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*Review Article*

## **Criminal, Civil and Ethical Framework for Advancements of Benefits of Biotechnology to Mankind**

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### **ABSTRACT**

For various reasons, the health status of a man declines with time depending on his environment, food and beverage intake, mentality, stress level, age etc. Fortunately, the ability of man to combat various diseases has advanced due to Biotechnology that is emerging worldwide and Nigeria is not left out. Footings in pharmaceutical biotechnology are embedded in the ability of plants, microorganism and animals to produce low and high molecular weight compounds which are functional for mankind and animals as therapeutics. The development in medical biotechnology has brought different ideas and mechanisms to combat the challenges of deteriorating health by making use of biological parts to treat patients. As with any new innovation, biotechnology comes with a lot of potentials but also with lots of risks, ethical and legal dilemma, hence, the need for law and regulations to serve as guide in the emerging industry. This article examined these criminal and civil issues using doctrinal research methodology and the analytical approach to explore the works of several authors in the field of biotechnology to examine its development. The study thereafter made recommendations on how to create an effective system that will harness the potentials of the biotechnology especially in the field of pharmacy and medicine. The study concluded that biotechnology can only excel for the benefits of mankind and the environment when pharmaceutical companies, researchers, scholars and government abide by the ethical and legal provisions on biotechnology in order to avoid the consequences of the risks.

**Keywords:** *Biotechnology, Pharmaceutical, Medical, Patents and Laws*

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### **INTRODUCTION**

The concept of Biotechnology goes as far back as the beginning of humanity, and it began with the art of agricultural revolution practiced by the ancient men, involving the use of artificial picking for livestock, crops and other domesticated animals. The modern day art of biotechnology started with the discovery of vaccines by Edward Jenner, and the invention of antibiotics by Alexander Fleming. As an advantage to man, microbial products and plants have been used for centuries, as natural preservatives in the protection of vegetables, milk and fruits, in the form of beer, bread, cheese, wine, yoghurt, pickles, vinegar, and many more fermented materials (Ramana *et al.*, 2017).

According to authors, Biotechnology is technology that has been based on biology. It harnesses the cellular and other bio-molecular procedures to build technological equipment, procedures and products that can help to improve the quality of lives and enhance human health. (Bio.org., 2018). Recently,

the perception of this technology is redefined away from one that instills the sense of danger and hesitation to that which is filled with prospect and hope. People are overcoming some of the biological limitations imposed by nature. This is further demonstrated through new trends such as Assisted Reproduction Technology, organ transplantation as well as genetic mutation and re-engineering. (Plein, 2018)

The rise in biotechnology will inevitably give rise to new moral, cultural, religious and of course, most importantly, legal questions because its exploits in knowledge and capabilities has given rise to new challenges (Clark and Pzdzernik, 2015) one of such challenges that has arisen is the issue of proprietary rights and interests that can be held over body parts. This forms the crux of this research. The fact that the main resource used as “tool of trade” in biotechnology are things like body cells, organs and tissues brings to the fore questions such as ownership and proprietary interests in materials being used. This seems to be testing the notion that the conservative and traditional belief that these body parts are

not supposed to be claimed by any individual (Dunham, 2008).

Although there has always been the fear of the consequences of biotechnology, it keeps advancing with regards to the advantageous applications and daring risks (Future of Life Institute, 2018). This is evident in the “increasing pace of progress – from low cost DNA sequencing to rapid gene synthesis to precision genome editing.” Another area of concern is the fact that DIY scientists take biotech instruments out of the lab.

Modern biotechnology has evolved from a molecular basis that grew from ‘increasing biochemical understanding of genetics and physiology’, (Clark and Pazdernik, 2015). This development will aid researchers, scholars, pharmaceutical companies, forensic scientists to advance biotechnology faster to the advantages of man’s health and environment. The Criminal Justice system across the globe will also benefit from modern biotechnology with the its impact on forensic laboratory in determining who commits a crime through the use of the deoxyribonucleic acid (DNA) of both the victim and the accused person. A bright point is that many of the advantages of biotechnology are visible and real, while many of the fears are based on doubts and assumptions. It is however more favourable to be proactive and aware of the risks rather than wait for the actualization of the risks before attempting to seek solutions, (Future of Life Institute, 2018). This study therefore examined the importance of biotechnology to mankind with the need to adhere strictly to the ethical and legal implications.

### **BIOTECHNOLOGY DEFINED**

There have been numerous definitions given to the concept of biotechnology. Albert Sasson reported that the first known definition of biotechnology was propounded by Karoly Ereky, a Hungarian agricultural engineer, who defined it in a piece titled “Biotechnology of Meat, Fat and Milk Production in Large Scale Agricultural Enterprises”,(Albert, 2005). According to him, biotechnology is the methods and techniques which allow the substances to be produced from raw materials using living organisms. Since 1919, Karoly Ereky is regarded as the father of biotechnology across the globe (Fari and Kralovansky, 2006).

Biotechnology has also been described as technology that is based on biology which “harnesses cellular and bio molecular processes to develop technologies and products that help improve our lives and the health of our planet”, (Biotechnology Innovation Organization, 2019). According to Norwegian University of Technology, “Biotechnology is technology that utilizes biological systems, living organisms or parts of this to develop or create different products”.

Biotechnology has been defined as the end result of years of man’s experience with the use of living tissues and fermentation to make products useful for mankind (docslide.us 2018).

Further, the Oxford Online Dictionary of English defines biotechnology as “the exploitation of biological processes for industrial and other purposes especially genetic manipulation of microorganisms for the production of antibiotics, hormones etc”. (oxforddictionaries.com 2018)

In law, biotechnology has been defined by Article 2 of the Convention on Biological Diversity (1992) to mean “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”

This work will, however, focus more on medical biotechnology, also known as red biotechnology (biotechnologie.de 2018). This is because the challenge in the concept of ownership of these biological materials has to do with human parts used as materials in medical biotechnology. More so, the improper transfer or illegal sale is totally criminal and it is punishable under the penal laws of any jurisdiction across the globe. In simple terms biotechnology is a biology based technology (Biotechnology Industry Organization 2014). It entails the manufacture of products aimed at improving the quality of human existence from biological processes, organisms or systems (Whats.com 2014). The use of biotechnology has assisted in harnessing and improving life over the years. Before the advancement in the technology, there has been the use of microorganisms for the manufacture of useful food like bread, cheese and also for the preservation of other daily needs (Biotechnology Industry Organization 2014).

From all these definitions, it is apparent that biotechnology is developing across the globe for the satisfaction of the human race in order to prolong lives and increase food production

### **TYPES OF BIOTECHNOLOGY**

According to European Intellectual Property Right (IPR 2014), there are about three sectors in which Biotechnology can be subdivided into and these may intersect, namely:

Healthcare biotechnology or red biotechnology which is very pertinent in the discovery of drugs like insulin, erythropoietin, etc. and contemporarily has today revamped “outcomes for patients and addressing unmet medical needs for the future”. The second sector is Agriculture biotechnology or green biotechnology. This plays important roles in plants enhancement so as to boost their immunity to “disease, tolerance for herbicides or difficult environment conditions, or to achieve higher yields with less inputs (water, fertilizers, etc.)” (IPR 2014).

Industrial biotechnology or white technology is the third sector. This represents new innovation in both the agricultural and health areas; this sector encompasses the application of biotechnology-based tools to traditional industrial processes (“bioprocessing”) and the manufacturing of bio-based products (biofuels, bio-plastics and bio-based chemicals) (Ibid).

### **BENEFITS OF BIOTECHNOLOGY TO HUMANS**

Without any gain saying, biotechnology has developed to the advantage and interest of mankind in various ways which include;

According to AMGEN Incorporation (2019), the following are the emerging medical treatment that biotechnology has advanced for the benefits of mankind;

a) \*Gene therapy: involves inserting genes into the cells of patients to replace defective genes with new, functional genes. The field is still in its experimental stages but has grown greatly since the first clinical trial in 1990.

\*Stem cells: are unspecialized cells that can mature into different types of functional cells. Stem cells can be grown in a lab and guided toward the desired cell type and then surgically implanted into patients. The goal is to replace diseased tissue with new, healthy tissue.

\*Nanomedicine: aims to manipulate molecules and structures on an atomic scale. One example is the experimental use of nanoshells, or metallic lenses, which convert infrared light into heat energy to destroy cancer cells.

\*New drug delivery systems: include microscopic particles called microspheres with holes just large enough to dispense drugs to their targets. Microsphere therapies are available and being investigated for the treatment of various cancers and diseases.

- b) **Cultivation Good quality Crops:** Agricultural biotechnology assists in improvement of plant quality because of the production of transgenic varieties of plants, as well as plants that can resist draught and various diseases (Chikaire et al 2012).
- c) **Livestock Improvement:** New vaccines for diseases affecting livestock are produced through biotechnology. There is also the development of DNA vaccines rinderpest, foot and mouth diseases and cowdriosis among other livestock diseases. (Chikaire et al 2012).
- d) **Facilitating the usage of renewable energy:** Biotechnological methods and products enable scientists to use renewable energy resources and also helps them to develop reusable or commercially viable by-products of biotechnology, this will increase the level of productivity and increase the potentials that can be derived from energy and material resources by ensuring 'maximum recycling' with minimal effluents (Chikaire et al 2012).
- e) **Modification in Genetic Make-up:** The use of biotechnology enhances the genetic make-up of plants and animals by inserting new genes that will benefit the organism or removing unwanted genes. It also changes the way plants are grown and animals are raised while boosting their values to the farmers and customers alike. (US National Science and Technology Council 2010). In short, modern trends in biotechnology have been providing so many opportunities for the development of improved qualities of product, plants and farmed animals, while retaining its economic benefits.

#### **WHAT ARE THE RISKS OF BIOTECHNOLOGY?**

Biotechnology may be more harmful than other scientific fields since microbes are very tiny and could be stubborn to detect. Furthermore, "Engineered cells could divide on their own" and spread wildly with unwanted implications, (Future of Life institute, 2018).

- a) **Unpredictable Consequences:** In 2014, scientists in the Center for Disease Control became exposed to the flu, Ebola and anthrax after repeated failed attempts at finding cures. Also, in 2011, a Netherlands Professor came under scrutiny when he made attempts to publish the details of a deadly airborne version of the flu virus engineered by his

lab. In the process of studying toxins and viruses for the purpose of understanding the dangers posed by them as well as their cures, a deadly substance could be mishandled and released by error, and it could lead to great danger to the public health (Future of Life institute, 2018). Another example is Mosquitoes which are disease carriers and carry deadly and harmful pathogens like dengue, Zika and malaria. Recently, concerns have been raised by Lawmakers, civilians and scientists regarding a mosquito prevention strategy which would function to genetically change and destroy the specie of mosquitoes that carry diseases. The technology which is known as a gene drive is fashioned to spread a gene amongst a population hastily, by means of sexual reproduction. With such technology, it is slightly possible that the gene drive once released to outer space, could mutate thereby circulating genes not predicted by the scientists (Francis, 2003).

In the course of finding cure to HIV, scientists dug into the DNA of people who are supposedly immune to the virus, and discovered that those people who are immune had a mutated protein on the blood+ cells surface which acts as a landing ground for HIV. Hence, scientists concluded that removing its genes from the cells of those at-risk or already affected could turn out to be a long lasting cure for HIV and AIDS. The process which involves performing a non-complex gene surgery with a "DNA scissors called CRISPR/Cas9" would help cure cancer, HIV and other genetic diseases. The trials of the "CRISPR/Cas9 in the cell of human have created problematic results due to mutations being found in areas of the genome that ought not to be targeted for DNA modification (Charleston et al 2018)

- b) **Weaponizing Biology:** Recently, there was an outbreak of diseases known as the Zika virus and Ebola. These viruses's had a natural origin. However, the effect is that there could be future outbreaks if biotechnology is used in a malicious manner. The creation and release of a bioweapon in form of an infectious disease or a poison would be difficult to detect and more difficult to stop because deadly cells have the capacity to keep circulating even after they are initially deployed. Any threat with regards to this is taken with utmost seriousness by the US government (Future of life institute, 2018)

Bioweapons are developed by both developed and developing countries with the know-how and resources to make them. An example is the case of North Korea getting things ready in case of external attack, by preparing an arsenal comprising of "anthrax, botulism, hemorrhagic fever, plague, smallpox, typhoid, and yellow fever." There is also the assumption that terrorists or other malicious groups could employ the use of bioweapons. There have been situations where biological or chemical weapons have been used, and an example is the incident that occurred after the 9/11 attack known as the anthrax scare. Toxic cells were circulated via mail and it led to the death of 5 people (Robert, 2017).

The threats of bioweapon should not be underestimated simply because it requires less expertise. The recent developments in biotechnology show that

bioweapons can successfully be made at little cost and without a specialized lab or scientific knowledge. The cost to chemically manufacture strands of DNA is falling rapidly, meaning it may one day be affordable to 'print' deadly proteins or cells at home. Bioweapons could also be used to erase an unwanted ethnic race or set of people (Joseph et al, 2002).

### **THE ETHICS OF BIOTECHNOLOGY**

In order to effectively change lives, biotechnology does not necessarily have to be dangerous. Humans have been modifying the genes of animals and plants for decades and only started to modify his own a while back. The emergence of cutting-edge instruments like CRISPR/Cas9 has raised a number of ethical concerns (Charleston, 2018). The question has been raised whether modifying the genes of humans relates to the act of "playing God". Most gene mutations that relates to diseases usually comes with an early death certainty or the risk of conditions such as Alzheimer's disease. Hence, it is difficult to decide the limits of the surgery and under what situations it should be carried out since the surgery could cause damage to the genetic build. Researchers and Lawmakers have battled with these concerns for years (Charleston, 2018).

The United Nations Universal Declaration on the Human Genome and Human Rights (1997) in Article 1 provides that "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 law further states that Human dignity and rights are to be totally revered while the welfare of individuals must be paramount, (Article 3, United Nations Universal Declaration on the Human Genome and Human Rights, 1997). In relation to decision taking on bioethical issues, "Professionalism, honesty, integrity and transparency in decision-making should be promoted, in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues" (Article 18, United Nations Universal Declaration on the Human Genome and Human Rights, 1997).

Every country must set up a multidisciplinary and pluralist ethics committee, promoted and supported at the appropriate level in order to:

- “(a) assess the relevant ethical, legal, scientific and social issues related to research projects involving human beings;
- (b) provide advice on ethical problems in clinical settings;
- (c) assess scientific and technological developments, formulate recommendations and contribute to the preparation of guidelines on issues within the scope of this Declaration;
- (d) foster debate, education and public awareness of, and engagement in, bioethics, (Article 19, United Nations Universal Declaration on the Human Genome and Human Rights, 1997).”

Researchers all over the world are advised to strictly adhere to the ethical provisions under this International Instrument.

### **GOVERNMENT'S EFFORTS ON BIOTECHNOLOGY**

Nigeria established the National Biosafety Management Agency (NBMA) in 2015 to regulate the country's biotechnology law and ensure oversight for utilizing and commercializing biotechnology products with a view to strengthening Nigeria's food security (Attache Report GAIN. 2017). Furthermore, In recent times, Nigerian Government has shown interest in acquiring biotechnology know-how. There have been formulation of policies for biotechnology and establishment of laboratories and agencies for the promotion of biotechnology in Nigeria. Such programmes includes: the International Institute for Tropical Agriculture (IITA), National Biotechnology Development Agency (NABD) Abuja, National Center for Genetic Resources and Biotechnology, NAGRAB, Ibadan, National Biosafety Frameworks, Federal Ministry of Environment, Abuja, and the Government of Nigeria's Sheda Science and Technology Complex (SHESTCO), (Uche, 2013)

In Nigeria, the International Institute for Tropical Agriculture (IITA) and the Government of Nigeria's Sheda Science and Technology Complex (SHESTCO) are the main institutes that oversee the process and application of basic biotechnology research. At the facilities, Nigerian researchers have the opportunity to carry out researches related to the field of biotechnology. An example of the recent progress of researchers is the transformation of a variety of local tomatoes. Also, the institute is involved in carrying out basic research on bio-engineered cowpea. Sources have claimed that the Bill and Melinda Gates foundation have plans to set up in Nigeria, a laboratory for biotechnology research, which would help with developing the capacity of biotechnology in Nigeria and other African countries. This is important as complex biotechnology instruments are now used worldwide to create and also help crops grow better, (Uche, 2013).

An important effort of the government towards biotechnology is the passing into Law of the National Biosafety Management Agency Act of 2015. It is an Act of the National Assembly which guides Biotechnology in Nigeria. The Act serves as a precaution, and defines criteria for the effective control and management of biotechnology in Nigeria. (NBMAA, 2015)

### **THE LEGAL FRAMEWORK ON BIOTECHNOLOGY**

The National Biosafety Management Agency Act of 2015 is the primary Act guiding biotechnology in Nigeria. The Act establishes the National Biosafety Management Agency which is the national authority on Biosafety related matters in Nigeria and specifies the penal liabilities that experts may execute.

### **CRIMINAL LAW**

Section 2 of the National Biosafety Management Agency Act of 2015 sets out the objectives of the agency as:

- “(b) safeguard human health, biodiversity and the environment from any potential adverse effect of genetically modified organisms including food safety: (c) ensure safety in the use of modern biotechnology and provide holistic approach to the regulation of genetically modified organisms (d) provide measures for the case-by-case assessment of genetically modified organisms and management of risk in order to ensure safety in the use of genetically modified

organisms to human health and the environment: (e) provide measures for effective public participation public awareness and access to information in the use and application of modern biotechnology and genetically modified organisms; and (f) ensure that the use of the genetically modified organisms does not have adverse impact on socio-economic and cultural interests either at the community or national level.” Section 3 of the Act also sets out the functions and powers of the agency. One of such functions is set out in paragraph F “develop risk management plan and strategy for protecting human health, biological diversity and the environment from potential risks associated with genetically modified organisms.”

The Act also makes provisions for the negative impact genetically motivated organisms may have on humans and the environment at large which may result in criminal responsibility as shown in section 34. Under the provisions of sections 35 (1) and (2), the Biosafety Management Act, “where GMO-related activities are carried out without prior approval, or where an individual (or entity) supplies false information relating to GMO activities, or contravenes any provision of the Act, liability arises for any damage that may occur as a result of such activity”.

The Act is a legal regime that ensures that all biotechnology products that are imported are compulsorily certified and labeled. The Act provides details on the handling, exchange and proper use of products and new agricultural biotechnology, to ensure that the safety of human health and the environment at large is secured. Further, the Act seeks to ensure that modern biotechnology is applied in a safe manner. The Act provides for penalties for offences related to the Act. In Nigeria, pharmaceuticals and biologics cannot be prescribed to Hospitals and patients until their usage has been legalized by National Food and Drug Agency Commission (NAFDAC). The same is the situation in the United States where the Food and Drug Administration evaluates new medicines and In the European Union, where the European Medicines Agency is responsible for that regulation. (AMGEN 2019).

### **CIVIL LAWS ON BIOTECHNOLOGICAL INVENTIONS**

Like every other field of technological innovations, patents in biotechnology research and innovations can be used for the protection of the rights of the researcher to exclude all others from the benefits that can be derived from the invention. These benefits need not be economic alone as moral rights are also protected under intellectual property. This will also enable the inventor/researcher have a complete protection and control the way the invention works, the way it was made and how it will be used. (Mildred 2003)

The justification for the protection of biotechnology inventions in Intellectual Property laws can be traced to the fact that: Patents Laws give the inventor and owner of the patent the opportunity to recoup the costs of developing the new invention; (Mildred 2003). It also requires that the new technology be used for the benefit and advantage of the society at large because allowing the new innovation to enter the public domain has the potentials to inspire further innovation and serve as a rich source of technical information.

The patent system is one of the ways to facilitate the cross boarder transfer of new technology from industrialized countries to developing countries though this is not the only way to do this and not all types of technology is patented. For patent to be carried out successfully there is a need to transfer the unpatented source information on how to manufacture and produce the patented technology (Date-Bah 2012). There is a need for the enactment of a uniform legislation that be applicable to all the member states. This led to the promulgation of Trade-Related Aspect of Intellectual Property Rights (TRIPS) Agreement 1994. This International Agreement makes provision for a more unified system and sets minimum acceptable standards for member states. TRIPS also assisted in harmonizing and globalizing legal aspects of intellectual property law. Moreso, it has same important provisions on how to acquire and transfer technology. Some of these provisions are in Articles 7 and 27. For example, Article 7 of the TRIPS makes provision for the important role of technology in enhancing socio-economic welfare of people as follows:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producer and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. Article 27(1), provides further that: Patents shall be available and patents rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

The above provisions have turned the issue of patent into a globalised and interconnected one as it not only provides protection of member states but also entails all areas of technology in the grant of patent. It is important to note that the main focus of Article 7 of TRIPS is premised upon the idea that users and inventors both have some form of leverage. The evolution of trips will be of immense benefits to many developing countries including Nigeria. This is because of provisions such as Article 27 (1) of TRIPS Agreement which makes it possible for holders of a valid patent to enjoy the monopoly of being the sole importers of their products to the developing countries. This is allowed because foreign patent holders often prefer to produce their inventions elsewhere and then import them into developing countries for sale. The main issue being addressed with this submission is that the developing nations, including Nigeria should not give or have an equal treatment when it comes to matters related to intellectual property like the nationals of the developed countries (Kur. 2008). This is because the developing countries do not have the necessary technology required to create inventions such as a good technology base, skills and technical know-how, well equipped research laboratories invention driven policies among others. Developing nations therefore, need a form of special treatment as incentive to encourage them to develop and then participate meaningfully in the international scene of patents and intellectual property. If we are to attain real modern trends in biotechnology in the coming years, there is a need to explore intellectual property

rights. This is because recognition of Intellectual property and aspects of trade, management and transferred has the potential to influence the trends in biotechnology. (Becca, A. 2004). This will no doubt extend the benefits derivable from research and allow participants and researchers alike reap the fruits from the sweat of their brows. Several researchers have noted that there needs to be a balance between biotechnology and distributive justice and as such, Intellectual property rights in Biotechnology will further enhance this and satisfy the various parties involved in research (Becca, A. 2004) There are many aspects of intellectual property that may become relevant to the discussion on Biotechnology but emphasis will be laid on the one that appears most important; Patents.

Simply put, a patent may be defined as a right exclusively conferred on an inventor which permits him/her to make, sell or offer for sale a particular innovation to the exclusion of all other in the country where the patent has been granted. In Biotechnology, these patents may cover stem cell technology, DNA research, interests in body parts, etc. (Cohen, J. 2002)

### **RECOMMENDATIONS**

The existing legal framework should be reformed and should include provisions that will allow family members to give or withhold consent in cases where the desires of the deceased were not known. Furthermore, the law should be amended wherein criminal liabilities are to be separated from the civil ones, while imprisonment should be included as punishment and not just payment of compensations to victims of illegal activities. This may lead to a steady increase in the readily available supply of organs available for transplantation. Taking a cue from the legal provisions in the British Commonwealth, Nigeria could adopt this policy in the National Health Act as statistics already show that close family members are very much willing to donate the organs of diseased relatives to help the steady increase in the supply of organs and body parts.

The Nigerian National Health Act should make provisions for an encompassing framework for cadaveric donation of organs in Nigeria. This, it is hoped, will boost the supply of organs needed to meet the transplantation requirement in Nigeria and Africa as a whole. There should be a separate legal provision aside from the National Health Act that will make specific provisions for issues arising from organ donation and transplantation. This is what is obtainable in other jurisdictions around the world and experts have argued that this will ensure a comprehensive and all-encompassing provision and regulatory mechanisms such as setting up different committees and giving the specific functions in relation to donation and transplantation. There should also be an online database and networking platforms as well as an organ donor register that will enable donors interact with recipients. This will enable a seamless connection between potential donors and potential recipients. This is what is obtainable in advanced countries such as the United States where the UNOS is operating. The law should also enable donors under 18 to give consent to organ donation where it can be seen that they understand the nature of the procedure involved in organ donation.

The proposed Act should also have provision for giving oral consent especially in cases of extreme emergencies. The process of organ donation must be heavily regulated and the Act should have a comprehensive framework on the rules and ethics of transplantation. The transplantation should be done only at accredited facilities and performing such transplantations outside such facilities should constitute a grievous offense under the Act for which there will be huge sanctions. This will deter people from going into black market transplantation with quack doctors.

There should be provision of a state-of-the-art intensive care unit so that the organs gotten from the donors can be processed without wasting time and losing the viability of the organs.

In addition, stakeholders should embark on massive enlightenment and educational campaign so as to imbibe the need and importance of organ donation and the benefits of having recognized property in body parts.

In conclusion, the argument for the recognition of proprietary interest and other biological parts/materials have argued based on the idea and notion of human dignity for the owners of such rights. In essence, their argument was premised on the fact that the idea of human dignity is premised on the idea of autonomy as every individual should possess the right to choose what is considered derogatory for him or her. It is so

By contrast, antagonists of this idea are of the opinion that dignity has to do with the sanctity of human person and thus, recognition of these classes of rights will have the potential to diminish the importance and value attached to human beings. Commercializing body parts and organs will thus lead to a whole spectrum of other evil deeds that will devalue the sanctity of life. A careful analysis of these arguments was done and then, the study concluded that the essentials of an absolute right to make decisions will entail the recognition of proprietary interests in organs. If we must achieve the desired effects of biotechnology and organ transplantation, the stakeholders must review the legal framework and key into some of the suggestions made above by way of recommendation and the, maybe the future of modern medicine will have impacts on the health of Nigerians.

Ultimately, biotechnology can only excel for the benefits of mankind and the environment when pharmaceutical companies, researchers, scholars and government abide by the ethical and legal provisions on biotechnology in order to avoid the consequences of the risks.

### **REFERENCES**

- Albert, S. (2005):** Medical Biotechnology: Achievements, Prospects and Perceptions. United Nations University Press.
- AMGEN Incorporation, What is Biotechnology?** <https://www.biotechnology.amgen.com/contact.html>, Accessed March 5, 2019.
- AMGEN Incorporation (2019):** What Does the Future of Biotechnology Therapies Look Like? <https://www.biotechnology.amgen.com/biotech-future.html>, Accessed March 5, 2019.

- Ariel, C., Future of Life Institute, (2018):** Podcasts: Governing Biotechnology from Avian Flu to Genetically Modified babies with Catherine Rodds, <https://futureoflife.org/2018/11/30/podcast-governing-biotechnology-from-avian-flu-to-genetically-modified-babies/>, accessed February 24, 2019.
- Attache Report GAIN, (2017):** Nigeria: Agricultural Biotechnology Annual <https://www.fas.usda.gov/data/nigeria-agricultural-biotechnology-annual-2>, accessed February 24, 2019.
- Becca, A. (2004).** The Biotechnology Process Patent Act of 1995: Providing Unresolved and Unrecognized Dilemmas in U.S. Patent Law, *Journal of Intellectual Property Law*, 12: 229
- Biotechnology Innovation Organization, (2019).** <https://www.bio.org/what-biotechnology>, accessed February 24, 2019.
- Charleston, N., Ben, A., George, C., M., Kevin. Esvelt., Martin. N., (2018).** Current CRISPR gene drive systems are likely to be highly invasive in wild populations. accessed March 5, 2019 at <https://doi.org/10.1101/219022>.
- Cohen, J. and Paarlberg, R. (2002).** Explaining restricted approval and availability of GM crops in developing countries. <http://www.bio.org/articles/what-biotechnology>, accessed March 8, 2019.
- David P. Clark and Nanette J. Pazdernik , (2015):** *Biotechnology: Applying the Genetic Revolution*, 2<sup>nd</sup> Edition, Elsevier. Department of Biotechnology and Food Sciences, Norwegian University of Technology, <https://www.ntnu.edu/ibt/about-us/what-is-biotechnology>, accessed February 24, 2019.
- Dunham, C. (2008).** Body Property Challenging The Ethical Barriers In Organ Transplantation To Protect Individual Autonomy, *Annals Health Law*, 17: 74-78
- European Intellectual Property Right (IPR), (2014), [https://ec.europa.eu/info/business-economy-euro/doing-business-eu/intellectual-property-rights\\_en](https://ec.europa.eu/info/business-economy-euro/doing-business-eu/intellectual-property-rights_en), accessed January 20, 2019.
- Fari, M. and Kralovansky, U. (2006).** The Founding Father of Biotechnology, *International Journal of Horticultural Science*, 12: 9-12.
- Francis F., (2003).** *Our Posthuman future: Consequences of the Biotechnology Revolution.* Farrar, Straus and Giroux Publishing.
- Future of life institute, (2018).** Benefit and Risks of Biotechnology, <https://futureoflife.org/background/benefits-risks-biotechnology/?cn-reloaded=1>, accessed January 16, 2019.
- Joseph, D., and Michael, W., (2002)** Bioweapons, Biodiversity, and Ecocide: Potential effects of biological weapons on biological diversity. *American Institute of Biological Sciences*, 52: 112-125.
- Mildred, C., Samantha, I., and Jon. M., (2003).** Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services (2003). *Journal of Molecular Diagnostics*, 5: 3.
- Plein, C., (1991).** Popularizing Biotechnology: The Influence of Issue Definition. *Science, Technology, & Human Values*, 16: 474-490.
- Ramana. K., Xavier. J., and Sharma R., (2017).** Recent Trends in Pharmaceutical Biotechnology. *Pharmaceutical Biotechnology Current Research* 1:1.
- Robert. J. (2017).** Summary of historical attacks using chemical or biological weapons. [www.johnstonarchive.net/terrorism/chembioattacks.html](http://www.johnstonarchive.net/terrorism/chembioattacks.html),
- Trade-Related Aspect of Intellectual Property Rights (TRIPS) Agreement (1994).** [https://www.wto.org/english/tratop\\_e/trips\\_e/trips\\_e.html](https://www.wto.org/english/tratop_e/trips_e/trips_e.html), accessed January 16 2019.
- Uche, N., (2013):** Agricultural Biotechnology Annual Nigeria's Agricultural Biotechnology Update, Global Agricultural Information Network, [https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual\\_Lagos\\_Nigeria\\_12-18-2017.pdf](https://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Lagos_Nigeria_12-18-2017.pdf), accessed February 2 2019.
- UN Convention on Biological Diversity, (1992),** <https://www.cbd.int/doc/legal/cbd-en.pdf>, accessed March 2 2019.
- United Nations Universal Declaration on the Human Genome and Human Rights:** [https://www.aaas.org/sites/default/files/SRHRL/PDF/IHRDArticle15/Universal%20Declaration%20on%20Bioethics%20and%20Human%20Rights\\_Eng.pdf](https://www.aaas.org/sites/default/files/SRHRL/PDF/IHRDArticle15/Universal%20Declaration%20on%20Bioethics%20and%20Human%20Rights_Eng.pdf), accessed March 2, 2019.