BIOLAW

I. theories: bioethics and biolaw
II. practice:
   beginning of life issues
   end of life issues
   allocation of resources
   enhancement
   pandemics
bioethics
bioethics


*bíos*, life, including all living organism

éthos, referring to values and duties
bioethics

• scientific and technological advance in the biomedical field opens new possibilities of intervention on life (human and non-human) and raises new moral questions
• anything that can be done, must be done anyway? are there limits/which?
ethics

ethical pluralism: which ethics for bioethics?
• libertarian theory
• utilitarian theory
• personalism
liberal-libertarian theory

- non-existence and the impossibility to know a common objective truth
- subjectivism
- principle of self-determination
utilitarianism

- an empirical/consequentialist moral theory
- priority to the ability to feel pleasure and pain, to prefer pleasure to pain
- principle of the maximisation of the interests/benefits, minimization of risks/costs for the greatest number
personalism

• possibility to know the common/objective truth
• recognition of the intrinsic dignity of the person in every human being, irrespective of the phase of physical-psychic development, the condition of existence (health or illness)
• principle of respect for life, therapeutic principle, liberty/responsability, justice/solidarity
bioethics/biolaw

• bioethics: good/bad; duty (non binding)
• biolaw:
  rules of behaviour - binding (sanctions) -
to guarantee social life
  laws (biolegislation)
  sentences (biojurisprudence)
  human rights
biolaw

• urgent need for rules that make social life possible and resolve conflicts
• delay at a legislative, doctrinal and jurisprudential level
biolaw

- reasons for the delay in biolaw:
  - the asynchrony between the dynamism of the progress and the slowness of the law
  - the interdisciplinary structure of bioethics
  - prudence (or precaution) of the legislator in front of uncertainties
biolaw

• fragmentation: phenomenon of “bioethical tourism”, the displacement of individuals claiming rights being prohibited in their country to go to the country that allows the implementation of those rights

• search for harmonization
the role of Bioethics Committees

- scientific updating activity, interdisciplinary dialogue
- ethical pluralistic and dialectic discussion
- in-depth examination of legal aspects at the national and international level

1. recommendations to government
2. public involvement
International committees

Unesco:
- International Committee for Bioethics
- Intergovernmental Committee for Bioethics

World Commission on the Ethics of Scientific Knowledge and Technology (Comest)

WHO, Department of ethics and health

WHO, Global Summit

EU, International dialogue on bioethics
European committees

- European Group of Ethics in Science in New Technologies EGE (European Commission)
- Bioethics Committee (Council of Europe) DH-BIO

European Commission, Nec Forum
National organism

Italian Committee for Bioethics
http://www.governo.it/BIOETICA/
born in 1990
advice to Parliament and Government;
information to society
opinions, motions
norms

• Convention for the Protection of Human Rights and Biomedicine of the Council of Europe (1997)

• Charter of Fundamental Rights of the European Union (Nice, 2000)

• Universal Declaration on Bioethics and Human Rights by Unesco (2005)
BEGINNING OF LIFE

1. status of embryos
2. reproductive technologies (surrogacy, ectogenesis)
3. prenatal (genetic) diagnosis
4. cloning
5. gene-editing
1. the status of the embryo

- ‘unborn’ from fertilization to the eighth week after fertilization (after which it is usually termed a fetus)
- the possibility to produce embryos in vitro
embryo

Carnegie Stages
(approx. postovulatory days)
status of the embryo

• the *negation of the rights* to the human embryo: human embryo is considered a mere set or material aggregate of cells belonging to the human species (conventional rights)

• the *recognition of the rights* of the embryo from the very moment of conception: the embryo is ‘already’ human (absolute rights of respect)
experimentation on embryo

- libertarians: lecit - embryo is not autonomous; value of freedom of research
- utilitarians: lecit - embryo is not sentient; utility of research
- personalism: illicit - absolute value of human life since the beginning

intermediate position: licit only the use of frozen/non-implantable embryos
2. reproductive technologies

- the increase in new technological possibilities
- the rise of sterility and/or infertility of the individual and the couple
- the persistence of the desire to have a child that is biologically one’s own
- pressing social demand for access to medically assisted procreation
distinctions

• assisted/artifical insemination/fertilization:
intracorporeal insemination (in vivo) = taking of the male gamete, insertion into the woman’s body
extracorporeal insemination (in vitro) = taking both gametes, treating them, fertilising them, transferring the embryo into the woman’s body
• homologous (gametes of the couple)/heterologous (donation of gamete)
• surrogate motherhood
• ectogenesis (artificial womb)
distinctions

- couple (married or not)
- single
- homosexuals (lesbians/gays)
- post-mortem
- delayed/postponed parenthood
embryo

- the status of the embryo: manipulation (overproduction, crioconservation, reduction, selection)

the over-production of embryos (for the purpose of having “spare” embryos for a later implantation immediately available, following a possible failure of the technique, thus avoiding the further removal of gametes and in vitro fertilisations)
the reduction of embryos, or the random suppression of some of the implanted embryos to avoid the risks of multiparous pregnancies (caused by the implantation of a high number of embryos to increase the probability of success of implanting in the womb)

the possibility of selecting the embryos produced, accepting some for implantation (following pre-implantation genetic diagnosis to determine the state of health and the presence of possible pathologies)
embryo

- libertarians/utilitarians: licit
- personalist: conditions for the use of technologies (respect of embryos)
family/parenthood

- the value of the family:

(asymmetry of the couple; single; same saxe; widow; old mother)
libertarian/utilitarians: permissive

arguments:
it is better to be born with only one parent or with homosexual or elderly parents than not to be born at all

procreative freedom: no empirical proof exists of any possible damage to the unborn child

the principle of non-discrimination
personalist: restrictive

arguments:
- personal status of the embryo
  the unborn child has an intrinsic dignity from the moment of conception (potentiality)
  (no overproduction; no reduction; no selection)
personalist perspective

- the value of the family:
problems of heterologous fertilization
the right of the embryo to know his/her origin-
asymmetry of the couple
the right to have a family: double parenthood (both living) of different sex, ensuring a social assistance
surrogacy

- oblateive gestation
- lucrative gestation (womb renting)
- therapeutic (woman without uterus)/non therapeutic (woman with uterus)
surrogacy

libertarians/utilitarians: lecit even with a contract of retribution and non therapeutic;
- self-determination;
- equality men/women;
- no evidence of trauma of separation, to be born is better than not
- similarity of wetnurse
surrogacy

personalist/feminist view: illicit
- depersonalization of birth; medicalization (health of the mother)
- relationship between the foetus and the mother
- fragmentation of maternity; control of the body
- commercialization of the woman’s body: social injustice (poor, illiterate)
3. gen-ethics: prenatal diagnosis

pre-natal diagnoses: the diagnostic procedures in genetics which make it possible to distinguish
- in the pre-implantation embryo
- in the fetus after implantation
(non invasive diagnosis: blood)
libertarians: permissive

arguments:
- self-determination (informed consent);
  usefulness
- advancement of science
- obligation towards future generations
  (wrongful birth/life: damage to procreation)
utilitarians: permissive

‘procreative beneficence’: prenatal diagnosis is not useful, since it is a costly process, and in any case risky to the health of the fetus and the mother: it is more useful (in the sense of less costly and less risky) to let the pregnancy reach its conclusion, and where diseases are found after birth, to practice euthanasia of the newborn (refraining from adopting any basic health measures for the newly-born infant)
the personalist theory

recommends a cautious attitude:
- risks
- false positive/negative
- genetic counselling (not directive)
Dolly
4. cloning

- *clone* means the set of the individuals with the same genetic patrimony.
- The fission of the embryo.
- The transfer of the nucleus (the nucleus of a somatic cell of an adult is taken and introduced into an oocyte, of which the nucleus has been removed).
- Vegetables, animals, humans.
the libertarian theory

• permissive: self-determination, advancement of science
• moderate permissive: acceptance of society, more experimentation

(high mortality rate, the possibility of contracting pathologies), the many risks to the life and health of the woman carrying the clone (even risks of dying), besides the foreseeable social damage)

attitude of caution and precaution: the prohibition can be reviewed in time according to the evolution of scientific knowledge and the degree of perception of social acceptance
the personalist theory: prohibitive fabrication of life
- the cancellation of the family
the clone is not the child of the subject from whom the cell with the genetic nucleus is taken, but a sort of twin deferred in time (or vertical twins)
- the asymmetry of men/women
the personalist theory: prohibitive

- a restriction of the freedom of the clone, in so much that its genetic patrimony would no longer originate from the unprecedented and unpredictable genetic combination of the paternal and maternal chromosomes, but from the already integrally determined genetic patrimony of the progenitor
animal cloning

problems:
experimentation on animals
biodiversity (the risk is the reduction of genetic variability, with the consequent loss of the ability to adapt naturally to the environment)
human’s health
5. gene-editing

• *gene-editing* means correction, applied to genetics: the use “molecular scissors” to cut DNA in order to correct them

• somatic cell, ‘germline’ (gametes, embryos)
gene-editing

on gametes to be used for fertilization and 
*human embryos to be implanted:* prudence
due to the high risks for the unborn child
the risk is the one of not correcting the
genetic defect and/or introducing
unintentionally modifications that can
transmit serious diseases
gene-editing

*on embryos*: problems:
- safety and effectiveness; possible birth of ‘genetically modified babies’ potentially at risk
- there are alternatives (prenatal diagnosis and embryo selection)
- the absence of informed consent
- justice in the distribution of resources: it is ethically problematic to invest in research applicable to a small number of cases, compared to research on therapy for individuals who are already severely ill
- the blurring lines between therapeutic purposes and enhancement
END OF LIFE

1. therapeutic obstinacy
2. refusal of treatment
3. euthanasia, assisted suicide
4. palliative care
5. living will/advance care directives
1. therapeutic obstinacy

‘prolonged artificial life support’ (or therapeutic persistence), the attempt by medicine to delay, beyond all limits, death to indefinitely lengthen life by postponing death (in the illusion of immortality)
therapeutic obstinacy

non proportionality:
ineffective cures (incurable patients, terminally ill patient, imminence death)
unbearable pain
difficulties of access to cures, high costs of therapies

experimental: risks higher than benefits
therapeutic obstinacy

- libertarians: self-determination
- utilitarians: quality of life
- personalist: duty to stop it, for the dignity of dying (even if claimed by the patient, who wants to live ‘at all costs’)

The stopping of therapeutic obstinacy is *not* euthanasia (or therapeutic abandonment)
2. refusal of treatment

• refusal (not beginning a therapy) or the renunciation (suspending the therapy)

• conditions of autonomy (competent patient, able to execute his will); condition of dependency (competent patient, needing a doctor in order to execute his will)
refusal of treatment

libertarians: lecit

- self-determination, unconditioned choice (informed consent)
- no coercitive imposition to cure oneself
refusal of treatment

personalist:

• autonomy/limit to the disposition of one’s own body: responsibility towards society, oneself, duty to cure

• risk that refusal can lead to a de-evaluation of the life of people who live in similar conditions of illness

• obligation of the physician to cure
3. euthanasia

the etymology of the term (‘sweet death’) is misleading with respect to today’s semantic significance

- the autonomous management of dying (in the illusion of dominating/controlling death)

- the relationship between patient/physician
definition

the action of the physician (active euthanasia)
the request of the patient
(voluntary euthanasia)

assisted suicide (assistance to die)

(refuse/renunciation: to let die
euthanasia/assisted suicide: killing)
libertarians

• permissive: right to die, self-determination

objections:
- authentic autonomy? (pseudo-euthanasia)
- conflict of autonomies? (the relationship between patient and doctor)
utilitarians

- permissive: quality of life

objections:
- subjectivity of the evaluation of quality of life
- slippery slope: different degrees of dignity
personalistic perspective

against euthanasia:
- right to live, to be cured and cared
- humanization of death (palliation)
- accompanying in dying (not to die)
4. living will, advance care directives

- written document,
- a competent person (a healthy person or a person who is at the initial stage of the illness)
- in advance with respect to the possible discovery of certain pathological conditions (or of the extreme consequences of certain incurable degenerative pathologies)
- to authorise the doctor (with the possible procedural control by a tutor/person of trust) not to treat him
living will

libertarians/utilitarians:
- also request of euthanasia/persistent treatment
- binding (the physician is obliged to apply it)
objections

- it is a decision expressed with a “cold mind”, abstracted from the situation, chronologically distant and not experienced before
- the continuous evolution of the progress in biomedical knowledge, some situations deemed incurable can be modified
advance directives/statements

• limit: not request of euthanasia or therapeutic obstinacy
only refusal of treatments, which may be refused by a competent person
not binding: wishes are taken into consideration
advanced healthcare planning”

• signed at the beginning of a degenerative incurable disease

• in this situation the abstract information become a concrete and unavoidable condition that will certainly be faced by the patient
5. palliative care

• cannot ‘heal’ the patient of the illness, but it ‘takes care’ of their suffering and needs (caring and not curing)
the humanisation of death

- the attention of the doctor and family close to the dying person,
- the accompanying of the dying person in alleviating pain
deep sedation

- with the intentional reduction of the patient’s consciousness up to its annulment, in a “continuous” or irreversible way
- incurable, terminal illness, imminence of death
- refractory pain/suffering
deep sedation

• hidden euthanasia?
• the patient’s condition of incurable pathology in an advanced stage close to death; the ascertainment of the refractoriness of the symptom and the consent of the patient
ALLOCATION OF RESOURCES

• *macro-allocation*: the decision of “what”, “how much” to distribute and “how” to allocate (policies)

• *micro-allocation*: the decision of “who” to treat (patient selection)
liberal-libertarian theory

- no one is responsible for natural and social inequalities
- the results of the “natural lottery” (i.e. the distribution of advantages/disadvantages by birth) and the “social lottery” (the distribution of advantages/disadvantages in ) are unfortunate, not “unfair” or unjust

bioethical criteria for patient’s selection: the ability to pay, the social worth of patients
utilitarian bioethics

- justice in distribution: collective advantages and social utility
- number of patients saved; number of years to live; quality of life
personalistic bioethics

- justice: equality, equity
- bioethical criteria for patient’s selection:
  *objective medical criteria* - evaluation of the clinical situation of the patients; case by case; need: urgency, gravity, effectiveness
  living aside the non-medical criteria
Covid-19: triage

Spain, *Plan de Contingencia para los Servicios de Medicina Intensiva frente a la pandemic COVID-19*: no access to elderly and people with disabilities

Italy (SIAARTI), *Recommendations of clinical ethics for admission to intensive treatments and for their suspension, in exceptional conditions of imbalance*: possibility to place «an age limit on entry into intensive care»; «those who have the most chance of survival an have more years of life saved, with a view to maximizing the benefits for the greatest number of people» and reducing costs
The Italian Committee for Bioethics

- **The Clinical Decision in Conditions of Lack of Resources and the Criterion of "Triage in Pandemic Emergency:"**
- “the principles of justice, fairness and solidarity, to offer all people equal opportunities to reach the maximum health potential allowed”
  “any other selection criterion, such as for example age, sex, condition and social role, ethnicity, disability, responsibility for behaviours contributing to the pathology, costs, is deemed ethically unacceptable by the Committee”
- “Age, in turn, is a parameter that is taken into consideration in view of the correlation with the current and prognostic clinical evaluation but it is not the only parameter nor even the main one. That is, a criterion must not be adopted, according to which the sick person would be excluded because they belong to a category established a priori” (one member: minority report: age as extraclinical criterion to be considered for the choice)
documents

- Comité Consultative National d’Etique, *Enjeux éthiques face à une pandémie*
- Nuffield Council on Bioethics, *Ethical considerations in responding to the COVID-19 pandemic*
- Committee for Bioethics of Spain, *Report on the bioethical aspects of prioritizing health resources in the context of the coronavirus crisis*
- Austrian Commission, *Management of scarce resources in healthcare in the context of the COVID-19 pandemic*
- Committee in Luxembourg, *Repères éthiques essentiels lors de l’orientation des patients dans un contexte de limitation des ressources thérapeutiques disponibles due à la crise pandémique du COVID-19*
- San Marino Committee, *Ethical issues regarding the use of invasive assisted ventilation in patients all age with serious disabilities in relation to Covid-19 pandemic*
- Slovenia, *Decision of physicians regarding the involvement of respirators in the treatment of patients severely affected with SARS-cov2 disease*
- Sweden, *Triage in primary care units*
documents

- DH-BIO Statement in the Context of the Covid-19 Crisis
- EGE, Statement on European Solidarity and the Protection of Fundamental Rights in the Covid-19 Pandemic affirms the principles of dignity, justice, solidarity, as the basis of a common European ethics
- UNESCO IBC-COMEST, Statement on Covid-19: Ethical Considerations from a Global Perspective
Covid-19: vaccines

no lottery, first come first served
medical risks
risks of transmission
exposure
psycho-social risks
identification of priority

• general principles/guideline:
• scientific and ethical justification
• flexible
• transparency
  - roles of experts (interdisciplinar)
  - societal/community engagement
ENHANCEMENT

*therapy* = a medical treatment necessary to prevent, sustain and restore good health

*enhancement* = beyond therapy

Intervening in the human body/mind of a healthy individual in order to alter existing physical, mental and emotional capacities for a quantitative increase and qualitative improvement in human beings
types of enhancement

technologies may be:
invasive/non invasive
with serious or non serious possible damages
reversible or irreversible
with immediate and long-term effects
transmissible/non trasmissible
applications

(cosmetic surgery/doping in sports)
• biological enhancement (*life-extension*)
• genetic enhancement (gene editing on embryos)
• cognitive enhancement
philosophical discussion

• ethical pluralism

1. perfectionism (technophilic): pros
2. antiperfectionism (technophobic): cons
3. intermediate perspective: pre-caution/case by case evaluation
perfectionism

libertarians: principle of self-determination

utilitarians: principle of utility: welfare (or happiness) = the best optimal balance of benefits over costs

J. Savulescu, N. Bostrom, J. Harris
pros

a) a *subjectivist view of health*, based on a state of complete physical, mental and social well-being
- impossibility to distinguish between health/illness
- impossibility to distinguish between therapy/enhancement
- enhancement and therapy are interchangeable, contiguous and equivalent
pros

b) a *contractualist approach* to medicine/research

the task of the physician/researcher is not only devoted to cure,

but also informing them about existing opportunities to intervene in their bodies and minds, based on subjective perception, wishes and will
c) *improvement is part of human development*, consciously or unconsciously, with reference to any individual or social opportunity

- vaccination enhances the healthy body’s resistance
- physical exercise enhances physical performance
- education improves intelligence and personality
pros

d) a biotech ‘shortcut’ that accelerates the achievement of desired results

enhancement is a stage of evolution: natural selection must be replaced by “deliberate choice” of the selection process, allowing to achieve the same result with much less effort (duty)
pros

e) justice (not injustice)
even if not everyone will be in the social condition to enhance him/herself
no prohibition would be justified because of economic reasons
free market, self-determination
anti-perfectionism

worries of possible harms of enhancing technologies
principle of dignity, responsibility, justice/solidarity, precaution

a) the possibility to identify *objective parameters for determining the concepts of health and disease*: the “regular functioning” of the organism indicates evidence-based biological referents on the state of health.

the obstacle or hindrance to the expression of organic functionalities, in attaining their own purposes is a pathological state (deafness and blindness are diseases)
cons

b) the relationship between patient-subject/physician-researcher: therapeutic alliance-responsibility

proportionality between risks and benefits

excessively risky interventions with regard to achievable benefits (ineffective, costly and burdensome for patients), irreversible and predictably inconclusive interventions, cannot be ethically justified (medicalization)
c) the inherent dignity of human beings
the enhancement of qualities, namely the highest possible expression of these characteristics does not, in principle, make man “more of a man” or “more worthy”
arbitrary choices of trait selection (what criteria? how much better? who evaluates what is better or worse?)
cons

d) enhancement is a mere external facilitation, that may allow us to achieve even excellent and better results, faster and more efficiently, enhancement interventions act directly on the body and mind to produce an effect: the subject remains passive and does not assume any role (or minimal role) in change
cons

achievement is the dimension of acquirement, accomplishment, attainment, in the sense of development and realization of potential naturally belonging to “becoming what we are” through an active effort and personal commitment that enable modification of one’s own natural capacities, as an authentic and substantial transformation, as personal growth (human flourishing; virtue)
e) reduction of freedom

enhancement becomes a form of ‘social despotism’ (extrinsic obligation) which is expressed in the hidden pressure exerted by society on citizens to adapt to standards (homologation)

a reduction of spontaneity, autonomy
cons

f) an *enhancement divide* (the *enhanced* and *unenhanced*): the problem of injustice:
distributive justice: the high costs of access to enhancement technologies ‘beyond therapy’) make it available only to those who can afford it.