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The Journey to Gene Editing; A Case for Regulation

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Abstract

'A little philosophy inclineth man's mind to atheism, but depth in philosophy bringeth men's minds about to religion"- Francis Bacon

Kenneth Muhangi is an Advocate, lecturer, author and recognized leading specialist in Intellectual Property and Telecommunications, Media and Technology (TMT) law. He also consults for the World Bank and represents Uganda at the World Economic Forum.

This paper provides a jurisprudential outlook on the aspects surrounding gene editing and the future of humans. The paper explores the history, nature and state of the universe and predicts the world of tomorrow. The paper is structured in three seemingly separate parts. The first part is foundational; exploring different world views relating to the creation of the universe with a focus on science and religion with Christianity as an example.

The first part provides a background that may not at first glance seem linked to the rest of the paper. Any literature reviewed is meant to epistemologically enhance the metaphysical, sociological and biological foundations posited, creating the practical issues that arise and the subsequent need for clear evidence-based regulation.

The topics advanced in the first part have been exhaustively discussed by scientists not necessarily needing legal elaboration but rather provides a sort of guidance to regulation related issues. The second part cogitates the dissonance created by the different world views and which world views have inevitably led to advancements in human based science-gene editing; in particular CRISPR- CAS9 and general AI that has attributes akin to (un) consciousness.

The paper ends by making a case for regulation as the proposed way to deal with the myriad of issued that have arisen from gene editing and the application of Artificial Intelligence (AI).

While this paper does not critique nor seek to look for/advance results, it appeals to the prima-facie human considerations concerning gene editing and AI, thus the philosophical, scientific and religious viewpoints explored.

Key words: *Gene Editing; Evolution; Higgs Field; Darwin; Quantum Physics; Philosophy, Data Protection and Privacy; Artificial Intelligence; Leveraging Data; patents, intellectual property, biopiracy*

Introduction

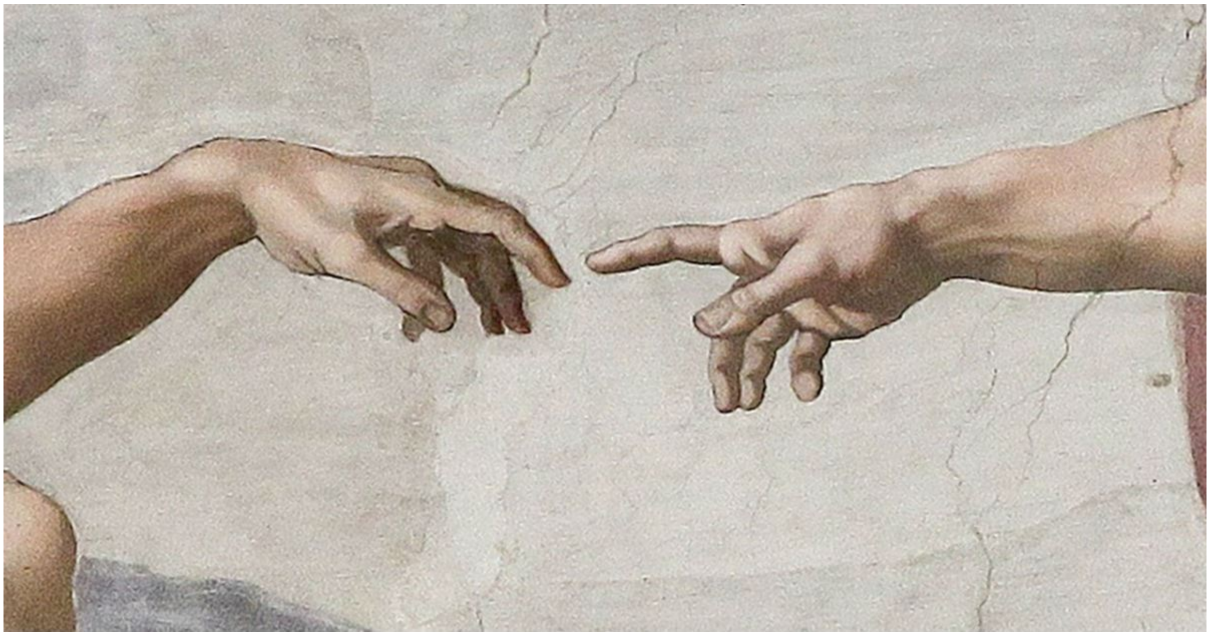

Image Source:

"As a child I could not make sense of anything unless I could place it in some sort of map. Like many people, I struggled to link the isolated fields I studied. Literature had nothing to do with physics; I could see no connection between philosophy with biology, religion and mathematics, economics and ethics. Today, a new framework for understanding is emerging in a globalized world. Linking these things can help us see things we cannot see from within the boundaries of a particular discipline. It lets us see the world from a mountaintop instead of from the ground." **David Christian, Origin Story-a Big History of Everything, 2018.**

Imago Dei is the Latin phrase for "Image of God". The biblical concept is rooted in Genesis 1:27[i] that reads;

"So, God created Mankind in his own image, in the image of God he created them; male and female he created them."

"Image of God" is quintessentially the incorporeal expression, associated uniquely to humans, which signifies the symbolic connection between God and humanity.[ii] Imago Dei refers to the inner self rather than the outward appearance and proposes that all Sapiens are self-aware, inherently rational and are born with divine beatitudes[iii] that separate us from the rest of creation.

There are many interpretations of the significance of Imago Dei but the widely accepted premise is that since all humans are created in the image of an all knowing God, we have a duty to emulate his divine attributes. In the last decade, this interpretation has riled debate on whether humans, like God should be allowed to modify or even create human life.

The Origin of the Universe

Ideas are the building blocks of social orders that exist within society. The success of a particular social order is often dependent on compliance by humans, ascribing to those societal ideals. Humans therefore consist the summation of their ideas. The pursuit of finding a conclusive homogeny underlying these ideas, enforces a consonance amongst them. A dissonance on the other hand, creates internal discord, whose effect often ripples through and affects a human's surrounding sociological structures.

Homo Sapiens are therefore imbued with a susceptibility towards cognitive dissonance. The cognitive dissonance theory posits that individuals experience a mental discomfort after taking actions that appear to be against their starting preferences[iv]. To minimize or avoid this discomfort, sapiens will change their preferences to more closely align with their actions[v]. This is attributed to the clash of seemingly conflicting world views that explain the creation of the known universe, especially as posited by various religious dogma, for example.

Philosophers and psychologists alike have conducted studies on cognitive dissonance and its effect on homo sapiens. A little more than 60 years ago, Leon Festinger published *A Theory of Cognitive Dissonance* (1957). Through this theory, hundreds of studies have developed sources and determinants of attitudes and beliefs, the internalization of values, the consequences of decisions, the effects of disagreement among persons, and other important psychological processes, especially in sociological contexts.[vi]

As presented by Festinger in 1957, dissonance theory began by postulating that pairs of cognitions (elements of knowledge) can be relevant or irrelevant to one another. If two cognitions are relevant to one another, they are either consonant or dissonant. Two cognitions are consonant if one follows from the other, and they are dissonant if the obverse (opposite) of one cognition follows from the other. The existence of dissonance, being psychologically uncomfortable, motivates the person to reduce the dissonance and leads to avoidance of information likely to increase the dissonance.[vii]

In 2007 and 2010, Egan, Louisa C, Paul Bloom, and Laurie Santos[viii] conducted studies[ix] that showed how sapiens (in this case toddlers) and primates (capuchin monkeys) that chose a certain kind of toy or candy would then, in the next round of experimentation, devalue other toys or candies, even when the initial choice was made without any existing rationale/motivation(blindly). This proved that the subjects of the experiment were more attached to their first choices for reasons of familiarity, convenience etc. and the already established norms with respect to the toys and candy.

Often therefore, primary/initial teachings, belief, convictions, principles and ethics held by societies, institutions and people are usually likely to be held on to by them, for the basic reason that they were introduced to them first. When these primary beliefs are then challenged for various reasons cognitive dissonance then becomes a more than probable outcome.

Today, religion and science, often pitted as opposing dogmas provide the most discussed and widely accepted propositions about how the world came to be. They are also the most widely recognized causes for or of cognitive dissonance; humans have been nurtured to choose either science or religion often, without any room for a comprehensive reconciliation of the two.

According to Genesis 2:7 for example, God created the first man, *"formed of the dust of the ground…. a living soul"*. In Genesis 2:21-22, God saw the man, Adam was lonely, caused him to fall into a deep sleep, took one of Adam's ribs and created a woman, Eve[x]. In contrast, Scientist David Christian[xi], theorizes that our universe began as a point smaller than an atom. Science doesn't yet fully understand how and why the universe appeared seemingly out of nothing, but particle physics has proven, through particle accelerators, which speed up subatomic particles to high velocities by means of electromagnetic fields, that something can appear from nothing.[xii]

Over the years, scientists have theorized and conducted various experiments in the hope of unearthing the true reason the universe exists. Inadvertently or otherwise, these theories have in often cases been used to discredit religion and vice versa. While religion relies on faith and the belief in the unseen, science is often associated with the requirement of evidence and employs tools that have helped humans understand that everything in the universe is made from a few basic building blocks known as fundamental particles governed by four fundamental forces[xiii]; gravity, the weak force, electromagnetism and the strong force[xiv].

Our best understanding of how these particles are related to each other is encapsulated in the Standard Model of particle physics[xv].

In the 1900's, physicists unraveled that there are very close ties between two of the four fundamental forces – the weak force and the electromagnetic force. The two forces are described in the Standard model and imply that electricity, magnetism, light and some types of radioactivity are all manifestations of a single underlying force known as the electroweak force[xvi] The Electro-Weak Force shows that even though particles may interact in somewhat different ways, they are ultimately controlled by the same guiding principles.[xvii]

In 1964, Peter Higgs and Francois Englert theorized about the standard model and the structure of the known universe. They hypothesized that the earth has its own mass that interacts with an invisible field, now called the "Higgs field", which permeates the known universe. It wasn't until much later, that Physicists invented the Large Hadron Collider[xviii] at the CERN research center in Switzerland which confirmed the existence of the Higgs field and Higgs boson particle[xix]. The confirmation eventually won Higgs the Nobel Prize in Physics in 2013 and completed the standard model of particle physics[xx].

The Higgs field discovery complimented the Big Bang theory[xxi]. Hypothesized in the 1920's by Catholic Priest and Scientist, George Lemaitre and Edwin Hubble, the Big Bang Theory proposes that the universe expanded explosively from an extremely dense and hot state and continues to expand today. Subsequent calculations have dated this Big Bang to approximately 13.7 billion years ago[xxii].

Within the first few seconds after the Big Bang, matter appeared. Matter according to Albert Einstein is a highly compressed form of energy demonstrated by the formula E=mc2; energy (E) is equal to mass (m) times the speed of light (c) squared, or E=mc2 which tells us how much energy is compressed inside a given amount of matter[xxiii].

The Higgs field, which was zero during the Big Bang, grew spontaneously so that the earth which interacted with it acquired a mass and this precipitated the beginning of life[xxiv].

Though the Big Bang theory cannot describe what the conditions were at the very beginning of the universe, it can help physicists describe the earliest moments after the start of the expansion.

The Evolution of Humankind

In the 18th Century, Charles Darwin propounded the idea of evolution, inspired by his grandfather Erasmus Darwin's *Zoonomia (*1794-1796).[xxv] Darwin began to work out different possibilities to explain species change. Initially, he supposed that species existed for a definite time, swallowed by entropy[xxvi] and replaced by another affiliated species averring thus;

"Each species changes. Does it progress. Man gains ideas. The simplest cannot help. —becoming more complicated; & if we look to first origin there must be progress."[xxvii]

Eventually, Darwin settled on the proposition that habits introduced into a population would first gradually become instinctual before they altered anatomy. And instincts—innate patterns of behavior—would be expressed automatically, without the intervention of conscious will- power[xxviii].

According to Noah Yuval Harari, the single greatest constant of history is that everything changes[xxix]. Darwin, hypothesized that change is inevitable and that new habits when ritualized by any social order over years, would change into predispositions; and these would eventually alter anatomical structures, thus evolving the species. It follows therefore, that the evolved species will pass these innate traits to future generations. Darwin's suggestions on habits leading to species change are consonantly like the Imago Dei premise that presupposes that all humans are intrinsically permeated with godlike habits/traits that are passed on to future generations.

As a naturalist, Darwin drew inspiration from legal philosophy and other disciplines believing that his prepositions had a wider interdisciplinary relevance and were thus connected with everything. The famous poet Dylan Thomas[xxx] sums up Darwin's unfolding and layered mind in his 1945 poem, Fern Hill thus;

"So it must have been after the birth of the simple light
In the first, spinning place, the spellbound horses walking warm
Out of the whinnying green stable
On to the fields of praise"

Darwin's principles have bridged gaps between disciplines more so in the field of entropy, artificial Intelligence and genetics. In 2008, Geoffrey Hodgson in his paper on Darwinism and the Social Sciences[xxxi], imagines a world of robots that learn and adapt in their struggle to survive. To avoid degradation and overcome problems, they receive information, and absorb energy and matter from their environment. They can also reproduce themselves and no two robots are identical. Extrapolations like Hodgson's around the future of the universe and the species are at the center of the Fourth Industrial Revolution (4IR). The recent years have been proliferated by studies involving deep machine learning and the use of genome-editing tools to modify DNA of human embryos. Such undertakings have aroused feelings of foreboding, owed to the ethical and safety considerations.

In 2020, the European Patent Office (EPO)declined to grant patent protection to an Artificial Intelligence (AI) inventor, 'DABUS machine', which was described as: "*a kind of connectionist artificial intelligence*"[xxxii].

In its summons to oral proceedings, the EPO indicated that the application had been rejected on the grounds that an inventor must be a human being as set out by the European Patent Convention (EPC)[xxxiii].

The EPO opined that although the AI had a name, the name given to a 'thing' is not equivalent to the name, first name or mononym given to a human being. The names given to natural persons serve not only to identify them, but also to enable them to exercise their rights, either in whole or in part – as in the case of minors or adults with incapacity, whose rights may be transferred as provided for by national laws – and, as such, are part of their legal personality[xxxiv].

Artificial intelligence thus has no legal personality and resultantly has no rights to either own an invention or transfer such ownership within legal parlance. *According to the EPO*[xxxv]*,*

"The designation of an inventor is mandatory as it bears a series of legal consequences, notably to ensure that the designated inventor is the legitimate one and that he or she can benefit from rights linked to this status. To exercise these rights, the inventor must have a legal personality that AI systems or machines do not enjoy,"

The EPO's decision may be interpreted with the mindset of philosophers like Jean-Paul Sartre (1905-1980) and Albert Camus. Sartre, a proponent of existentialism focused on the conceptualization of the authentic self, choice and purpose as being at the core of human existence. Sartre characterized humans as beings who are self-aware, with independent consciousness. Consequently, all humans are imbued with original choice tethered to the individual's freedom[xxxvi];until Artificial Intelligence reaches a level of independent consciousness similar to natural humans' machines will therefore remain 'things'.

Genome (gene) Editing

Developments in the field of Artificial Intelligence (AI) alone, relating to enhancement of humans are limited to altering/modifying existing human tissue rather than somatic cells[xxxvii]. These enhancements cannot be passed to future generations and advances in the field of AI may not have the same evolutionary effect on the species that gene editing posits[xxxviii]. Gene editing refers to technology that gives humans ability to change an organism's DNA. Although research into gene editing of human cells has mostly focused on repairing or eliminating mutations that cause disease, gene editing has also given scientists the means to enhance human features[xxxix]. This ability to enhance human traits and features, to 'create' humans from a cellular level may be the harbinger of the next generation of humans.

Numerous gene editing technologies have been developed none more recognized than the, Clustered Regularly Interspaced Short Palindromic Repeats and It's associated protein 9; collectively often referred to by the acronym, CRISPR-Cas9[xl]. CRISPR-Cas9 is a faster, cheaper, more accurate, and more efficient gene editing method[xli] that is now at the center of discussions involving the future of the species.

CRISPR-Cas9 was adapted from a naturally occurring gene editing system in bacteria. The bacteria capture pieces of DNA from invading viruses and use them to create DNA segments known as CRISPR arrays kept in the bacteria's memory bank[xlii]. The CRISPR arrays allow the bacteria to remember the viruses (or closely related ones) so that If the viruses attack again, the bacteria produce RNA segments from the CRISPR arrays to target the viruses' DNA. The bacteria then use Cas9 or a similar enzyme to cut the DNA apart, which disables the virus. Once the DNA is cut, the cell's own DNA repair machinery replaces the existing segment with a healthy customized DNA sequence and eliminates the damaged strains entirely.

Currently, most research on genome editing is done to understand diseases using cells and animal models. It is being explored in research on a wide variety of diseases, including single-gene disorders such as cystic fibrosis, hemophilia, and sickle cell disease. It also holds promise for the treatment and prevention of more complex diseases, such as cancer, heart disease, mental illness, and human immunodeficiency virus (HIV) infection[xliii]. Sangamo Therapeutics[xliv]one of the leading genome research entities, has explored genome editing as a potential cure for HIV/AIDS. The hope is that intravenous infusion of modified T cells will enable patients to stop taking antiretroviral drugs.

Most of the changes introduced with genome editing are limited to somatic cells[xlv]. However, recent developments have seen changes made to genes in egg or sperm cells (germline cells) or in the genes of an embryo which could be passed to future generations[xlvi].

Concerns have arisen regarding gene editing using technologies such as CRISPR-Cas9; including whether it is ethical to use this technology to enhance normal human traits such as eye color or intelligence.

Germline cell and embryo genome editing are illegal in many countries, but the subject remains a grey area in many other countries[xlvii]. In 2018, a scientist in China announced that he had created the world's first genetically edited babies, twin girls using CRISPR. The fete was allegedly achieved by implanting into the mother's womb, a modified HIV resistant embryo[xlviii].

Although medicine has been the key driver for the pursuit of gene editing, the risk of creating 'designer babies/humans' whose cells/bodies are genetically engineered with affinities towards superhuman athletic ability, intelligence, improved cognitive ability and the like is imminent.[xlix]

Intellectual Property, Data & Privacy concerns

Advancements in biology that facilitated CRISPR enabled researchers to understand humans at a subatomic/cellular level. Similar to computer code[l] which uses words and short phrases to translate binary data[li] into a language humans can understand with ease, gene research uses letters and numbers to understand biological processes stored in the form of data.

Data is at the core of gene research, but data protection laws[lii] do not expressly regulate the ownership of DNA and/or other data from biological processes. Data from biological processes is for all intent and purpose, personal data as it refers to information that relates to an identified or identifiable person, a data subject[liii]. Part (e) of the Interpretation section (Section 2) of Uganda's Data Protection and Privacy Act[liv], widens the scope of personal data to include all other information, which is in the possession of a data controller and includes an expression of opinion about the individual. This includes medical records and any representation of numbers or words that can be used to identify an individual[lv].

Resultantly, concerns around the sanctity of personal data have marred gene editing based research. Such data like all data is kept in physical locations susceptible to security and data breaches. In Uganda, sections 17 & 18 of the Uganda Computer Misuse Act, 2011 and section 35 of the Data Protection and Privacy Act, 2019, criminalize the unauthorized release/disclosure of such personal data.

The aforementioned sections are reinforced by Recital 51 of the GDPR[lvi] that provides that personal data, such as data revealing racial or ethnic origin which is, by its nature, particularly sensitive in relation to fundamental rights and freedoms merit specific protection as the context of their processing could create significant risks to fundamental rights and freedoms. Article 17 of the International Covenant on Civil and Political Rights (ICCPR) also provides that, "no one shall be subjected to arbitrary or unlawful interference with his privacy, family, home or correspondence, nor to unlawful attacks on his honor and reputation".[lvii]

Although personal data can be owned as property and can be protected as confidential information under trade secrets, ownership of data and/or products from biological processes is expressly prohibited by law. Article 27 of TRIPS *(Agreement on Trade-Related Aspects of Intellectual Property Rights, 1995)* encapsulated under Section 8 (3) of Uganda's Industrial Property Act, 2014 excludes discoveries, mathematical methods, scientific theories and biological processes from Intellectual Property protection. This is so because biological processes and products from such processes are considered as being from nature and for the benefit of humankind. The exclusion of biological processes from Intellectual Property protection, specifically patents, deters bio-prospectors, who appropriate biodiversity and commercialize valuable genetic resources[lviii].

Furthermore, Article 5 of the Convention on Biological Diversity CBD(1992) acknowledges the sensitivity of genetic resources and in accordance with the Charter of the United Nations and the principles of international law, recognizes the sovereign right of States to exploit their own resources as long as the activities do not cause damage beyond the limits of national jurisdiction.

A case for Proactive Evidence based Regulation

Since concerns around ethics, data protection & privacy, safety and the threat of eugenics are at the forefront of arguments against tampering with what many consider a preserve of an all-knowing creator, regulation may offer consonance.

Universally, many nations lack *sui generis* legislation that legalizes or criminalizes gene editing in humans. Article 15 of the Convention on Biological Diversity CBD (1992), recognizes the rights and authority of each States to research and exploit the use of genetic resources. A 2014 survey of 39 countries by Motoko Araki and Tetsuya Ishii found that many European countries legally prohibit any intervention in the germline. The Council of Europe's Oviedo Convention[lix] provides that predictive genetic tests should be used only for medical purposes. It specifically calls for a prohibition on the use of genetic engineering of the germline or changing the makeup of later generations and builds on earlier European conventions.

Other countries have advisory guidelines that make it difficult to undertake somatic cell-based research. The United States for example, has a complicated regulatory scheme that would make it very difficult to perform any germline modification[lx].

Most national laws generally recognize individuals' freedom to contract, and it is implied that if the researcher/scientist and embryo donor agree to gene experimentation, the agreement would be respected. informed and unequivocal consent is the writ scientists and researchers who want to genetically engineer human cells must follow.

Article 15 (5) of the Convention on Biological Diversity CBD (1992), provides that access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party. Consent must be freely given, specific, informed, unambiguous and without undue influence. In Hall v Hall LR 1 P&D 481, Sir J. P. Wilde, at p. 482 opines that persuasion is not unlawful, but pressure of whatever character if so exerted as to overpower the volition without convincing the testator will constitute undue influence, though no force has been either used or threatened.

Regulation is a tool that can and should be used to allow for technology transfer & development that spurs further research for future generations. Gene based regulation should be evidence based, eclectic and for the benefit of nationals and the scientific community[lxi]. Accessibility, credibility and relatability ensure that the biological research eco-system is fair to all competitors. This is particularly important for start-ups because it ensures availability of information, confidence and certainty for market access[lxii].

According to Ponte and Gibbon[lxiii], regulation must be safety based with careful consideration given to norms that will more likely foster technological development, and thus avoid unnecessary brakes on the process of technological change. Contextually, regulatory sandboxes may offer the flexibility required to allow guided research while emphasizing focus on healing rather than enhancement. A regulatory sandbox is a framework set up by a regulator to allow small scale, live testing of innovations by private firms in a controlled environment (operating under a special exemption, allowance, or other limited, time-bound exception) under the regulator's supervision.[lxiv]

The concept of regulatory sandboxes was developed in a time of rapid technological innovation and attempts to address the frictions between regulators desire to encourage and enable innovation and the emphasis on regulation.'

Multi-jurisdictional industry fin-tech sandboxes have been deployed to deal with the new opportunities brought by 4IR. In Africa for example, Ecobank Group recently announced the launch of a pan-African banking sandbox which gives its partners and fintechs across 33 African Countries access to an Application Programming Interface to develop innovative financial solutions.[lxv]

Regulatory sandboxes are at the crux of evidence-based regulation first recognized in the late 1980s and early 1990s. At the time, the United States of America's energy industry underwent rapid structural changes that required dynamic changes in regulation away from block regulation for vertically integrated utilities. (A vertically integrated utility is one that owns all levels of the supply chain: generation, transmission and distribution. Historically, all utilities were vertically integrated and had a monopoly on the production and sale of power)[lxvi].

The regulatory system created monopolies that stifled competition as some utilities had an exclusive right to sell power. The distribution utilities in some states were functionally separate from generation and transmission, and in other states the distribution utility was structurally separated. Restructuring required replacing the monopoly system of electric utilities with one that advocated for competing sellers. This precipitated the introduction of performance-based regulation as an alternative to cost-of-service regulation.[lxvii] This model is still used to date.

Switzerland's Federal Office of Civil Aviation (FOCA) approaches oversight in the same way for drone usage. FOCA's early coordination with security authorities that had oversight authority over critical infrastructure assets enabled FOCA and industry coordination in a collaborative manner. In essence, FOCA employs regulatory sandboxes that sieves drone applications on a case by case basis.

FOCA's evidence based approach, follows recommendations from, the Joint Authorities for Rulemaking on Unmanned Systems, JARUS.[lxviii] JARUS, introduced specific operations risk assessments (SORA), a rapidly evolving document that helps facilitate performance based regulation by constantly updating operating procedures[lxix].

Looking specifically at regulation of human germline modification, regulatory sandboxes have been applied in South Korea that has developed a system of conditional approval, which would allow for some use of a product prior to the accumulation of the level of evidence that is required in systems such as that in the United States[lxx].

Japan utilizes the same approach and uses a conditional approval pathway specifically for regenerative medicine and gene therapy products. Singapore employs a risk-based approach similar to Japan's, using performance indicators to guide regulators and classify the level of risk likely to be caused by gene editing research[lxxi].

These approaches ensure that regulators are cognizant of the risks associated with gene editing especially the scourge of income equality that may pit the rich against the poor. The benefits of gene research should aid the whole of mankind and governments must be careful not leave the future of the species in hands of the rich.

End

Historian and biologist Noah Yuval[lxxii], postulates that every point in history is a crossroads. A single travelled road leads from the past to the present, but myriad paths fork into the future. Some of these paths are wider. Smoother and better marked, and are this more likely to be taken, but sometimes history or the people who make history- takes unexpected turns. In the next decade, gene editing, deep machine learning, nanotechnology, biotechnology, materials science, energy storage, and quantum computing[lxxiii] will have precipitated a rapid evolution of the species. This undoubtedly reads more like fiction rather than fact but the road to human cloning and enhancement has been marked and will most likely be taken.

Governments can support gene-based research whilst managing risk by ensuring that ethical and anti-competition issues are addressed. Implementing regulation based on evidence and pegged to key performance indicators (KPIs) will address the management of risk, and ensure compliance.

Resultantly, rather than wait for mobocracy, regulation will be critical in forestalling the adverse effects of gene editing and will ensure that laws, norms and rules exist to guide technological development rather than stifle innovation processes.

Notes

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