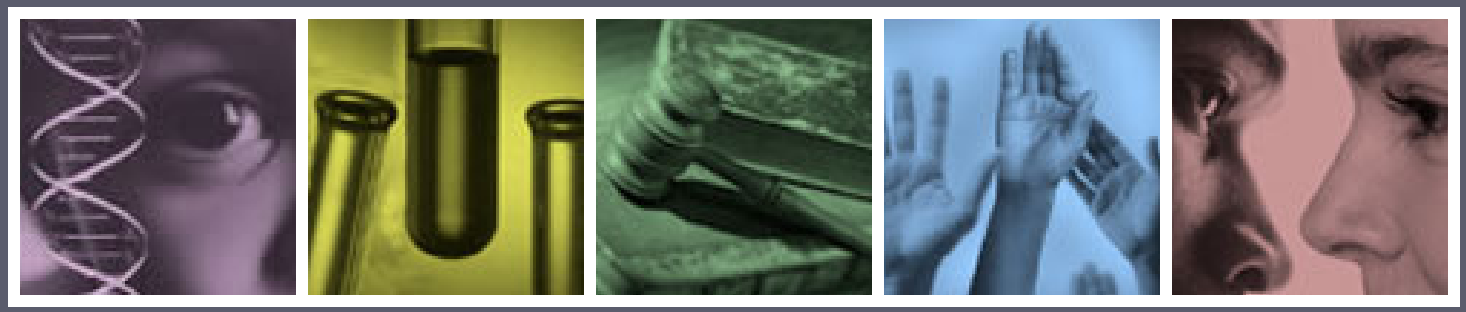
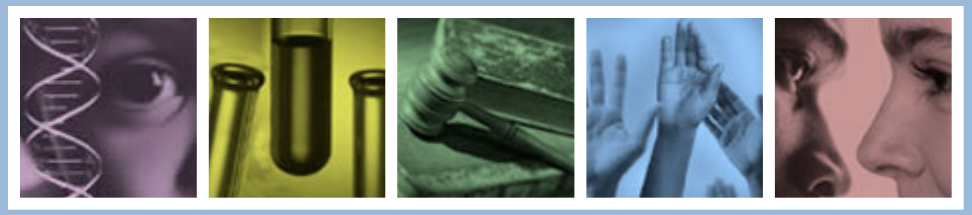
Prisons as BioRepositories:
The Racial Impact of Using Prisoners in Clinical Studies



Osagie K. Obasogie, J.D.
Center for Genetics and Society
31 March 2007

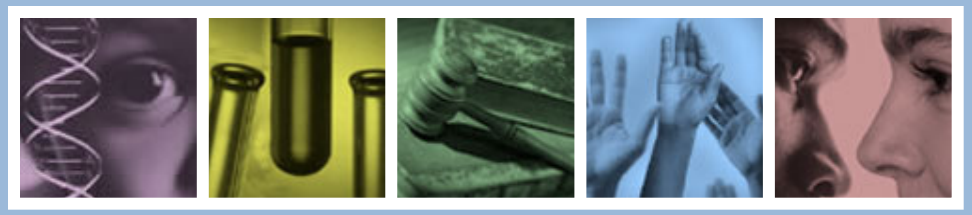
Center for Genetics and Society



Mission statement: “working to encourage responsible uses and effective governance of the new human genetic and reproductive technologies.”

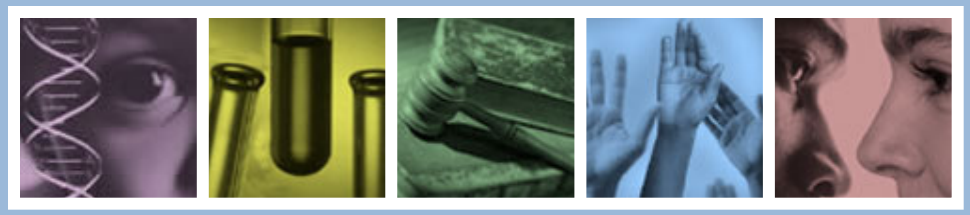
- Pro-science and Pro-regulation
- Effective Policy Options
- Science in the Public Interest

Why we are here…

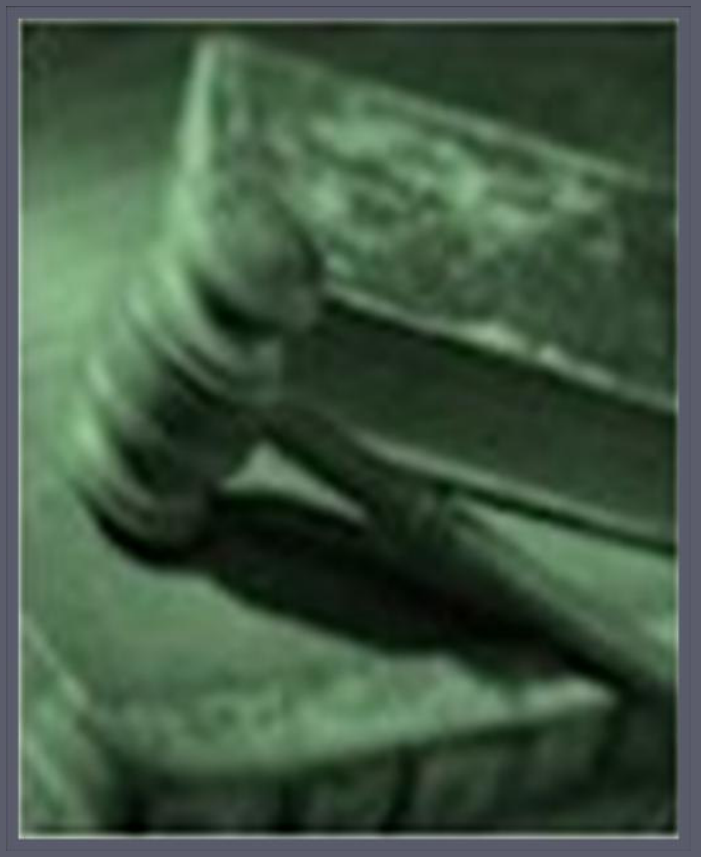


Emerging genetic and reproductive technologies have the potential to:

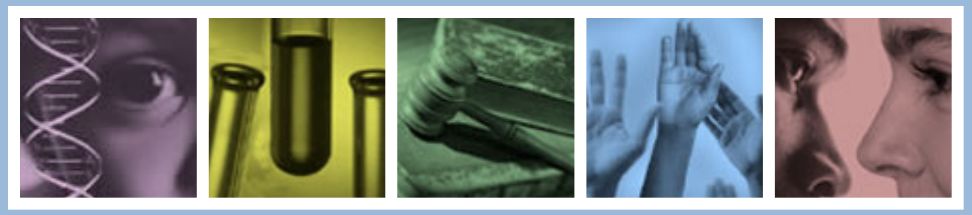
- Deepen social and health inequalities
- Lead to a future where social problems are viewed solely as genetic or biological issues.
- Put human subjects at risk



Prisoners as Research Subjects: Changing Landscapes

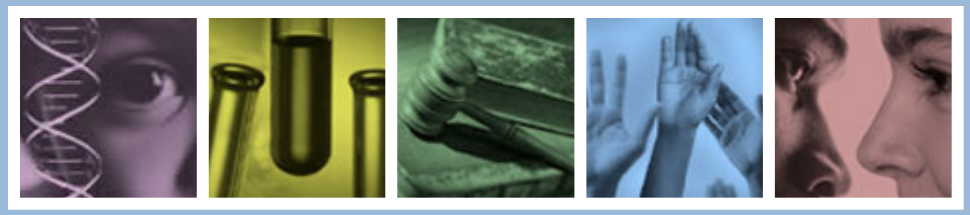


History



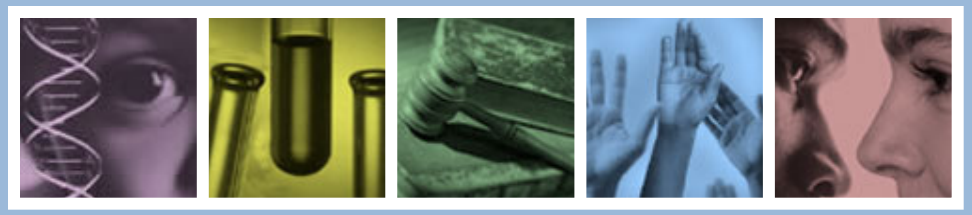
- Throughout much of the 20th century, using prisoners for medical research was routine.
- This led to many notorious abuses, rationalized by a "utilitarian ethic."
- Testicular Transplants
- Purposefully infected with diseases and given experimental drugs
- Injected inmates with radioactive, carcinogenic, and hallucinogenic substances

Example: Statesville Prison Experiments



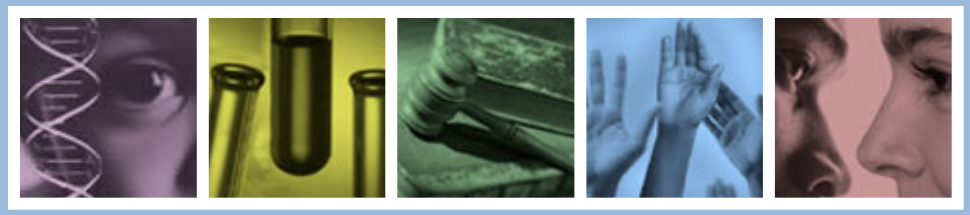
- During World War II, more than 400 prisoners were used in an intensive two year malaria study.
- Mosquito bites, high fevers, nausea, vomiting, blackouts, and numerous untested medicines.
- Commutations of sentence or parole was granted to 317 of the 432 research subjects.
- Counsel for Nazi doctors at Nuremberg pointed to Statesville experiments to defend their actions.

Tipping Point (1): Tuskegee Syphilis Study



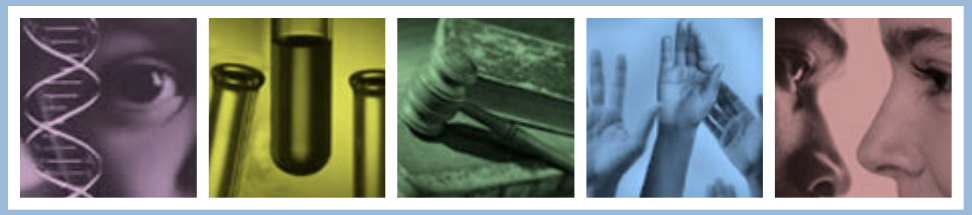
- 1932- 1972
- Study on syphilis disease progression
- 399 Test Subjects (+200 control); Poor rural Black males
- Subjects did not give informed consent and were not told about their diagnosis; instead told they had “bad blood” and could receive free health care, a hot meal, and $50 for funeral.
- By 1947, penicillin became standard treatment. Researchers withheld medicine and treatment information to study how syphilis spreads and kills.

Tipping Point (2): Holmesburg



- Until mid 1970s, 90% of all pharmaceutical products were tested on prisoners.
- From 1951-1974, over 30 companies in collaboration with UPenn conducted experiments at Holmesburg.
- Prisoners used to test mostly skin creams and detergents, but were also used to test dioxin, chemical warfare agents, and other harmful substances.

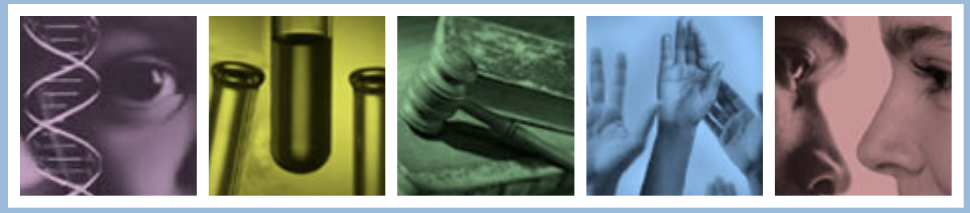
Abuse Exposed

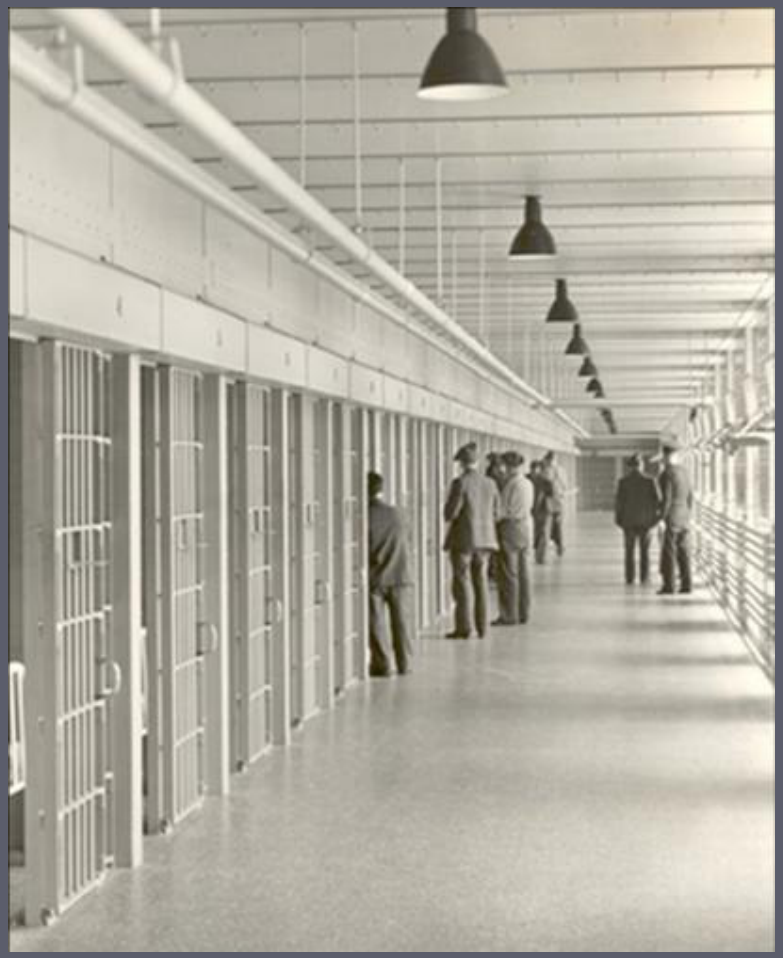


Edward Anthony
Former Holmesburg Inmate and Research Subject

- These events raised awareness of how medical research interacts with vulnerable populations.
- By 1975, only 12 state prison systems hosted medical experiments. In 1976, the federal government severely restricted research on federal prisoners, later codified in 45 CFR 46, Subpart C.

45 CFR 46, Subpart C

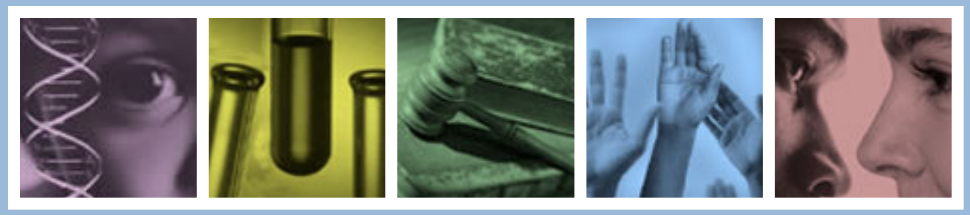




- Only permits four types of research with prisoners
  - Causes and effects of incarceration/criminal behavior
  - Prisons as institutions or prisoners as incarcerated persons
  - Conditions that particularly affect prisoners
  - Practices that can help improve prison conditions

- Does not allow research that
  - uses prisoners as a convenience population
  - does not benefit prisoners

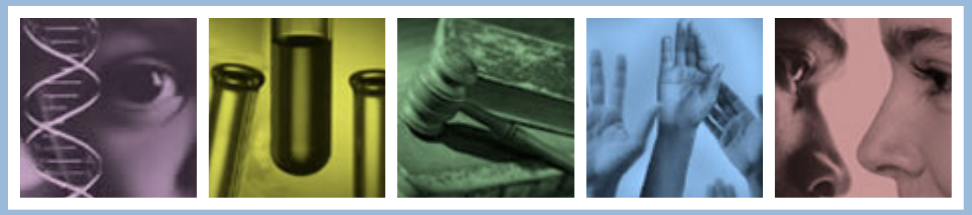
Key Concerns

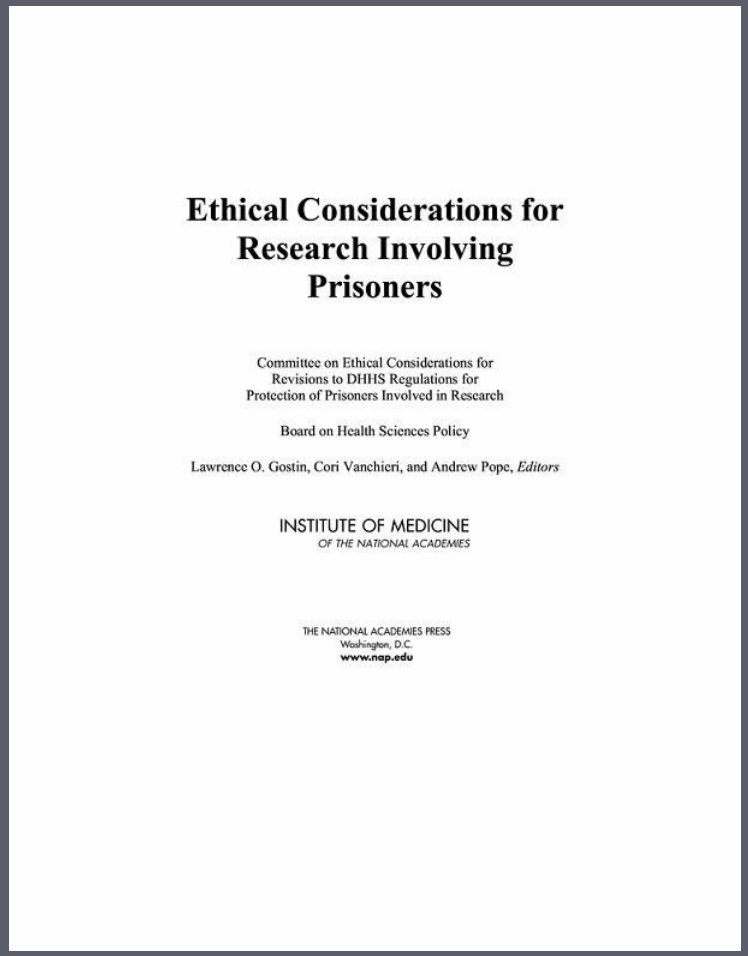


- Guidelines come from National Commission's Report and Recommendations: Research Involving Prisoners (1976)

- Three Key Concerns:
  - Informed Consent
  - Undue Inducement
  - Only exposing prisoners to minimal risk and inconvenience

Proposed Policy Shift





Ethical Considerations for Research Involving Prisoners

Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research

Board on Health Sciences Policy

Lawrence O. Gostin, Cori Vanchieri, and Andrew Pope, *Editors*

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

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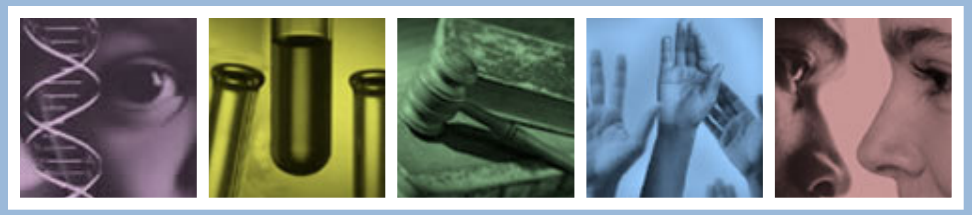
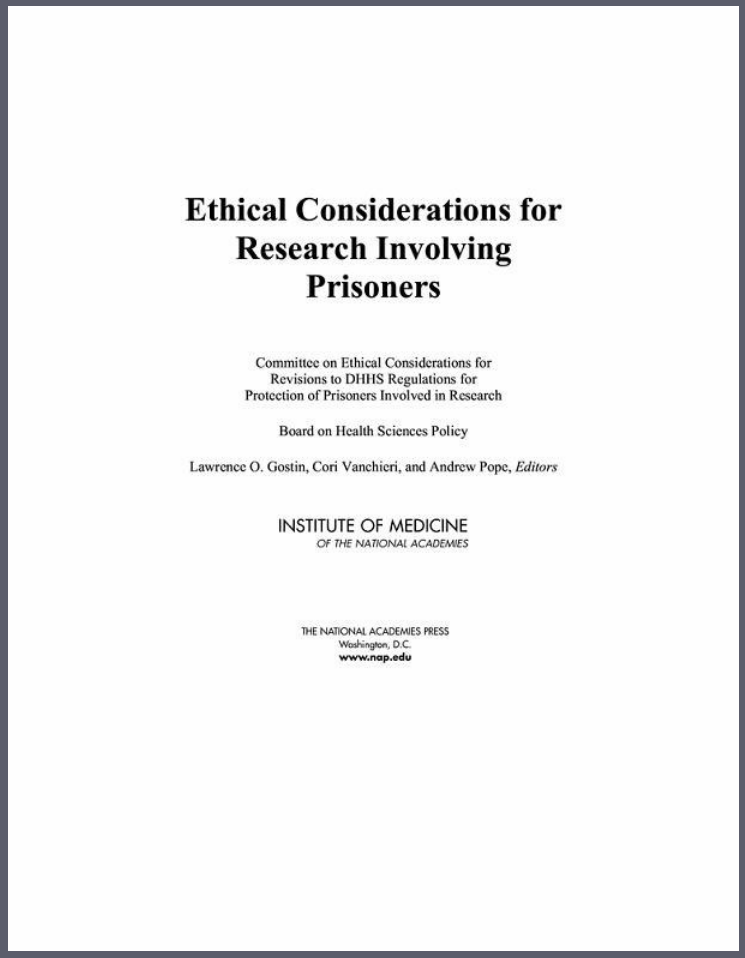
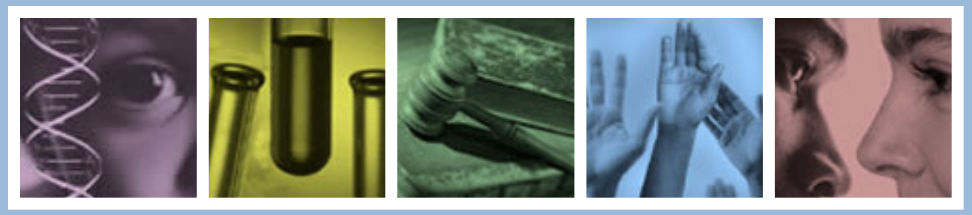
- IOM created a new committee to reexamine findings by 1976 committee. Results released in August 2006 report.
- Committee concluded, in part:
  - Concept of "informed consent" too narrow
  - Default rule against using prisoners also seen as too narrow ; propose "risk/benefit" analysis

Rationale



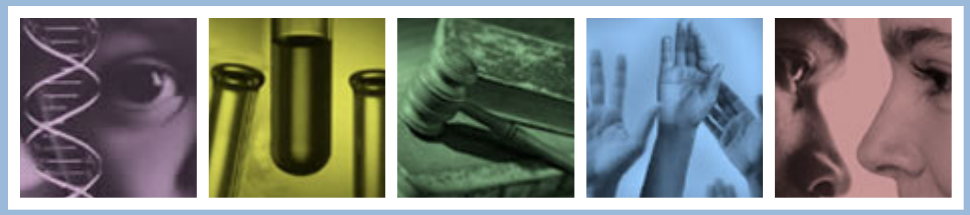


- Reasoning not based upon current prison conditions
  - Report notes that committee "visited one prison and one prison medical facility" (143)
- Committee cites changing ethics literature as a major influence
  - "Respect for persons" formerly meant protecting research subjects from abuse; now it "requires that research subjects be treated as autonomous individuals." (137)
  - 1976 guidelines "discount the notion that researchers can be trusted to act virtuously" (142)
  - "Distributive justice" in the 1970s meant protecting prisoners from harm. Since the 1990s the ethics literature emphasizes ensuring subjects have access to potential benefits.



Could there be other influences shaping this policy change?

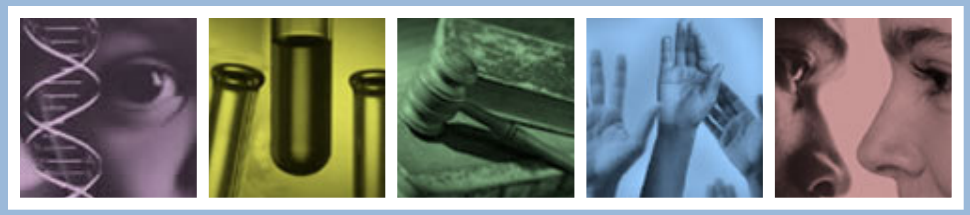
Big Pharma



- Single most profitable industry over last 40 years
  - $550 billion last year
  - Unprecedented growth: 20% per year; average Fortune 500 company is 7%.
- Patent Crisis
  - Companies making the top 28 selling drugs will lose a total of $50 million in revenue as patents expire from 2003 - 2008.
- Example: Claritin®
  - Schering-Plough's sales fell by 18% and suffered net loss of $92 million after losing U.S. exclusivity.

Source: Bloomberg Markets, Big Pharma's Shameful Secret (December 2005)

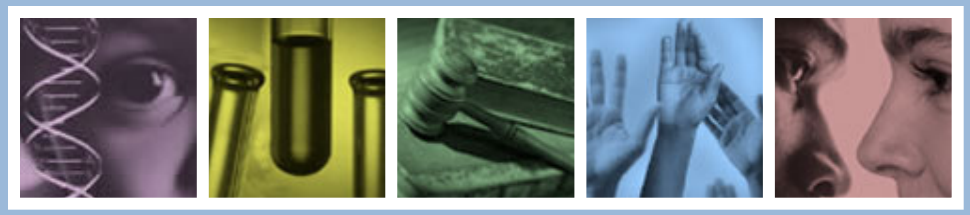
Clinical Trials

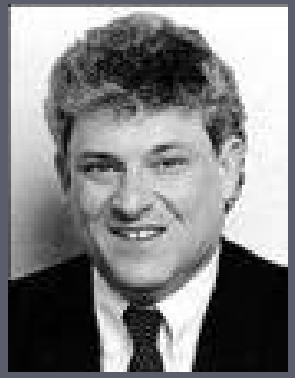


- Search for new money making drugs is fueling a surge in human testing.
- 36,839 new clinical trials from 2001-2004
  - Six times more than in period 1981-85
- Demand has created separate industry in running clinical trials
  - 75% of all clinical trials paid for by drug companies are done in one of 15,000 private test centers or doctors' offices
  - Specialize in "efficiency;" companies lose as much as $5 million a day waiting for FDA approval
  - IRB's overseeing trials often operate in secrecy, e.g. name of members and deliberations aren't disclosed
  - Doctors and hospitals compensated for recruits
- Little public oversight

Source: Bloomberg Markets, Big Pharma's Shameful Secret (December 2005)

Concerns





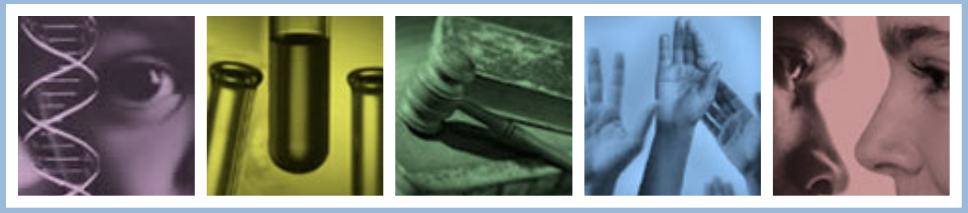
Arthur Caplan
University of Pennsylvania

- "This whole world gives me hives, this privatized review process. I've never seen an IRB advertise by saying 'Hire us. We're the most zealous enforcer of regulations you could have." People say, "We'll turn it around faster. We're efficient. We know how to get you your deadlines."

Marcia Angell
Harvard Medical School
Former Editor-in-Chief, New England Journal of Medicine

- "Human subjects are in very short supply, so it's not surprising that under growing pressure to find them, there are sometimes ethical violations."

IOM Panel: Conflicts of Interest?

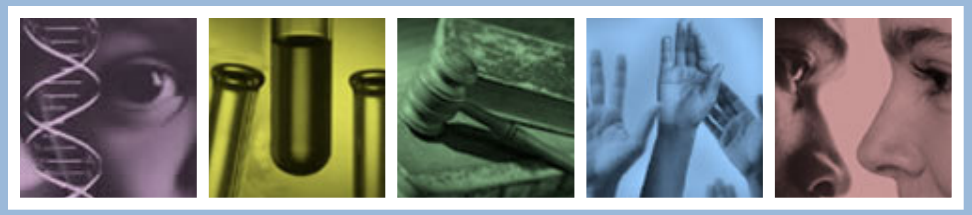


Wendy Visscher
RTI International
Director, Office of Research Protection

- RTI International is a independent non-profit that supports "client" research
  - AstraZeneca
  - Bristol-Myers Squibb
  - Dow Pharmaceutical
  - Eli Lilly and Company
  - GlaxoSmithKline
  - Pfizer
  - Johnson & Johnson
- RTI's "clients" are direct beneficiaries of expanded pool of human subjects

Who Will This Impact?

Race and Prison



- Blacks are 12.1% of pop.; Hispanics are 12.5%.[1]
- Blacks make up 40.2% of federal inmates; Hispanics 31.4%.[2]
  - State inmates: Black = 47.5%, Hispanic = 23.3% [3]
- War on Drugs
  - Drug offenses make up 54% of federal prisoners[4]
  - Federal Household Survey- most illicit drug users are White (72%). Blacks make up 15%. Hispanics 10%. [6]
  - Yet, Blacks make up 36.8% of those arrested for drug violations. Over 42% of those in federal prisons and 58% in state prisons for drug violations are Black.[7]
  - Before federal mandatory minimums, Blacks' sentences were 11% higher than whites; now 49% higher [5]

[1]Source: US Census Bureau, Department of Commerce, Census 2000 Redistricting Data, http://www.census.gov/population/cen2000/phc-t1/tab01.txt

[2] Federal Bureau Prisons, http://www.bop.gov/news/quick.jsp#1

[3] Harrison, Paige M. & Allen J. Beck, PhD, US Dept. of Justice, Bureau of Justice Statistics, Prisoners in 2004 (Washington, DC: US Dept. of Justice, Oct. 2005), Table 12, p. 9.

[4] Federal Bureau Prisons, http://www.bop.gov/news/quick.jsp#1

[5] Federal Bureau Prisons, http://www.bop.gov/news/quick.jsp#1

[6] Substance Abuse and Mental Health Services Administration, National Household Survey on Drug Abuse: Summary Report 1998 (Rockville, MD: Substance Abuse and Mental Health Services Administration, 1999), p. 13

[7] Id.

Prison Conditions

- 1 in 6 prisoners suffer from mental illness [1]
  - Three times rate in general population
- Lack of Health Care
  - Drug Resistant strains of Tuberculosis
  - Illicit drug use and needle sharing
  - High rates of HIV and Hepatitis C
  - Inadequate access to doctors
- Prisoner Abuse
  - Custodial rape
  - Abusive treatment by guards
  - Violent attacks by other prisoners
- What does “choice” or “informed consent” mean here?

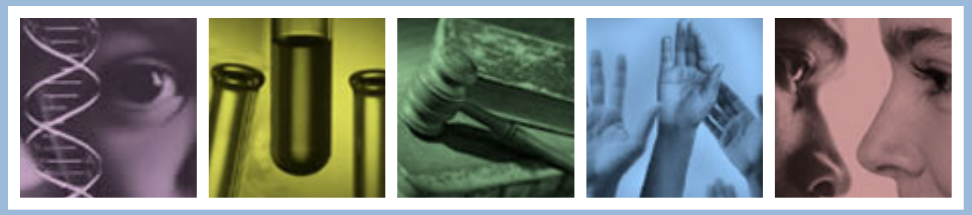
[1] Human Rights Watch, http://hrw.org/english/docs/2003/10/22/usdom6472.htm

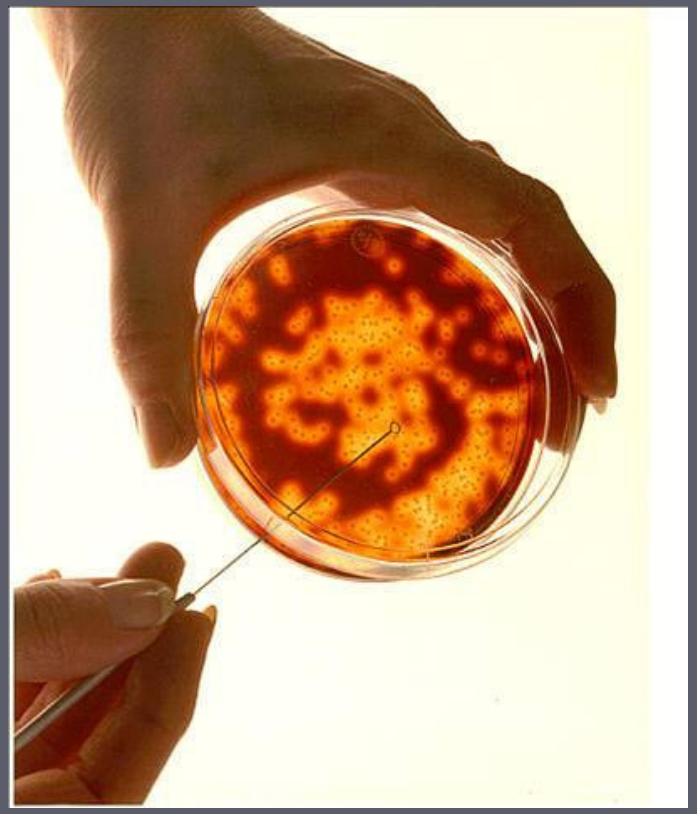
Where Is This Going?

Prisons as Repositories

- This may be part of a growing trend to treat prisons as biomedical repositories.
- South Carolina: Bipartisan effort to introduce legislation that shaves 180 days off of sentences for prisoners who donate organs.

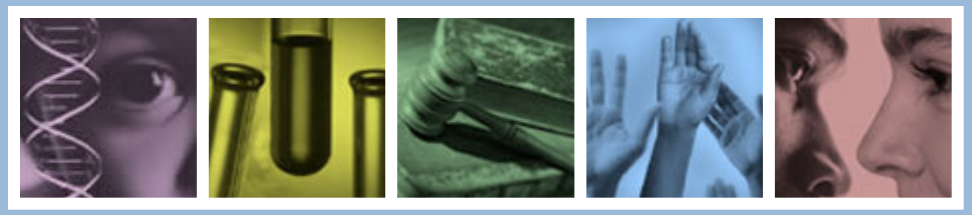
Human Biotechnology





- Manipulate life's building blocks to alter the natural world.
  - Examples: Stem cell research, gene therapy
  - Can have both beneficial and harmful applications
- Same companies looking for the next blockbuster drug are investing millions in biotechnology
- This technology is largely untested and will require tens of thousands of human subjects to develop.

A Global Perspective

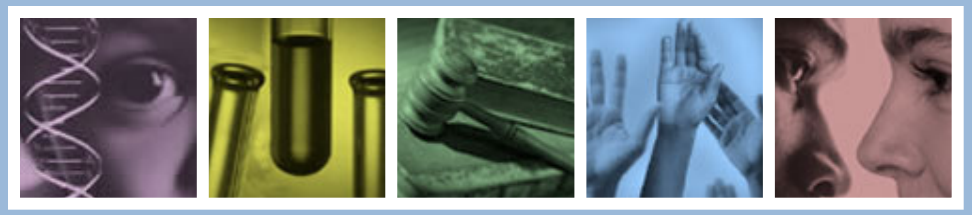


- Outsourcing clinical trials to poor countries
  - Some estimate that as many as ½ of global clinical trails occur outside of companies' home countries.
    - India, China, Brazil, Africa
  - Consultants estimate that clinical trials market in India alone will be $1.5 billion by 2010.

Human Subject Protections in the Gene Age

- Protecting human subjects means protecting society from questionable applications
  - Designer babies
  - Human enhancement
- Bioethicists need to think beyond traditional paradigms
  - Informed consent
  - Individual choice
- Strong human subject protections can promote medical research

Regulation and Oversight



- Market dynamics have the potential to create situations where vulnerable communities are disproportionately subject to potentially harmful clinical trials.
- Some communities – such as prisoners – are particularly vulnerable to exploitation and should only partake in research that directly benefits them.
- Greater oversight is needed to protect all human subjects.