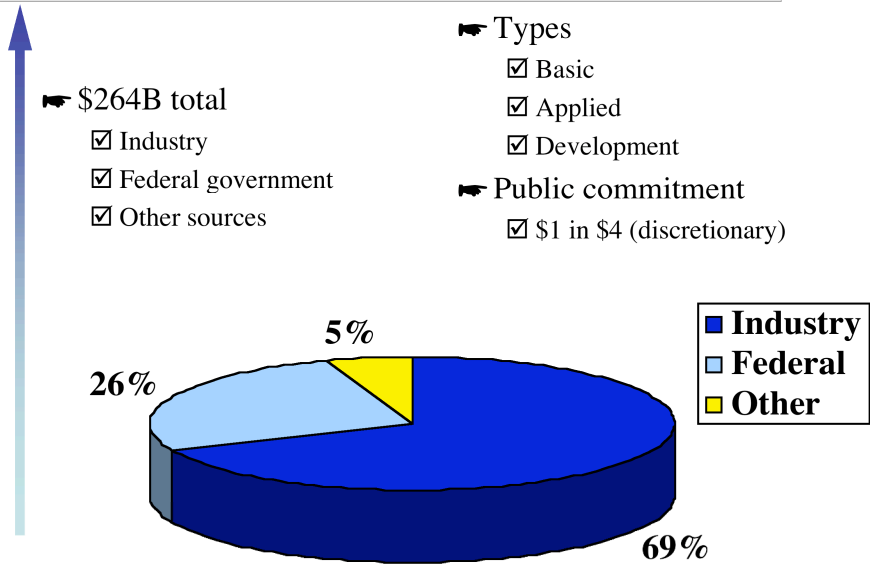
☑ Corporate tax = 10%



National expenditures (2002)

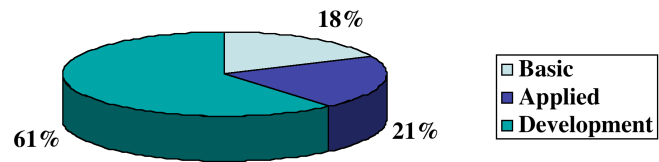


Public commitment to research (2002)

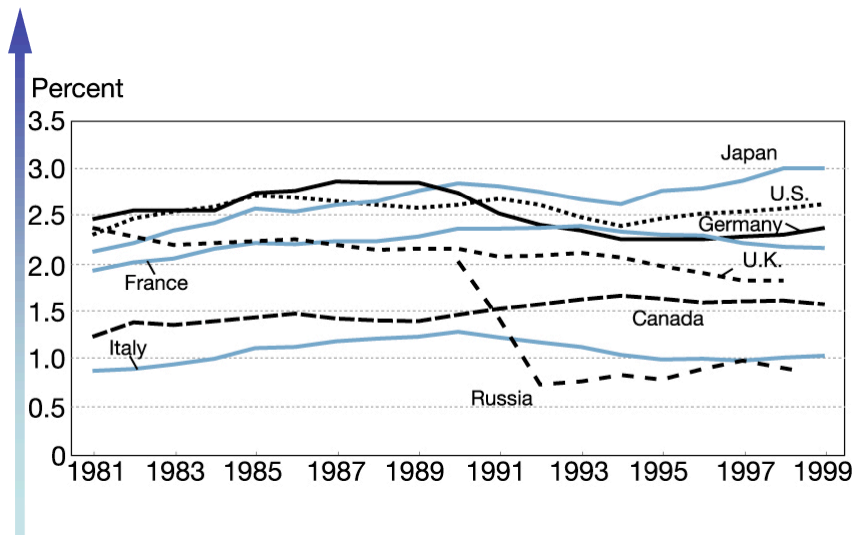


Types of research

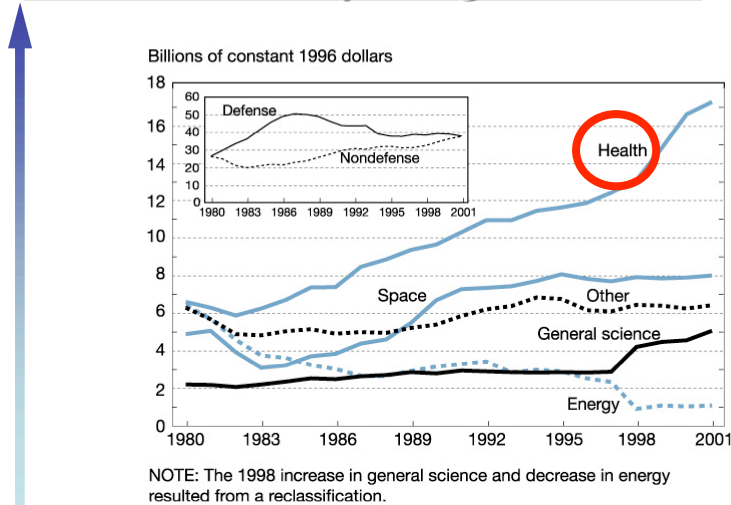
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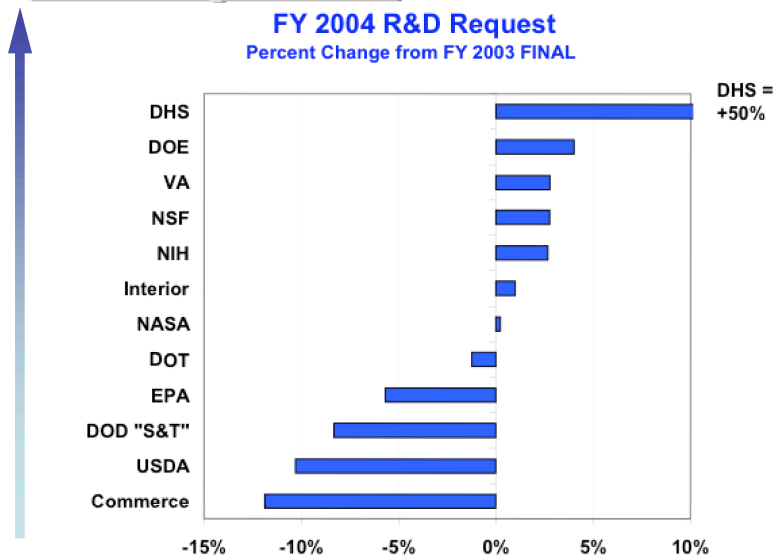
Total R&D as a percentage of GDP



Federal R&D by budget function



Current priorities



Abnormalities ↔ Ideals

