

Etički aspekt upotrebe genetičke informacije

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Advanced Certificate Program in Research Ethics for Central and Eastern Europe (CEE) and Central Asia



A screenshot of the program's website. The header includes "Advanced Certificate Program RESEARCH ETHICS IN CENTRAL AND EASTERN EUROPE" on a red background, "The Bioethics Program" in large text, and "Union Graduate College Mount Sinai School of Medicine" with locations "SCHENECTADY, NY / NEW YORK CITY" and "VILNIUS, LITHUANIA". A navigation menu lists: HOME, PROGRAM, APPLY, COURSES, FACULTY, ALUMNI, ABOUT US, CONTACT US, GLOBAL FORUM, LINKS, and NEWS. Two main content boxes are visible: "ADVANCED CERTIFICATE RESEARCH ETHICS" with a "CLICK HERE" link, and "APPLICATION INFORMATION" with a "CLICK HERE" link. A large image on the right shows a person in a lab coat using a pipette.



<http://graduate.clarkson.edu/program/bioethics-ms-advanced-certificate/>

Nuremberg Code (1947)

<http://www.hhs.gov/ohrp/archive/nurcode.html>

1. **The voluntary consent** of the human subject is absolutely essential
2. Fruitful results for the good of society
3. Previous knowledge should justify the research
4. To avoid unnecessary physical and mental suffering and injuries
5. No experiment should be conducted, where there is an *apriori* reason to believe that death or disabling injury will occur
6. **Benefits outweighs the risks**
7. To protect the subjects against the experiment's risks
8. Scientifically qualified persons
9. **Liberty to quit** from the experiment at any time
10. Termination whenever necessary



Declaration of Helsinki (1964)



<http://www.wma.net/en/30publications/10policies/b3/>

WMA

- Osnovni principi
 - Respect for the individual
 - Right to make informed decisions
 - **Proxy consent**
 - Duties of physicians and researchers to the patients and participants
 - **The welfare of the subjects always above the interests of science and society**
 - **Vulnerable groups**
- Operativni principi
 - Scientific background
 - Risks/benefits
 - Dobrobiti za ispitanike/grupu
 - Obučeni istraživači
 - Governance by Ecs
 - Transparentnost
 - Conflict of interest in publications
 - **Randomisation (placebo, best proven treatment)**

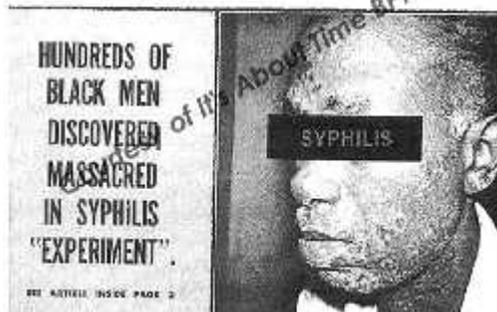
LEGISLATION



Tuskegee Syphilis Study



**GERM WARFARE
DECLARED
AGAINST BLACKS!**

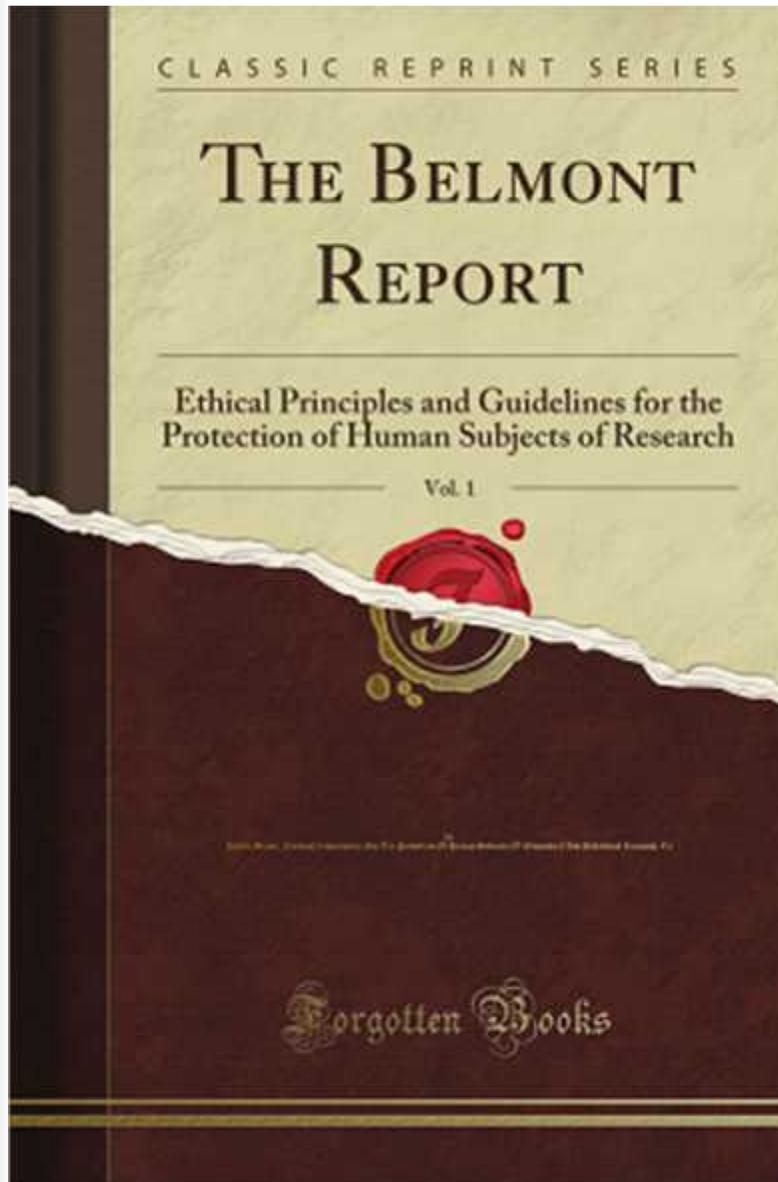


- U.S. Public Health Service from 1932. to 1972.
- The natural course of untreated syphilis in black American men
- Unknowing participants in the study
- They were not told that they had syphilis
- They were not offered with the effective treatment



Belmont report (1979)

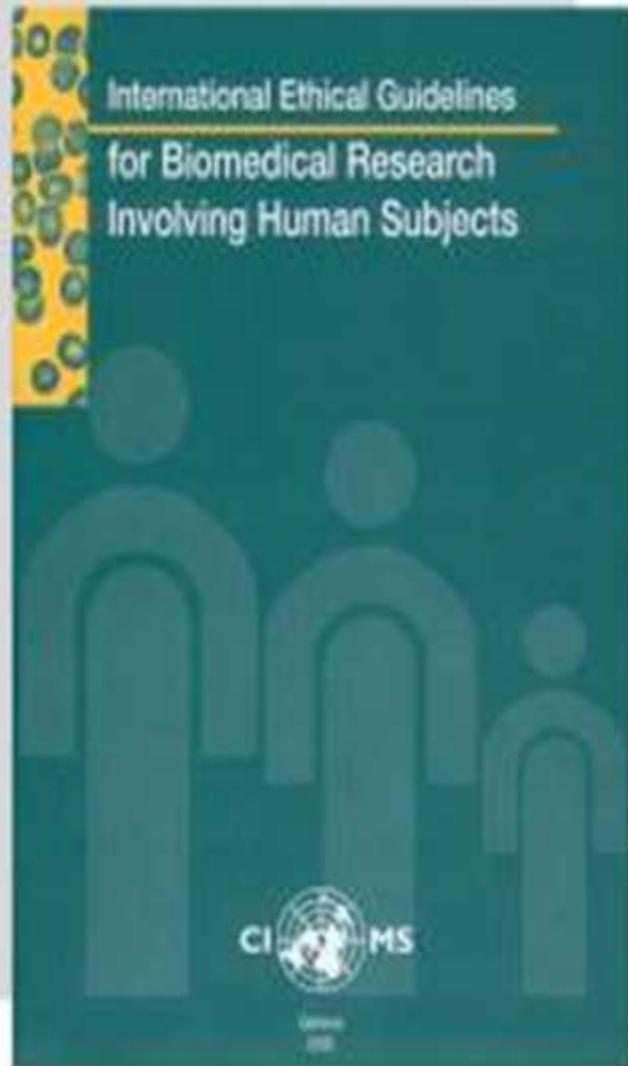
<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>



- **Respect for persons**
 - Individual autonomy
 - Protection of individuals with reduced autonomy
- **Beneficence**
 - Maximize benefits and minimize harms
- **Justice**
 - Equitable distribution of research costs and benefits

CIOMS guidelines (1993)

http://www.cioms.ch/publications/guidelines/guidelines_nov_2002_blurb.htm



- *ethical **justification** and scientific validity of research*
- **ethical review**
- *informed consent*
- **vulnerability** of individuals, groups, communities and populations
- *women as research subjects*
- *equity regarding burdens and benefits*
- *choice of control in clinical trials*
- **confidentiality**
- **compensation** for injury
- **strengthening of national or local capacity for ethical review**
- *obligations of sponsors to provide health-care services*

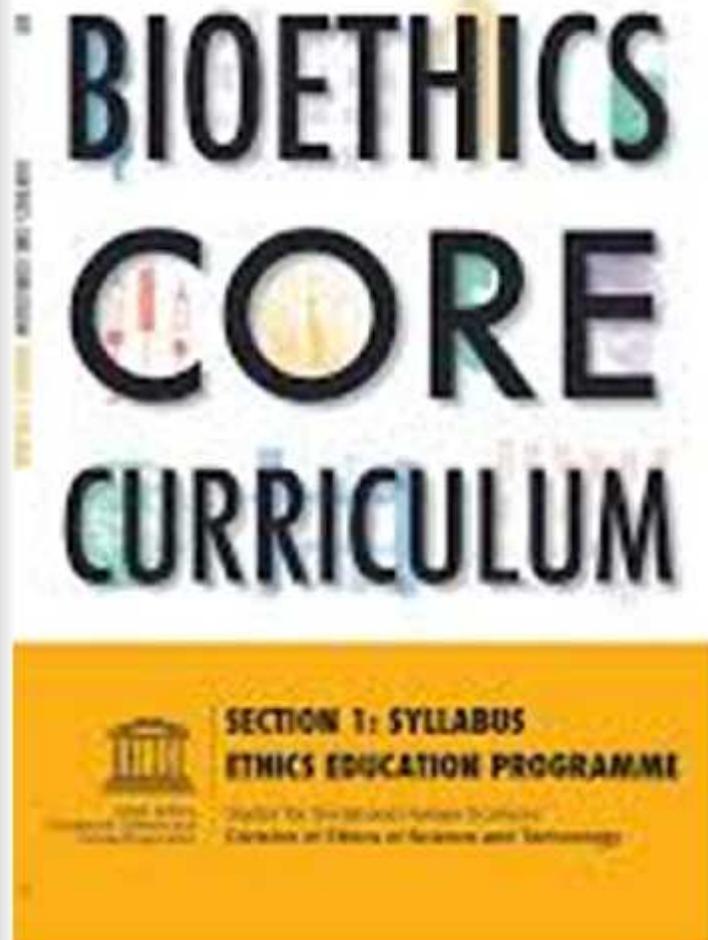


UNESCO Universal Declaration on Bioethics and Human Rights (2005)

<http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/>



United Nations
Educational, Scientific and
Cultural Organization



- This Declaration addresses ethical issues related to medicine, life sciences and associated technologies as applied to human beings, taking into account their social, legal and environmental dimensions.
- The *Guinness Book of Records* describes the Declaration as the world's "Most Translated Document".



Universal Declaration on the Human Genome and Human Rights (1997)

http://portal.unesco.org/en/ev.php-URL_ID=13177&URL_DO=DO_TOPIC&URL_SECTION=201.html

■ Article 2

- (a) Everyone has a right to **respect for their dignity** and for their rights regardless of their genetic characteristics.
- (b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to **respect their uniqueness and diversity**.

■ Article 6

No one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity.

■ Article 5

- (c) **The right of each individual to decide whether or not to be informed of the results of genetic examination** and the resulting consequences should be respected.

■ Article 11

Prohibition of reproductive cloning



International Declaration on Human Genetic Data (2003)

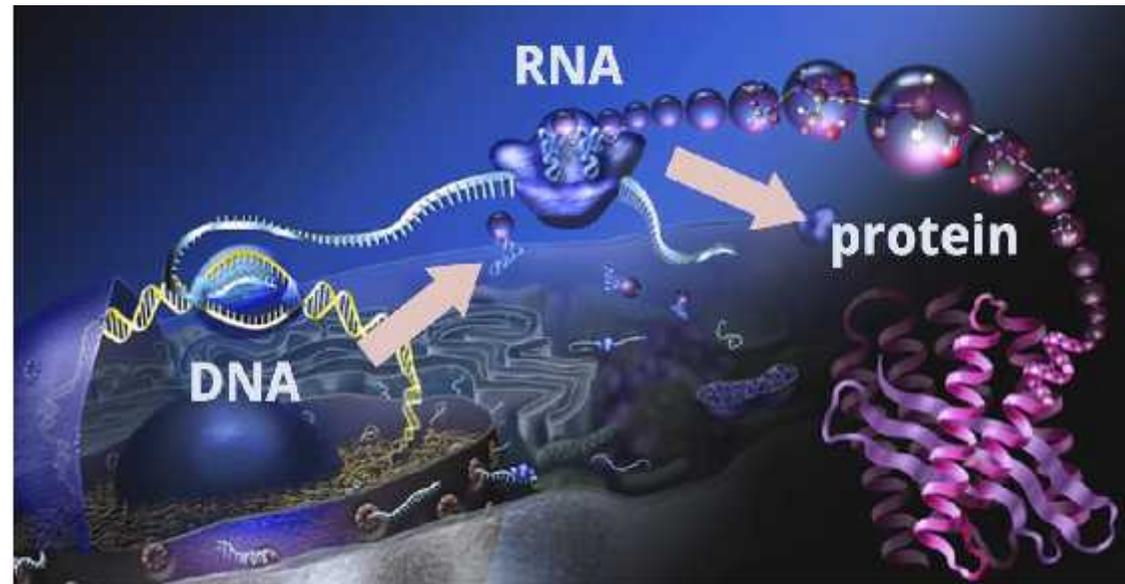
<http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genetic-data/>



- Aims and scope
- ✓ **respect of human dignity** and protection of **human rights** and fundamental freedoms
- ✓ Requirements of **equality, justice and solidarity**
- ✓ **to set out the principles which should guide States in the formulation of their legislation and their policies on these issues**
- ✓ except in the investigation, detection and prosecution of criminal offences and in parentage testing that are subject to domestic law that is consistent with the international law of human rights.



Šta je genetički test?



- Test koji otkriva genetičku informaciju
- Genetička informacija-
- ✓ DNK sekvenca
- ✓ zaključak koji se donosi na osnovu sekvence
- ✓ Informacija koja ukazuje na DNK sekvencu
- Genetička informacija- o pojedincu, porodici, grupi, populaciji

Zašto je genetička informacija posebna?

- *“The **shared** nature of genetic information”*
 - suprotno našem individualističkom načinu razmišljanja
- *“**Identifying** nature of genetic information”*
- *“**Probabilistic** nature of genetic information”*
 - Rizik za obolevanje
 - prediktivno/presimptomatsko testiranje
- *“**Permanent** nature of genetic information”*
- Zloupotreba genetičke informacije

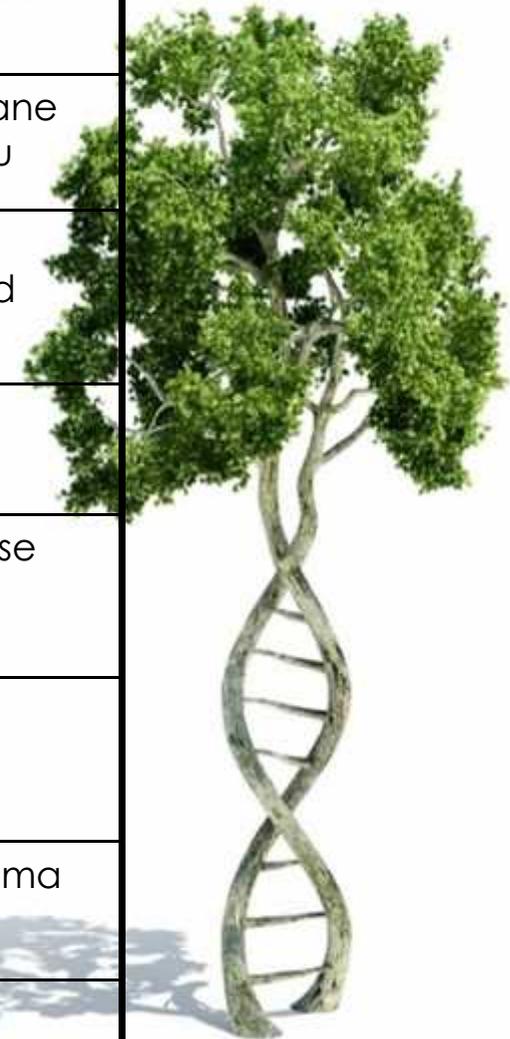
‘THE ANGELINA EFFECT’

Celebrities call attention to gene testing as piece of breast cancer prevention puzzle



Vrste genetičkih testova

Dijagnostički	Uspostavljanje ili potvrda dijagnoze kod osobe koja pokazuje simptome
Prediktivni	Detekcija mutacija u genima koje su povezane sa poremećajima koji nastaju kasnije u životu
Identifikacija nosilaca mutacija	Ne utiče na zdravlje osobe koja se testira ali utvrđuje verovatnoću da se bolest ispolji kod potomstva
Prenatalni	Testiranje fetusa u slučaju da postoji rizik za određeno oboljenje
Preimplantacioni	Implantacija samo onih embriona koji ne nose genetičke poremećaje
Testiranje u forenzici	Identifikacija osumnjičenih
Testiranje u istraživanju	Potruga za novim genima i njihovim funkcijama
Farmakogenetički	Personalizovana medicina



Prediktivno genetičko testiranje

- **Susceptibility**, not certainty
- Awareness **without effective intervention** or prevention
- Are the **risks** connected with the knowledge of susceptibility to genetic disease proportional to the benefits that such knowledge may provide?

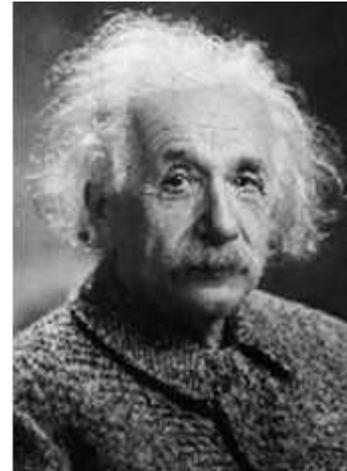


Prediktivno genetičko testiranje

- Respect for person's autonomy?
(**right to know/right not to know**)
- **Confidentiality** in family?
- Psychological risks?
(positive/negative result)
- How to avoid
discrimination/stigmatization?
- **Duty to help or duty to avoid harm**?
- **Limit** the testing to those conditions that can be prevented/treated?
- Ill, healthy, 'asymptomatic but ill' or as an 'unpatient'—since he/she may develop symptomatic disease in the future?
- "Geneticizacion"



Genetička diskriminacija



- **Genetic information non discrimination act 2008 (GINA), USA**

- ✓ Title I- prohibits issuers of **health insurance** from discrimination on the basis of the genetic information of enrollees.
- ✓ Title II- prevents **employers** from using genetic information in employment decisions such as hiring, firing, promotions, pay, and job assignments

Keep the GINA in the bottle 😊



Genetička diskriminacija



- **1989** EU resolution- ban of the use of genetic test for insurance
- Adopted by Council of Europe
- **Prohibition** (Belgium, Denmark and France), **Voluntary moratoria** (indefinite- Finland, Germany, limited (UK), **Middle road**- only authorizing the use of genetic susceptibility tests beyond a certain level of insurability and with the consent of the individual concerned (Netherlands, Sweden)
- **Srbija- Zakon o prevenciji i dijagnostici genetičkih bolesti, genetički uslovljenih anomalija i retkih bolesti (Zojin zakon)**
- ❖ **Član 9- Zabrana diskriminacije u postupku genetičkog ispitivanja**

Our DNA is our unique identifier!

- **Bio-banks** (indefinite use of data, future research unspecified, large scale data sharing, privacy, confidentiality, ability to withdraw, cultural factors, stigmatization, forensic databases...)
- Must balance scientific utility with privacy protection
- Data Sharing Policies and Genomic Privacy

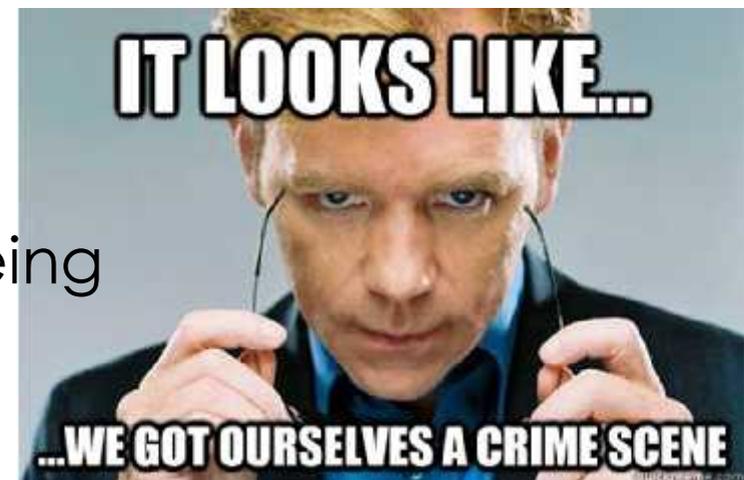


Forensic DNA databases

- 1995. prva forenzička baza podataka u UK
- Unfairness- being treated like a criminal
- Big brother state
- Loss/misuse of data
- Having a "criminal record for the rest of the life"
- Discrimination
- Possibility of being falsely accused
- "Widening the net" not being effective



I WANT YOU
TO SUBMIT TO A DNA TEST



Forensic DNA databases



- When should DNA be collected?
- Whose DNA should be stored?
- How should access and uses be restricted?
- What safeguards are needed to prevent miscarriages of justice?
- When should cross-border sharing be allowed?



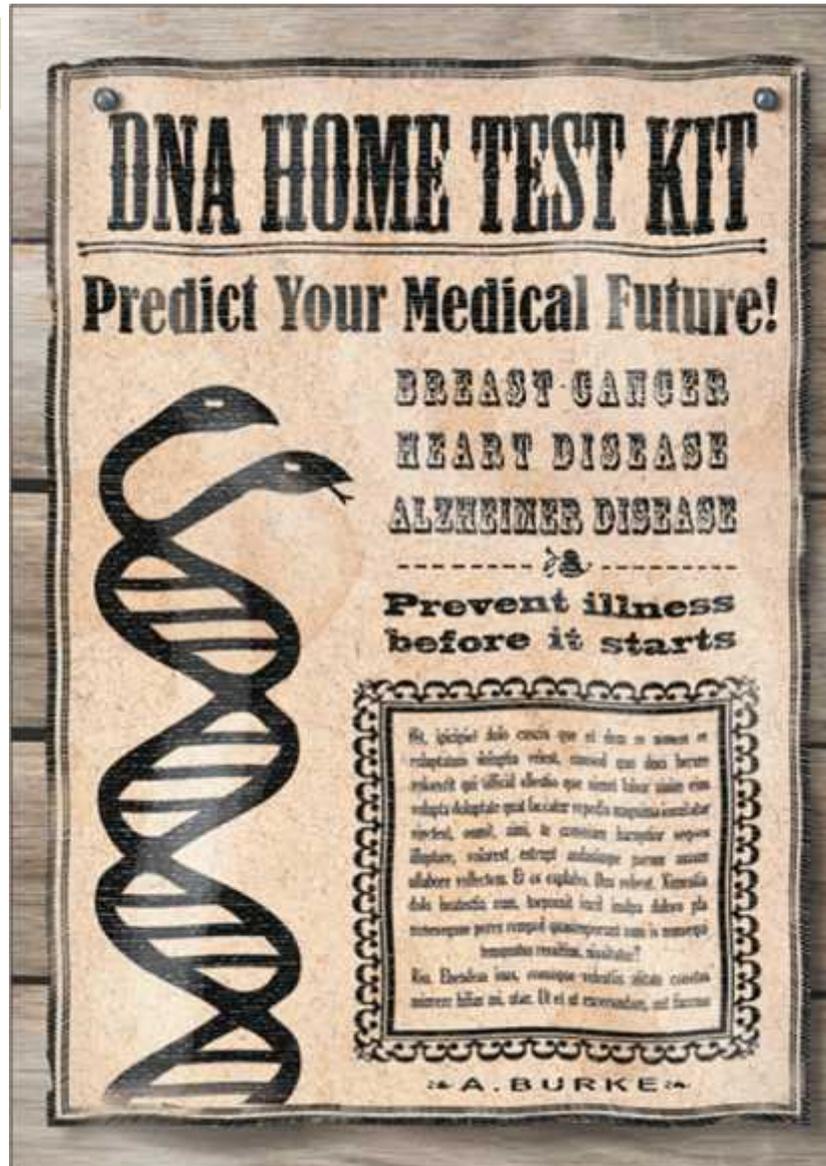
Incidental findings in genetics

- **Discovering an incidental finding can be lifesaving, but it also can lead to uncertainty and distress without any corresponding improvement in health or wellbeing**

Communicate the plan to the participants/patients!

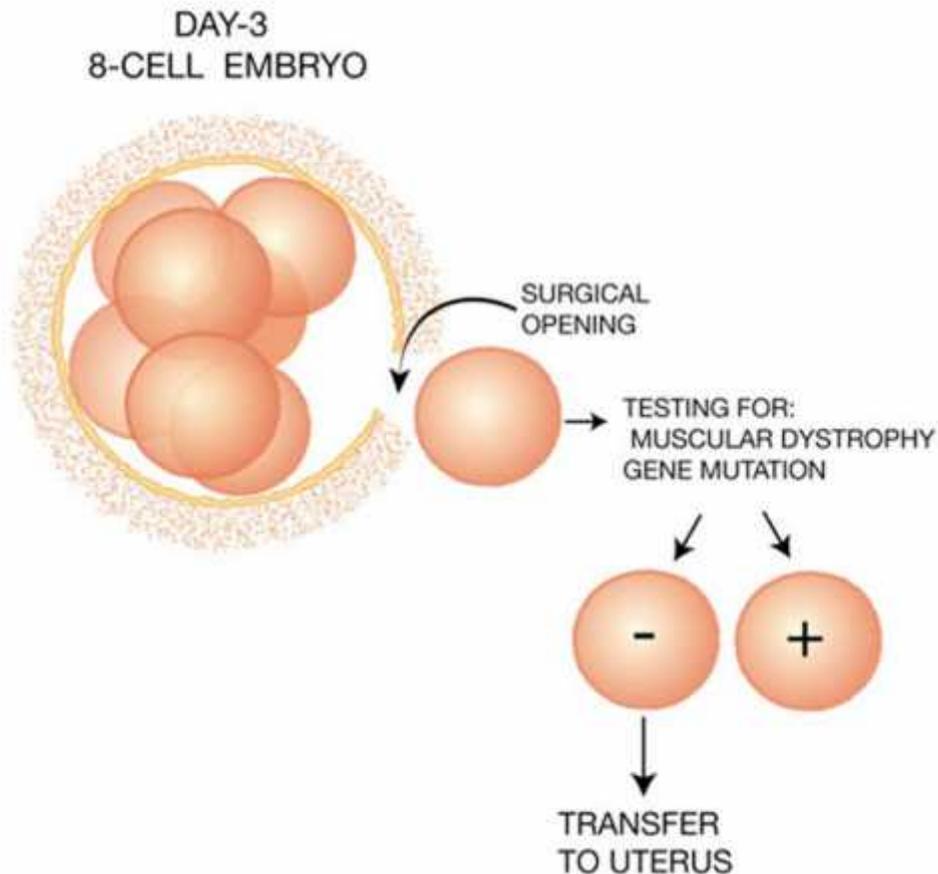


DTC testing in genetics



- Misleading/misusing
- Invasion of genetic privacy
- Breach to confidentiality
- Non-certified labs
- Vulnerability
- **The possibilities of non-consent or a lack of informed consent**

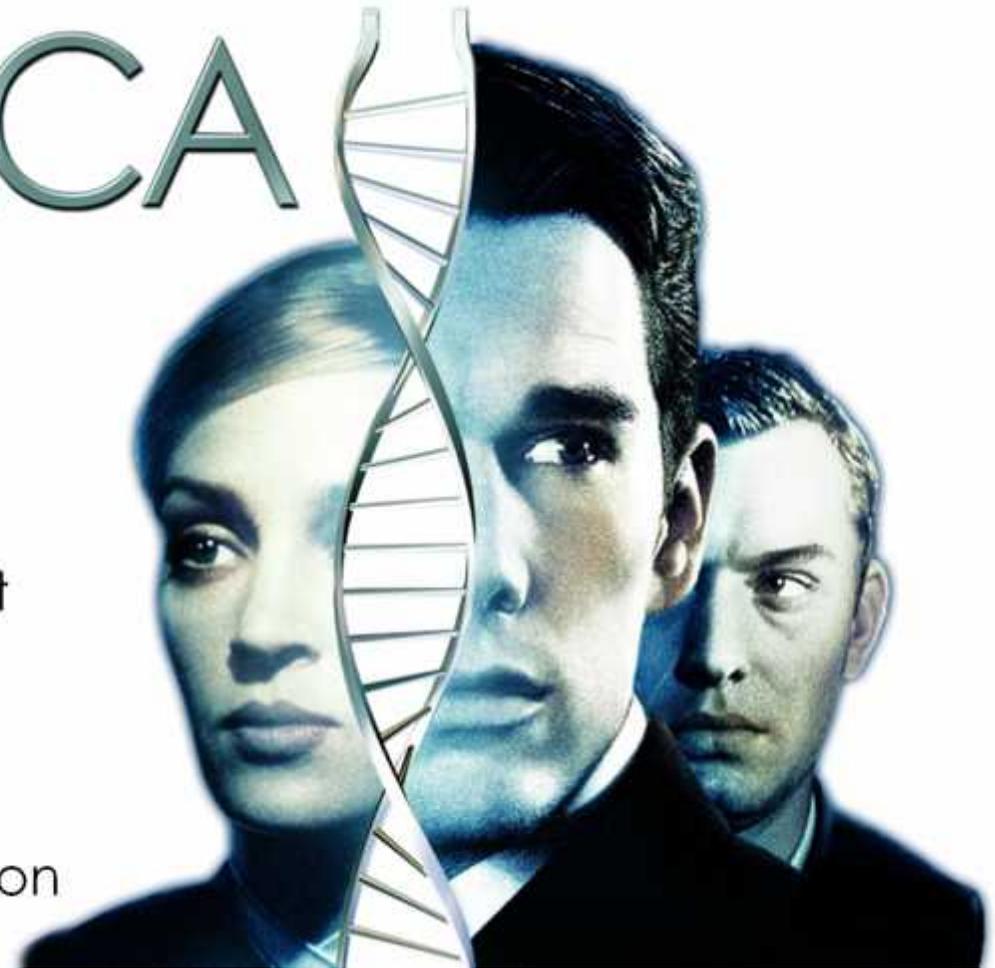
Preimplantaciono genetičko testiranje



- Više od 100 genetički uslovljenih anomalija
- Pre implantacije
- Smanjen broj spontanih pobačaja

GATTACA

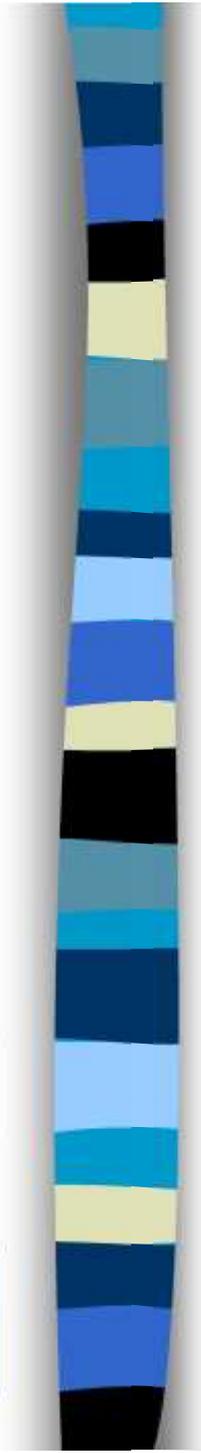
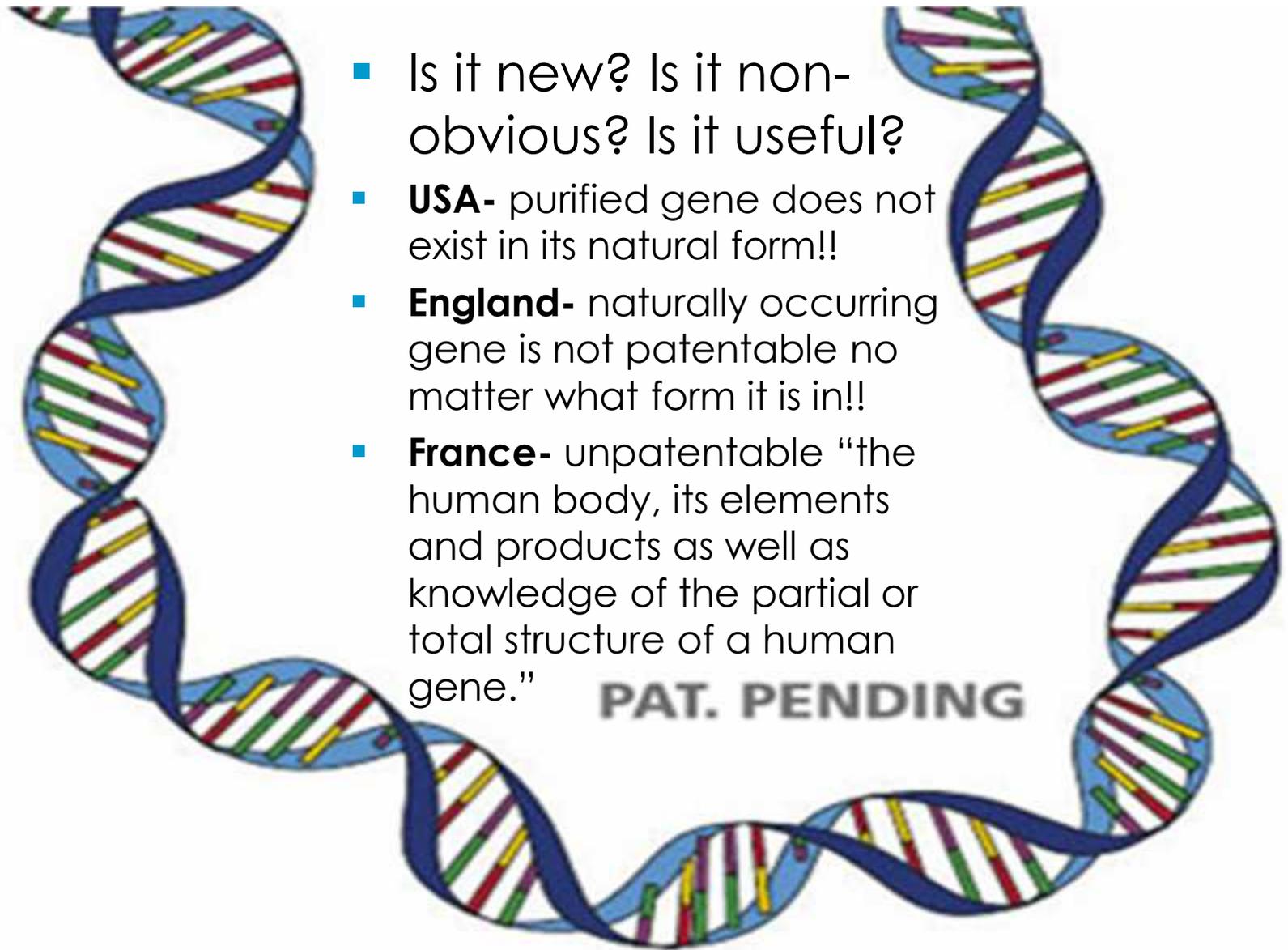
- When the life starts?
- Selection based on genetics?
- Increased inequality
- Avoidance of late onset diseases/ susceptibility conditions
- Savior sibling
- Non medical sex selection



"The great challenge to mankind today is not only how to create, but to know when to stop creating"

Lord Emmanuel Jacobvitz

Who owns your DNA?

- 
- 
- Is it new? Is it non-obvious? Is it useful?
 - **USA-** purified gene does not exist in its natural form!!
 - **England-** naturally occurring gene is not patentable no matter what form it is in!!
 - **France-** unpatentable "the human body, its elements and products as well as knowledge of the partial or total structure of a human gene."
PAT. PENDING

Who owns your DNA?



- American patent office- patent diagnostics involving single genes!
- **Myriad**- the only company in the US to offer *BRCA1/BRCA2* testing
- Obstacle to biomedical research worldwide
- “outrageous” price
- \$3,120
- Discrimination?

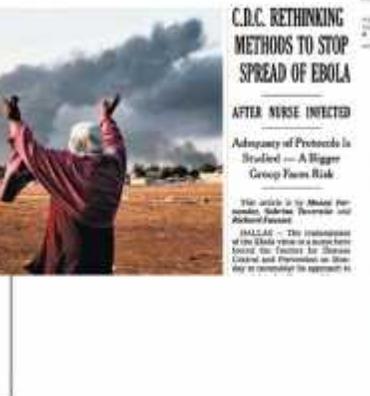
Association for Molecular Pathology v. Myriad Genetics (June 13, 2013)

The Court held that merely isolating genes that are found in nature does not make them patentable.

ZAKLJUČAK

- Nove tehnologije-
novi problemi
- Nova otkrića- stari
problemi u novom
svetlu
- Etika istraživanja na
ljudima će iznedriti
mnogo novih
problema
- <https://www.youtube.com/watch?v=ApjebtaI8bQ>





Birth of Baby With Three Parents' DNA Marks Success for Banned Technique



- Biological issues
- The question of parenthood
- Implication for the society



Donald J. Trump ✓
@realDonaldTrump



Following

I consider my health, stamina and strength one of my greatest assets. The world has watched me for many years and can so testify-great genes!

RETWEETS
752

LIKES
1,893



7:19 AM - 3 Dec 2015



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ОБРАЗОВНО-НАУЧНИ ПРОГРАМ



Radio-televizija Srbije



https://www.youtube.com/watch?v=_-80Y-gZ7o8

<https://www.youtube.com/watch?v=PcCYLWH0O3M>

