ISSUES OF LIFE KENNETH ALONSO, MD, PHD, FACP

Assessing the ethical dilemma

- Determine the facts
- Define the conflict
 - Understand both patient and physician values
 - Explore alternative solutions
 - Assess the consequences
- Seek advice from scientific, religious, community resources as needed
- Use a competent translator if language is a barrier
 - Recommend an action
 - Remove oneself if there is a moral conflict

	Ethics	Morals
		personal compass of right and wrong.
Where do they come from?	Social system - External	Individual - Internal
Why we do it?	Because society says it is the right thing to do.	Because we believe in something being right or wrong.
Flexibility	Ethics are dependent on others for definition. They tend to be consistent within a certain context, but can vary between contexts.	Usually consistent, although can change if an individual's beliefs change.
The "Gray"	A person strictly following Ethical Principles may not have any Morals at all. Likewise, one could violate Ethical Principles within a given system of rules in order to maintain Moral integrity.	A Moral Person although perhaps bound by a higher covenant, may choose to follow a code of ethics as it would apply to a system. "Make it fit"
Origin	Greek word "ethos" meaning"character"	Latin word "mos" meaning "custom"
Acceptability	Ethics are governed by professional and legal guidelines within a particular time and place	Morality transcends cultural norms

- Genetic engineering is the freedom of selfdetermination (autonomy) at a basic level.
- Man defines man in his choice of genetic attributes to express or suppress.
- The cloning of a whole human organism raises the fundamental question of the quiddity of humanness.
- The fullness of human life is implicit in its living genetic mechanism as an integral and necessary part of its biography and complete meaning.
- The advent of CRISPR technology alters the discourse.

- Current debates reflect a biological assumption that gametes alone transmit the "blueprint" for human development.
- The living genetic mechanism is contained in each and every cell, not simply recombined germ cells.
- Have we the right to counteract, irreversibly, the evolutionary wisdom of millions of years, in order to satisfy the ambition and curiosity of a few scientists, the business interests of a few corporations, and the desire to create a super-race?

- The theoretical advantage of twinning is the production of identical human genomes [cloning].
- Removing a cell from a developing embryo (to generate an embryonic stem cell) damages the remaining embryo.
- Separation of the embryo to produce multiple embryos, while used in animal breeding, has failed in human experiments.
- Embryo separation and transfer is prohibited in the UK.

- Altered nuclear transfer is a technique that deliberately takes a human embryo, removes genes permitting further development, and transfers the edited nucleus to another cell.
- What is produced is a cell clone that is similar to that of a [benign or malignant] tumor.
- It is pathologic.
- The potential for future human development is terminated.
- The resulting product is then used for stem cell generation.
- How does this differ from abortion?

- In the mid-20th Century the major United States corporate agriculture interests used tax supported foreign aid programs to implement worldwide use of hybrid grains producing high yields when chemical fertilizers and pesticides are uniformly applied.
- This "Green Revolution" altered resource utilization in agriculture and has had a profound social impact as a result of required shifts in capital expenditure in the affected regions.
- The reduction in cereal grain genetic diversity has been dramatic.

The largest wild grain repositories are now in private hands.

- Each one of us is a carrier of various recessive disorders.
- To set as an aim the elimination of all risk of passing on genetic disease would involve genetic alteration of the gametes of virtually all adults.
- That is a reduction in genetic diversity not necessarily desirable from an evolutionary perspective.
- The value of a man is then not dependent on personal identity but only on those biological qualities that can be appreciated and therefore selected.

- El sistema CRISPR/Cas se utiliza principalmente como herramienta de ingeniería genómica para inducir roturas de doble cadena en el ADN dirigidas a un sitio.
- La edición genómica real se produce en el proceso de reparación de las roturas de doble cadena creadas por el sistema CRISPR/Cas.
- Es programable, ya que se pueden realizar enzimas o modificaciones adicionales en el sistema para permitir no solo roturas de doble cadena de ADN, sino también intercambios de nucleótidos, activación (o silenciamiento) de genes o edición genética.

- En la edición del genoma, la optimización de codones se realiza para lograr la máxima expresión de proteínas en humanos. Se basa en el hecho de que organismos específicos prefieren usar codones específicos.
- Sin embargo, la optimización de codones puede provocar un cambio en las funciones reguladoras y estructurales multifuncionales de las proteínas resultantes.
- Se producen problemas de conformación, plegamiento y estabilidad de las proteínas. Las proteínas no deseadas pueden ser reconocidas como extrañas por el sistema inmunológico y no ser eliminadas por el cuerpo, lo que provoca daños en múltiples órganos.

- El uso de un nucleótido sintético como N1-metilpseudouridina para generar el ARNm que se utilizará para cambiar el gen deseado(como en la "vacuna Covid") aumenta sustancialmente la tasa de errores de traducción.
- Además, altera las vías de señalización en el sistema inmunológico innato. Tambien inhibe la activación de p53, permitiendo que no se elimine cualquier eror producido en la edición del gen.
- La infección viral no es bien tratada por el huésped; los antígenos extraños no se eliminan. La enfermedad autoinmune, así como la progresión del cáncer, hano sid provocado

- En una estrategia ex vivo, la edición del genoma se lleva a cabo en células aisladas derivadas del paciente, después de lo cual las células diseñadas pueden expandirse y reintroducirse en el paciente.
- Se puede descartar las células si hay erores producidos durante la edición de la genoma.
- En qué se diferencia del aborto o de la destrucción del exceso de embriones producidos durante la fertilización in vitro (otro tipoo de aborto)?
- En los pocos casos en que se ha intentado esto, los resultados han sido decepcionantes (VIH, terapia contra el cáncer); se han descrito efectos adversos importantes (βtalasemia y anemia falciforme, por ejemplo).

- En una estrategia in vivo, la edición del genoma se lleva a cabo dentro de los tejidos humanos.
- Es posible alterar la estructura genética de una población entera (como fue hecho con las "vacunas Covid")
- Las mayores depositos de ADN humano estan en manos privadas (y, a consecuencia, con gobiernos)

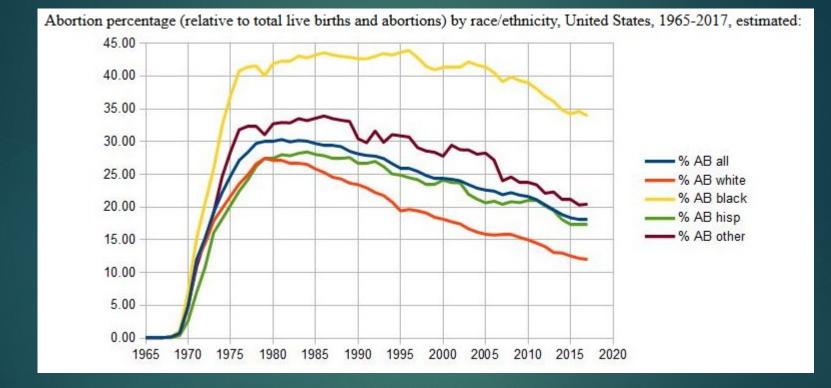
- Recientemente se ha descrito la reprogramación epigenética de la línea germinal humana in vitro, que evita la necesidad de espermatozoides u óvulos.
- Se han presentado patentes para la creación y el mantenimiento de embriones artificiales.

Eugenics

- Exclusion from reproduction based on race, diminished intelligence, or poverty is eugenics
- Eugenics perverts the basic relations of the human person: parental, filial, sibling, the extended family, community.

Eugenics

- In the US, blacks constitute 12% of the population, and 27% of those aborting
- Native Americans, Pacific Islanders, and Asians constitute <10% of the population, and 16% of those aborting</p>
- Hispanics not identifying as white or black constitute 18% of the population, and 18% aborting
- Whites constitute 60% of the population, and 11% aborting.



Eugenics

The motivation between prudence and eugenics can be distinguished:

Is the rabbinic prohibition on marriage with someone with a hereditary disease unreasonable?

Should a man and woman each of who carry the Tay-Sachs gene bring forth children, knowing they will be diseased?

F. Rosner, Judaism, Genetic Engineering, and Genetic Therapy. Institute for Jewish Medical Ethics. Conference. 1997. San Francisco.

- Fertilization is surely the beginning of a human being as such.
 - But is it already endowed with a human soul?
- "Have we to suppose its givenness in order to explain the entelechy [towards development of] a fully human life?"
- "Individual" means not being divisible, being unique also by excluding replication.
- Identities of undifferentiated "pre-embryos" are indeterminate. <u>Tissue differentiation and</u> <u>organogenesis are identity conditions</u>.

- The first question, then, is whether "pre-embryos," undifferentiated cells, are human life.
- If the cells are not human life by virtue of divisibility, then as the whole organism replaces itself [a sleep of Theseus] how is the human organism distinguished at any time from a simple life form?
- Totipotent stem cells stand in meriological relationship [contained within the set] to pre-embryos.
- The recombined gamete (or the somatic cell stimulated to enter replication) is human. But when is it life?

- The definition of person in the UK is set at 14 days and is based on the last date at which the primitive neural streak develops.
- Department of Health and Social Security, Reprint of the Committee of Inquiry into Human Fertilization and Embryology. London. HMSO. 1984. Cmnd. 9314, Para 11.22.
- In modern parlance, mind, psyche, and soul are interchangeable.
- But soul is the innermost aspect of man, that by which he is in God's image.
- "Spirit and matter in man are not two natures united, rather their union forms a single nature."

- But is there a distinct hypostasis at fertilization (day 0), at implantation (day 4), or at the development of the neural streak (day 12-14)?
- The distinction permits a medical intervention such as assisted fertilization or contraception.

"The spiritual soul, the essential constituent of every subject belonging to the human species, which is created directly by God, can be neither generated by parents, nor produced in artificial insemination, nor cloned."

"[W]hen a new person is born of the conjugal union of the two, he brings with him into the world a particular image and likeness of God himself: the genealogy of the person is inscribed in the very biology of generation ...God alone is the source of that 'image and likeness' which is proper to the human being ...Begetting is the continuation of Creation..."

John Paul II, Gratissima Sane .1994. Vatican.

- "Thus the fundamental task of the family is to serve life, to actualize in history the original blessing of the Creator: that of transmitting by procreation the divine image from person to person."
- John Paul II Familiaris consortio. 1981. Vatican
- Following Jewish or Christian thought man, is ensouled at conception
- Following some Islamic teaching, man is ensouled at 120 days

- "Nor are those considered as acting against nature who in the married state use their right in the proper manner although on account of natural reasons either of time or of certain defects, new life cannot be brought forth."
- * "For in matrimony as well as in the use of the matrimonial rights there are also secondary ends, such as mutual aid, the cultivating of mutual love, and the quieting of concupiscence which husband and wife are not forbidden to consider so long as they are subordinated to the primary end and so long as the intrinsic nature of the act is preserved.
- Pius XI Casta connubi 1930 Vatican

- The Anglican Church was opposed to "contraceptioncontrol from motives of selfishness, luxury, or mere convenience."
- The Lambeth Conferences 1867-1930.
- A position from which it departed in 1930.
- The Reformed church thundered, "If submission to the biological pattern is necessary to receive the blessings of marriage, all methods of conception-control must be rejected without distinction."
- K. Barth, Church Dogmatics, III, op. cit., pp300-311.
- Barrier methods are always illicit.

Intercourse with a menstruating woman has long been condemned.

- Hormonal contraceptives are intended to first prevent ovulation.
- However, in a small percentage of cases of ovulation and fertilization in users of such drugs, it is possible for the presence of artificial progesterone to hinder the transport of the fertilized egg (embryo) to the endometrium.
- The altered state of the endometrium dosed with progesterone also complicates the implantation of any possible embryo, effecting that cell's death
- This is the moral objection to use of hormonal contraceptives.

- Timing of intercourse based on the fertility cycle is an acceptable method of family planning.
- The Standard Days Method (cycle beads) identifies days 8-19 of the menstrual cycle for women with cycles between 26 and 32 days long, as the potential fertile window
- Unexpected conception rates using this approach are comparable to the failure rate of hormonal contraceptives
- There are no pharmacologic adverse effects with the method

- To abstain from intercourse during the fertile period, however, is to give proof of a true and authentic love.
- Paul VI Humane vitae 1968 Vatican
- As with the use of oral contraceptives, it is the mens rea [mental state or intent] of the parties that distinguishes whether the act is licit.

Sexual activity outside of marriage

- Traditionally, any sexual relations apart from a spousal relationship are forbidden.
- The relationship violates the understanding of family and threatens social stability
- It changes an act of mutual submission into a transaction

The children of such unions were not accorded rights of family protection nor of inheritance. That stance moderated in the nineteenth century.

Sexual activity outside of marriage

- In the US >50% of live births were to single mothers (2017)
- 28% whites
- 69% blacks
- 68% Native Americans
- 12% Asians
- 70% Hawaiian or Pacific Islander
- 52% Hispanic not identifying as white or black

https://www.cdc.gov/nchs/data/nvsr/nvsr68/nvsr68_13-508.pdf

Sexual activity outside of marriage

That modern methods of contraception are available and facilitate such activities underscores the great moral hazard of their use

Is the prescription of oral contraceptives in such a circumstance a participation in such activity?

Title VII

The Civil Rights Act of 1964 prohibits discrimination "because of such individual's race, color, religion, sex, or national origin."

The Supreme Court in Bostock v. Clayton County, Georgia, 590 US 644 (2020), decided that Congress intended that sex included sexual orientation (as it relates to employment)...although in 56 years Congress has made no effort to expand the definition of sex (a binary definition).

Title IX was an part of an educational reform bill that passed in 1972 that was intended to promote equal access for women students in universities. The original aim was athletics.

Title IX has largely succeeded.

"No person in the United States shall, on the basis of sex, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance."

- The federal government views equal access in terms of <u>quotas</u> although that <u>is explicitly rejected in the law.</u>
- It is also explicitly rejected in the California constitution.
- Universities initially responded in the area of athletics by slashing non-income producing men's sports even at a club level.
- The Obama administration decided that "sex" really means "gender" although that position was rejected by the courts.
- Trans-gender individuals may compete in women's sports. Is this fair?

- In 2011, the Obama administration sent a "Dear Colleague" letter to higher education institutions, citing the web-based Campus Sexual Assault survey indicating that 1-in-5 women were victims of "completed or attempted sexual assault while in college," and outlining how its Department of Education would assess compliance with Title IX.
- For how the authors of the survey view their findings: <u>https://time.com/3633903/campus-rape-1-in-5-sexual-assault-setting-record-straight/</u>

- The letter required schools to make findings of sexual harassment and assault based on a "preponderance of the evidence" rather than the more demanding "clear and convincing" standard then in use on many campuses.
- The letter also "strongly discourages" schools from permitting the parties personally to cross examine each other because it "may be traumatic or intimidating" to complainants.
- What occurred was a stripping of due process rights to men.
- This is a type of Lawfare.

- In 2017, the Trump Administration rescinded the 2011 "Dear Colleague" letter because it created a failed system.
- New rules went into force in 2020.
- Proposed was a definition of harassment as "unwelcome conduct on the basis of sex that is so severe, pervasive, and objectively offensive that it effectively denies a person access to the school's education program or activity"
- Activity off-campus was no longer considered.

- The rules also permit schools to choose either the preponderance of the evidence standard or the more difficult clear and convincing standard, <u>as long as schools</u> <u>use the same standard in other judicial proceedings</u> <u>carrying the same maximum penalty.</u>
- The most controversial change requires schools to adhere to due process standards.
- They must hold live hearings, with cross examination by attorneys permitted.
- If a student requests it, schools must provide an advisor to conduct cross examination.

- Male and female student have a drunken hookup.
- He wakes up, terrified she's going to file a sexual misconduct complaint, so he goes to the Title IX office and files first.
- She is found guilty and suspended [until the complainant graduates].
- She claims in a separate civil suit that this was retaliation because she had filed a sexual misconduct complaint against a friend of his [same circumstances]. Retaliation is also punishable.

- Doe v. Miami Univ. [6th Cir. No. 17-3396, 2018 WL 797451, *12] found that a school acts in a discriminatory manner when it finds that both a male and a female student are intoxicated and engage in sexual activity yet chooses only to discipline one of the students.
- It violates the equal-protection rights of their students when there is no rational basis to differentiate between male and female students.

In Doe v Miami, the court found that even if only one student makes a report, if the school possesses knowledge that both were intoxicated, "the school has an affirmative obligation to investigate both students for misconduct without waiting for a 'report'."

- Many universities have a mandatory reporting rule for all faculty.
- This strips rights of privacy from everyone.
- If a student seeks advice on a possible sexual assault or otherwise discloses that in a class writing, for example, the faculty member is required to report it and entrain the judicial process, regardless of the interests of the student.
- Many faculty sidestep this reporting requirement by cutting short the conversation and directing the student to a university office to deal with this matter

- Of the hundreds of lawsuits filed on actions taken under the "Obama guidance letter," Federal courts routinely ajudicate in favor of due process.
- In June 2022, the Biden administration proposed rules that return to the Obama era.
- Stripped is any semblance of due process. A single individual may investigate and ajudicate the matter. There is no hearing, nor is there an opportunity for the accused to examine the evidence put forth, nor is there an opportunity to cross-examine the accuser.

- Further, the proposed rules extend sexual harassment to include language and transgender issues.
- Many colleges now instruct faculty to call students by their names on the college register, and to avoid the use of pronouns when referring to a particular student.
- The proposed rules also permit denunciation by rumor and not by formal complaint.
- The proposed rules also extend to participation in sports, as well as use of dressing rooms and restrooms.
- Several federal circuits have blocked the Biden rules from taking effect in August 2024.