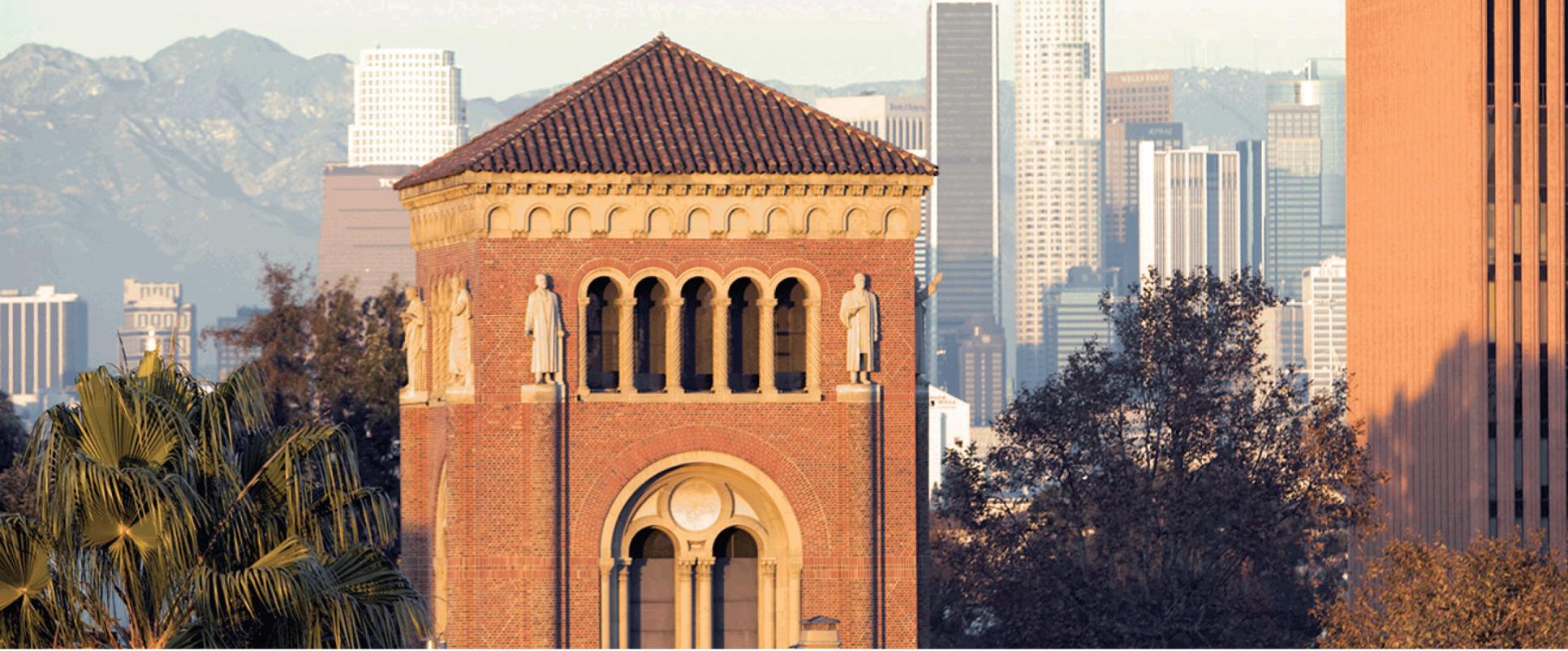


# The Past, Present, and Future Impact of National Bioethics Advisory Bodies

PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES  
26<sup>TH</sup> MEETING ★ AUGUST 31, 2016 ★ PHILADELPHIA, PA

**USC** Gould  
School of Law





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# Overview



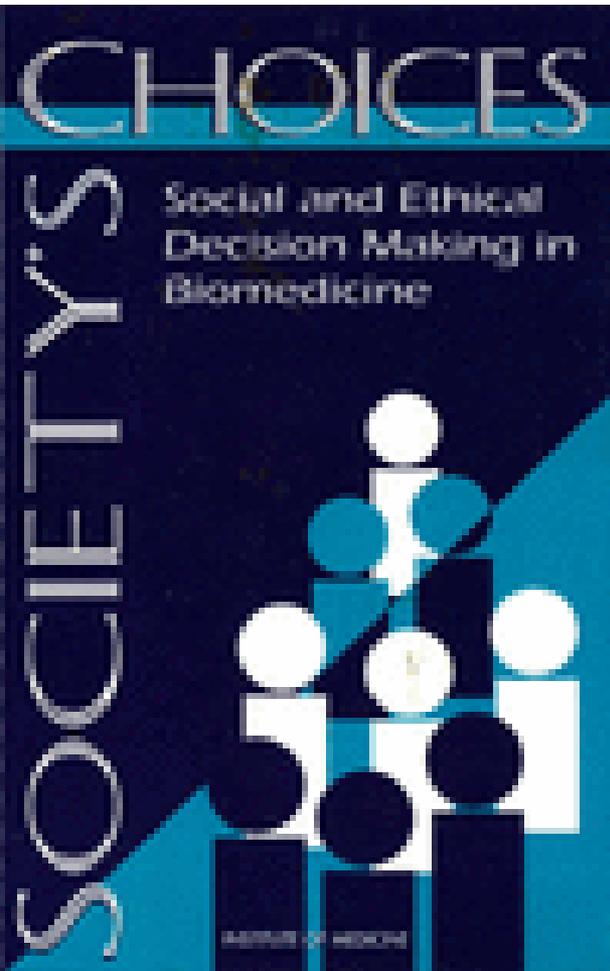
## **Do we need a bioethics commission— and if so, why?**

- What can we learn from the past?
  - Authorization, appointment, location
  - Subject matter
  - Objectives/functions

## **Looking to the future**

- The advantages of continuity
- The need for high standards & objectives

# Do We Need a Bioethics Commission?



Institute of Medicine committee (1995), chaired by Harvey Fineberg, then the Dean of HSPH

**It concluded: YES** – definitely needed to help individuals, medical professionals, and society resolve the dilemmas generated by biomedical developments

## **Ethics bodies at different levels:**

- Hospitals and research centers
- Professional associations
- State government
- **National**
- International



# Specialized Bodies

## **-FEDERAL BODIES**

- Tuskegee Syphilis Study Ad Hoc Advisory Panel (DHEW, 1972-73)
- Recombinant DNA Advisory Committee (NIH, 1975-)
- Ethics Advisory Board (DHEW, 1978-79)
- NIH-DOE Joint Working Group on ELSI of Human Genome Research (1989-)
- Human Embryo Research Panel (NIH, 1994)
- Secty's Advis'y Comm. on Human Res. Protect. (2003-)

## **-NATIONAL ACADEMY & PROFESSIONAL BODIES**

## **-INSTITUTIONAL BODIES (IRBs, Ethics Committees, etc.)**

# Federal Bioethics Bodies



Body	Years	Created by	Appointed by
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	1974-78	Congress (Action-forcing)	Secretary of HEW
President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research	1980-83	Congress (Action-forcing)	President
Biomedical Ethics Advisory Committee	1988-90	Congress	Congress (BEB)
Advisory Committee on Human Radiation Experiments	1994-95	President	President
National Bioethics Advisory Commission	1996-2001	President	President
President's Council on Bioethics	2001-09	President	President
Presidential Commission for the Study of Bioethical Issues	2010-16	President	President

# Authorization, Appointment & Location

- **Authorization: Early bodies created by Congress**
  - **Action-forcing power:** federal departments and agencies must publish the recommendations & respond within given period (ineffective for reports issued close to end of commission's life & more symbolic more than true legal "power")
  - Topics: Mandate; President; Own initiative
- **Appointed by President (post-National Comm.)**
  - Diverse membership
- **Located: outside or within a department**
  - Hard to play certain roles when inside agency

# Federal Bioethics Bodies



Body	Years	Cr. by	Ap. by	AMC
National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research	1974-78	Congress	Sect.	Consultant (Rpt on Fetal Research)
President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research	1980-83	Congress	Pres.	Executive Director
Biomedical Ethics Advisory Committee	1988-90	Congress	Cong.	Chair
Advisory Committee on Human Radiation Experiments	1994-95	President	Pres.	
National Bioethics Advisory Commission	1996-2001	President	Pres.	Member
President's Council on Bioethics	2001-09	President	Pres.	Witness
Presidential Commission for the Study of Bioethical Issues	2010-16	President	Pres.	Witness (2)

# Federal Bioethics Bodies



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Presidential Commission for the Study of Bioethical Issues	2010-16	President	President

# Federal Bioethics Bodies



Body (# of repts)	Years	Cr	Ap	Hum Sub Research	Impact of New Sci	Public Health	Health Care	Other
Nat'l Comm'n (10)	74-78	C	S	7 + * (psycho)	1		2	Belmont Report
President's Commission (10 + 2)	80-83	C	P	3 + IRB Guidebk; Whistle- blowing	1		4-Clin. 1-H.C. Access	Summing Up
ACHRE (1)	94-95	P	P	1				
NBAC (6)	96-01	P	P	4	2			
President's Council (6 + 4)	01-09	P	P		4+ white paper		2+*+ white paper	Essays Readings
Presidential Comm'n (10)	10-16	P	P	5 +**	3	1 - Ebola	****	Delib. & Educ.

# What is Bioethics (in the Reports)?



## 1. Ethical issues in research with human beings

- Origins: Tuskegee; Beecher (1966); IRBs
- Fairly constant (except President's Council)
- Major focus: federal support/regulation
- Your work: less regulatory & more connected to practice & social impact (*e.g.*, Genome Sequencing; Incidental Findings; Brain science)
  - **Integration of ethics across: social impact, research and clinical application is attractive**

# Federal Bioethics Bodies



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NBAC (6)	96-01	P	P	4	1-Cloning 1-ESC			
President's Council (6 + 4)	01-09	P	P		4+ white paper		2+*+ white paper	Essays Readings
Presidential Comm'n (10)	10-16	P	P	5 + **	3	1 - Ebola	****	Delib. & Educ.

# What is Bioethics (in the Reports)?



## 2. Impact of developments in science & medicine

- Can focus on federal policy/research funding (genetic engin.; cloning; embryonic stem cells)
- Can focus on researchers/institutions (your reports on brain science & synthetic biology)
- Can also be a very broad examination, aimed at general public [personal ethics] (National's Commission's "special study" & President's Council's reports on Biotechnology & Pursuit of Happiness; Reproduction & Responsibility)

# Federal Bioethics Bodies



Body (# of repts)	Years	Cr	Ap	Hum Sub Research	Impact of New Sci	Public Health	Health Care	Other
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Presidential Comm'n (10)	10-16	P	P	5 + **	3	1 - Ebola	****	Delib. & Educ.

# What is Bioethics (In the Reports)?



## 3. Public Health Ethics

- Plainly, of great importance
- Perhaps surprising that it has not been examined by a previous commission
  - Relatively new field for bioethics
- Main audience: federal and state health officials and legislators
- Related to human subjects research (report on countermeasures to safeguard children)

# Federal Bioethics Bodies



Body (# of repts)	Years	Cr	Ap	Hum Sub Research	Impact of New Sci	Public Health	Health Care	Other
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Presidential Comm'n (10)	10-16	P	P	5 + **	3	1 - Ebola	****	Delib. & Educ.

# What is Bioethics (In the Reports)?

## 4. Health care delivery and clinical medicine

- Plainly, of great importance
- Was particular focus of President's Commission
  - Large impact: death determination; life-support
- Main audience: physicians, hospitals, patients
- Secondary audience: state & federal legislators
- Singular report on “access to health care,” a **fundamental issue** for medicine & society

# Federal Bioethics Bodies



Body (# of repts)	Years	Cr	Ap	Hum Sub Research	Impact of New Sci	Public Health	Health Care	Other
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# What is Bioethics (In the Reports)?



## 5. Other (two types of additional reports)

- Summaries of principles and issues
  - Explain basis for conclusions (*Belmont Report*)
  - Also review work completed (*Summing Up*)
- Educational needs of professionals & public
  - President's Council (readings & essays)
  - Presidential Commission (integration of deliberation and education—as fundamental to science, ethics, and democracy)

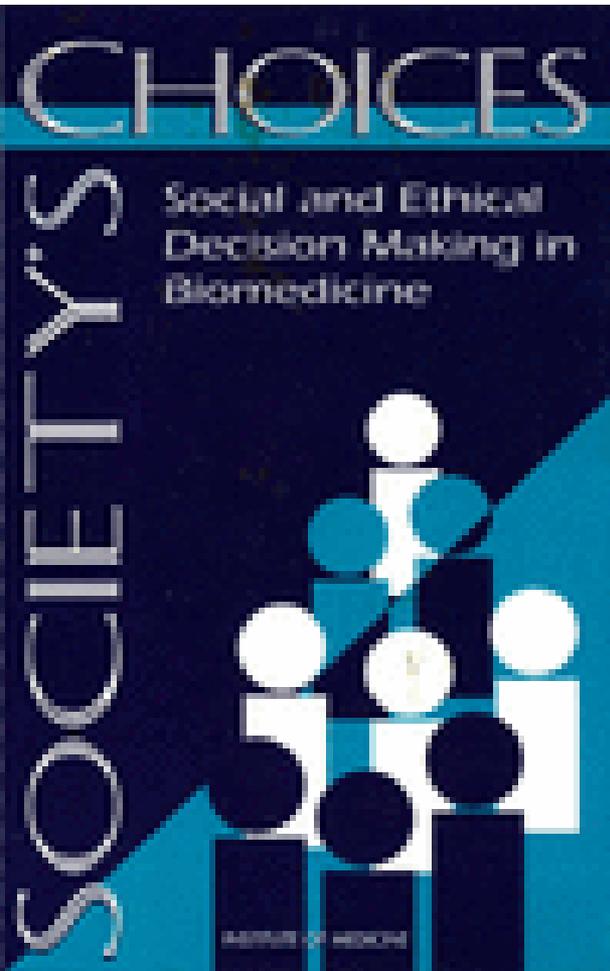


# Objectives/Functions

- **Laying to rest:** solidify emerging consensus
- **Crucible:** identify common elements in differing views; articulate implications; define agenda
- **Watchdog:** examine problems; oversee
- **Dumping ground/lightning rod:** taking issues out of the political spotlight (at least for now)
- **Light unto the Path:** guidance for individuals, scientists, physicians, and government



# Objectives/Functions



**A. Intellectual integrity:** Logic, Scholarship & Sound Judgment

**B. Sensitivity to Democratic Values:** Respect for the affected parties; Representation of diverse views; Openness

**C. Effectiveness:** Communication; Authority

**D. Consensus & Results**



# Looking to the Future

## The “HEARD” Model

**H**eritage (inherited and bequeathed)

**E**nvironment (familiarity/novelty; urgency; controversy)

**A**udience (the 5 Ps: **P**rofessionals, **P**ublic, **p**eers, **p**ublic officials, **p**ress)

**R**esponse (information; standards; laws & regs)

**D**issemination (mode & timing)



# Looking to the Future

## The “HEARD” Model

### **H**eritage : the value of continuity

- Bioethics commissions in other countries
- Emphasizes the search for common principles and agreement on practical conclusions (even when reasoning may differ)

### **R**esponse (information; standards; laws & regs)

- Again, emphasis on high standards (“intellectual integrity,” “democratic values” & consensus)

# Thank You



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