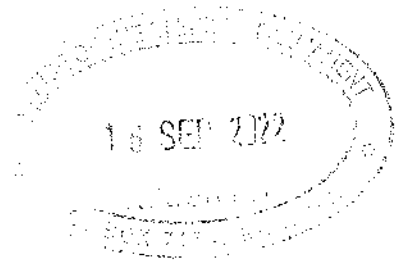


PARLIAMENT OF UGANDA



**REPORT OF THE COMMITTEE ON HEALTH ON THE
UGANDA HUMAN ORGAN DONATION AND
TRANSPLANT BILL, 2021**

SEPTEMBER, 2022

OFFICE OF THE CLERK TO PARLIAMENT

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3.0 OBJECT OF THE BILL

The object of the Bill is to establish a legal framework for the regulation of organ, cell and tissue donation and transplantation in Uganda by:

- Establishing the Uganda Organ Donation and Transplant Council to oversee and regulate organ, cell and tissue donation and transplantation in Uganda;
- Designating Mulago National Referral Hospital as the pioneering transplant centre;
- Prescribing a criteria to be followed when designating a hospital/institution as an organ, tissue or cell donation and transplant centre;
- Regulating the conduct of donation and transplant activities;
- Establishing policies and procedures for designated transplant centres and approved banks, including ethical standards and educational services to the public;
- Establishing a donation and transplant system which ensures equitable access to quality donation and transplantation services to donors and potential recipients;
- Establishing standards for storage of harvested organs, tissues and cells;
- Establishing a system of distribution of organs, tissues and cells;
- Providing for the transplant of organs, tissues and cells;
- Establishing and maintaining a national waiting list for potential organ, tissue and cell donors and recipients drawn from designated transplant centres and other hospitals and health facilities;
- Creating a database of information of donors and recipients to be retained by the transplant centres, hospitals and health facilities;
- Establishing procedures for the transplantation of organs and tissue from living donors including due diligence;
- Establishing procedures for the transplantation of organs and tissue harvested from cadavers;
- Prescribing appropriate consent to be given by donors;
- Prescribing requirements to be fulfilled before carrying out a post-mortem examination of a confirmed brain dead donor;
- Establishing a human organ and tissue database and reporting requirements;
- Prescribing offences and penalties related to issues of organ and tissue donation and transplantation.

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4.0 JUSTIFICATION FOR THE BILL

Worldwide, there is a sharp rise in trafficking of human organs with the poor and other vulnerable groups in society facing a high risk. Organs are unlawfully donated, transplanted and even stolen courtesy of a complex network of buyers, sellers and brokers at the international level. The forceful donations start with inhumane and illegal activities like human trafficking, kidnap and murder.

Uganda does not have a legal framework to regulate organ, tissue and cell donation and transplantation, yet it is increasingly becoming an area of health care used to cure infectious, genetic and non-communicable diseases.

There is need to protect the dignity and identity of every person and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to donation and transplantation of organs, tissues and cells of human origin.

Annually, Ugandans spend a lot of money on medical tourism to countries like India, Turkey, UK and the USA through out of pocket expenditure. This upsets the country's balance of payments. Those who cannot afford have a poor quality of life which may result into death.

5.0 METHODOLOGY

While considering the Uganda Human Organ Donation and Transplant Bill, 2021; the Committee applied the following methods:

5.1 Meetings

Physical meetings

The Committee held meetings with the following entities:

- Ministry of Health (MoH)
- Uganda Medical Association (UMA)
- Uganda Human Rights Commission (UHRC)
- Uganda Law Society (ULS)
- Uganda Blood Transfusion Services (UBTS)
- Centre for Policy Analysis (CEPA)
- Association of Funeral Service Providers of Uganda (AFSPUL)
- Joint Clinical Research Centre (JCRC)

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- Lubaga Hospital
- Coalition of 43 civil society organisations specialising in health rights advocacy
- Pharmaceutical Society Uganda (PSU)
- Uganda Medical and Dental Practitioners Council (UMDPC)
- Plastic Surgeons (skin grafting specialists)

Zoom meetings

- Dr Guarav Kharay, a bone marrow specialist from Apollo Hospitals in India
- Officials from the University of Derby, United Kingdom

5.2 Written memoranda

The Committee received written memoranda from the following:

- Uganda Law Reform Commission
- Laboratory technology students from Clarke International University, Institute of Allied Health Sciences and Makerere University College of Health Sciences

5.3 Document review

The Committee reviewed and made reference to the following documents:

- The Declaration of Istanbul on Organ Trafficking and Transplant Tourism (2018 edition)
- Status of Human Organ and Tissue Donation and Transplantation in the WHO African Region
- Applicable laws

5.4 Workshop

The Committee held a workshop with medical specialists in various fields of organ, tissue and cell therapy like kidney, heart, lung, liver, cornea, stem cells, plastic surgery (skin) and a post-operative care nurse.

6.0 COMPLIANCE WITH GENDER AND EQUITY, HUMAN RIGHTS AND SUSTAINABLE DEVELOPMENT GOALS

HUMAN RIGHTS

Prohibition of children as potential donors

Clause 72 explicitly prohibits any donation from a living child. Children are vulnerable and are never in position to consent to such procedures. This is important in protecting children from exploitation and abuse. However, this provision only applies to living children.

Protection of poor and vulnerable persons

The risk of exploitation of vulnerable and poor persons is high. Guiding principle 5 of WHO Guiding Principles on Human Cells, Tissue and Organ Transplantation states that, "The human body and its parts cannot be the subject of commercial transactions." In order to protect persons from exploitation, the bill under Clause 86 prohibits commercial dealings in human material for transplantation. This means that monetary or any other form of compensation for organs, tissues or cells other than reimbursement of donation related expenses is prohibited. The sale of one pair of organs such as eyes or kidney by a living donor for financial or other form of compensation is also prohibited.

The success of transplantation as a lifesaving treatment should not require nor justify victimising of the poor or vulnerable people as the source of organs for the rich.

Requirement for registered practitioners to obtain authority and consent before harvesting any organ, tissue or cell

Clauses 61 and 67 require all registered medical practitioners in transplant centres to obtain consent before harvesting of any tissue, cell or organ from a donor. Clause 71 also provides for authority for removal of human organs, tissue and cells. The process of obtaining the consent shall be written or spoken in a language that is understandable to the donor or the recipient

next of kin under sub clause 61(6). Obtaining consent from any donor before harvesting is necessary to ensure that the right to health is respected and protected.

GENDER AND EQUITY

Fair and equitable system

Clause 53 describes organ, tissue and cell donation and transplant as a fair and equitable system. Subsection (5) that access to organs, cells and tissues shall be provided without regard to recipient sex, age, religion, race, colour or financial standing. In other words, access to transplant of organs, cells or tissues is based on the principle of non-discrimination. This is further galvanised by Clause 52 which provides for a national waiting list for potential recipients that promotes equity and national solidarity.

Informed Consent

Any intervention in the health field can only be carried out after the person concerned has given free and informed consent to the procedure. Clause 67 (4) (b) and (c) includes the responsibility of the Council to inform the donor of the long-term benefits and risks related to the procedure. This will enable donors to make informed decisions about the donation. In accordance with the WHO guiding principles on human cell, tissue and organ transplantation, there needs to be an adequate balance of interests of recipients and donors. Benefits to both parties should outweigh the risks associated with the donation and transplantation.

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SUSTAINABLE DEVELOPMENT GOALS (SDGs)

SDG – 3 Good health and well being

The Bill is in line with SDG number 3- Good health and well being which aims at ensuring healthy lives and promoting well-being at all ages.

Transplantation of an organ, tissue or cell is a life-saving procedure which gives patients with mal or non-functioning organs to have a better quality of life and live longer. The patients can be children or adults.

7.0 COMMITTEE OBSERVATIONS AND RECOMMENDATIONS

PART I – PRELIMINARY

PURPOSE OF THE ACT

Clause 2(c)

Clause 2 of the Bill lists the purpose of the Bill. Clause 2 (c) designates Mulago National Referral Hospital as a pioneer transplant centre.

The Committee observed that:

Designating Mulago as a pioneer transplant centre may prevent other facilities that are ready for organ, tissue and cell harvesting and transplantation from commencing. Different types of organs can be harvested and this clause presumes that Mulago will have to pioneer in transplantation of all the different organs, tissues and cells.

The provision also presumes that Mulago meets all the standards and is ready for transplant activities.

The Committee recommends that Clause 2(c) be deleted.

Clause 2(d)

Clause 2(d) provides for designation of hospitals as organ, tissue and cell transplant centres.

The Committee observed that a hospital should be accredited before designation.

The Committee recommends that the word accreditation be inserted in Clause 2(d).

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The Committee further observed that the amount of data generated from organ, cell and tissue harvesting and transplantation is a repository for knowledge and research for teaching purposes and development of medicines, new transplant techniques, prevention and policy development.

The Committee recommends that a new paragraph (j) be inserted to provide for a framework for scientific research and development in organ, cell and tissue donation and transplantation.

CLAUSE 3 - APPLICATION

Clause 3 lists organs, tissues and cells which can be donated and transplanted.

Clause 3(c)

The Committee observed that blood is among the list of organs, tissues and cells yet facilities like hospitals and health centres where blood transfusion is ongoing, will fall short of the criteria for accreditation for organ, tissue and cell transplant centres. This means that hospitals and health centre IVs where blood transfusion is taking place will have to shut down blood transfusion services.

The Committee recommends that paragraph (c) of Clause 3 be deleted.

Clause 3(n)

The Committee observed that cells constitute organs and therefore, there is no need to make a separate mention of them in (n).

The Committee recommends that the word cells is deleted from the list.

The Committee observed that hair has not been listed yet it is a tissue for transplant.

The Committee recommends that the word cells is replaced with hair in paragraph (n).

Clause 3(s)

The Committee observed that paragraph (s) is restrictive and does not envisage emerging developments in the field of organ, tissue and cell donation and transplantation.

The Committee recommends that paragraph (s) be amended to delete the words, "related to those in paragraphs (a) to (r)"

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PART II – THE MINISTER AND THE HUMAN ORGAN TRANSPLANT COUNCIL

ASSISTANCE AND SUPPORT

According to Clause 6, the Minister can provide assistance and support to any person providing or proposing to provide a service relating to human organ, cell or tissue donation or transplantation.

The Committee observed that the assistance and support referred to is ambiguous and can be exploited.

The Committee recommends that Clause 6 be deleted.

UGANDA HUMAN ORGAN DONATION AND TRANSPLANT COUNCIL

Clause 7(5) states that, “The Council shall be independent but shall work in collaboration with the Uganda Medical and Dental Practitioners Council, especially in relation to disciplinary cases against registered medical practitioners certified by the Council under this Act to undertake organ, tissue and cell donation and transplant activities.”

The Committee observed that Uganda Medical and Dental Practitioners Council is one of the four professional bodies of health workers. The others are Uganda Nurses and Midwives Council, Allied Health Professionals Council and the Pharmacy Board.

The Committee recommends that Clause 7(5) of the Bill is amended to replace Uganda Medical and Dental Practitioners Council with the relevant professional bodies.

COMPOSITION OF THE COUNCIL

The Committee observed that the Bill does not have a provision on composition of the Council.

The Committee recommends that a new clause be inserted after Clause 7 to provide for composition of the Council.

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Clause 29 (3) states that, "Where, after the due diligence carried out under subsection (2) and after giving an opportunity to the applicant to be heard, the Council is satisfied that the applicant does not meet the requirements of this Act and the regulations made under this Act, the Council shall, reject the application giving reasons for the refusal in writing.

The Committee observed that a hospital should be accredited before designation to ensure compliance with approved standards.

The Committee recommends that Clause 29(1) be amended to include the word accredited.

The Committee observed that the timeframe within which to communicate the Council's decision is not stated.

The Committee recommends that Clause 29(3) be amended to include 30 days as the timeframe within which to communicate the Council's decision to the applicant.

The Committee further observed that quality assurance and control is a continuous process and as such, transplant hospitals need annual accreditation and designation so as to ensure that they continuously adhere to standards.

The Committee recommends that a new paragraph (5) be added to provide for a hospital designated as a transplant center to be accredited annually for suitability to offer services and issued an accreditation certificate which expires by the 31st of December of every calendar year.

QUALIFICATION FOR DESIGNATION AS A TRANSPLANT CENTRE

Clause 30 lists qualifications for designation as a transplant centre.

Clause 30(a) states that a designated transplant centre shall have, "Intensive Care Unit and High Dependent Unit beds dedicated to the transplant programme connected to the theatre by a sterile corridor or interconnectivity with dialysis capability;

Clause 30(b) states, "specialised medical professionals, including a transplant surgeon, physician, anaesthesiologist, intensivist and transplant nurse qualified and experienced in the type of organ, tissue or cells to be harvested and the transplant activities to be carried out;"

Clause 30 (c) states that a transplant centre should have two adjacent theatres; one for the donor and another for the recipient.

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Clause 30(g) states that, "any other requirement that the Minister may prescribe by regulations or standards issued by the Minister."

The Committee observed that:

- *Clinical pharmacists and counsellors are missing from the list of key professionals needed. Clinical pharmacists trained in organ transplant understand the medicine requirements and in the event of adverse reactions, they are capable of responding. Professional counselling is needed before the procedure to avoid cases of depression.*
- *The requirements for an intensive care unit and adjacent theatre apply to donation and transplant of solid organs;*
- *The need for therapeutic drug monitoring facilities is not indicated among the requirements.*
- *The need for a well-stocked pharmacy is missing from the list of requirements.*
- *The provision caters for solid organ transplants and ignores cells and tissues.*

The Committee recommends that:

- **Clause 30(a) and 30(c) be amended to state that the provisions qualify for solid organ transplants.**
- **A new sub-clause be inserted after (f) to provide for a requirement for therapeutic drug monitoring facilities.**
- **A new sub-clause be inserted after (g) to provide for a requirement for a pharmacy stocked with relevant medicines and supplies.**
- **A new sub-clause be inserted after (h) to cater for cell and cornea transplant centres whose requirements will be prescribed by the Minister.**

DESIGNATION BY A MINISTER

Clause 31 (1) states that, "The Council shall, after being satisfied that a hospital meets all the requirements of this Act, regulations made under this Act, standards issued by the Minister and any other applicable law, recommend the hospital to the Minister for designation as a transplant centre."

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The Committee observed that different institutions are qualified in different in different areas of transplantation.

The Committee recommends that the sub-clause be amended by inserting the requirement by an institution to offer specific transplant services for which the facility is qualified to do so.

REGULATION OF CONDUCT OF DONATION AND TRANSPLANT ACTIVITIES

Clause 33(4) states that, "The Council shall, in a manner prescribed by regulations, approve local and expatriate transplant surgeons before they can undertake transplantation activities under this Act."

Clause 33(5) states that, "A transplant surgeon shall not be approved under subsection (4) unless he or she is registered by the respective professional Councils."

The Committee observed that the mandate mentioned in 33(4) and 33(5) is for Uganda Medical and Dental Practitioners' Council.

The Committee recommends that Clause 33(4) and 33(5) be deleted.

APPROVAL OF BANKS

Clause 34(7) states that, "the national blood bank shall be accredited by the Council, but shall in its day to day activities report to the Minister."

The Committee observed that Uganda Blood Transfusion Services has a system in place for the collecting, processing, storage and distribution of blood countrywide. The Committee was informed by the Minister that a separate law will be developed to regulate blood and its products.

The Committee recommends that Clause 34(7) be deleted.

POLICIES AND PROCEDURES FOR DESIGNATED TRANSPLANT CENTRES AND APPROVED BANKS

Clause 35 (1) of the Bill states that, "Designated transplant centres and approved banks shall maintain policies and procedures which shall detail all aspects of retrieval, processing, testing and storage and practices for organs, tissues and cells."

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Clause 35(3) states that, "Modifications of standard procedures and development of new procedures shall be approved by the registered medical practitioner."

The Committee observed that there will be no consistency and standardisation if each designated transplant centre develops their own policies and procedures.

The Committee further observed that there will be no independent review of these policies and regulations developed by the designated transplant centre.

The Committee recommends that Clause 33(1) be amended to provide that all policies developed by the designated transplant centres shall be approved by the Council and should conform to the regulations.

EDUCATIONAL STANDARDS TO THE PUBLIC

Clause 37(1) states that, "Each designated transplant centre shall assist hospitals and health centres in establishing and implementing protocols for making routine inquiries regarding organ, cell and tissue donations by potential donors."

Clause 37(4) states that, "Every designated transplant centre shall produce or have available literature and media items that provide education and awareness creation for donation of organs, tissues or cells."

Clause 37 (5) states that, "A designated transplant centre shall be responsible for establishing and assisting in the dissemination of the materials referred to in subsection

The Committee observed that:

- *The word "protocols" is not consistent with other laws.*
- *There will be no consistency and standardisation if each designated transplant centre develops their own education and awareness literature and media items.*
- *There will be no independent review of education and awareness literature and media items developed by the designated transplant centre.*

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The Committee recommends that the word protocols in Clause 37(1) be replaced with guidelines.

The Committee further recommends that Clause 37(4) and 37(5) be amended to provide that all education and awareness literature and media items developed by the designated transplant centres shall be approved by the Council.

PART VII-STORAGE OF ORGANS, TISSUES AND CELLS OUTSIDE THE BODY

FRAUDULENT ACTIVITY

Clause 51 (1) states that, "Where a designated transplant centre or approved Bank discovers that a fraudulent activity has occurred in the distribution, shipping or labelling of any organ, tissue or cell imported or exported by the designated transplant centre or Bank, an investigation shall be conducted to identify the root cause of the fraudulent activity.

The Committee observed that scope of fraudulent activities in organ, tissue and cell donation and transplant goes beyond distribution, shipping or labelling.

The Committee recommends that Clause 51(1) be amended by expanding the scope for fraudulent activity to harvesting, transplanting, returning or recall.

NATIONAL WAITING LIST

Clause 52 states that, "The Council shall establish and maintain a national waiting list for potential organ, tissue and cell donors and recipients drawn from designated transplant centres; hospitals and health centres."

The Committee observed that the procedure for people who donate is done real time, hence no need for waiting.

The Committee recommends that Clause 52 is amended by removing the word donors.

FAIR AND EQUITABLE SYSTEM

Clause 53(3) states that, "The Council may also authorise the importation of organs, tissues and cells from an international transplant organisation referred to in subsection (2)."

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The Committee observed that use of the word importation may be misinterpreted to mean commercialisation of organs, tissues and cells yet the Bill prohibits the sale of organs, tissues and cells.

The Committee recommends that Clause 53 is amended by replacing the word, "importation" with "sharing" where sharing means medically sanctioned transboundary movement of organs, tissues or cells from one organ bank to another in cases where there are agreements approved by the Minister.

TRANSPLANTATION ACTIVITY

Clause 54 (1) states that, "The retrieval and preservation of human organs, tissues and cells for transplantation shall only be performed by a registered health professionals approved by the Council and in accordance with this Act, regulations made under this Act, any other applicable law and standards issued by the Minister.

The Committee observed that the retrieval team includes various health professionals who are not only licensed by their respective professional bodies. Subjecting them to approval by the Council may constitute double licensing.

The Committee recommend that relevant professional bodies should replace the Council appearing in Clause 54(1).

Clause 54(4) states that, "All transplant activity shall be performed to the highest professional and ethical standards."

The Committee observed that ethical standards are set by the professional bodies.

The Committee recommends that Clause 54(4) should be amended by putting a provision for all transplant activities to be prescribed by the relevant professional bodies.

Clause 54(5)

Clause 54(5) states that, "When a person has been confirmed brain dead by the team in care, the Council shall immediately be notified to send an independent neurological team to confirm the death for purposes of donation."

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The Committee observed that the team which confirms brain death includes other professionals like neuro surgeon, neuro physician, anaesthesiologist and intensivist.

The Committee recommends that the word neurological be deleted.

Clause 54(8) states that, "The independent team in (5) shall consist of a neuro surgeon, neuro physician, and an anaesthesiologist or intensivist."

Clause 54(9) states that, "The independent team and organ retrieval team shall be self-sufficient and shall not require anesthetic, theatre or surgical staff from the donor hospital and shall be available 24 hours a day without other elective commitments during their time on call and able to respond appropriately if there is more than one donor on the same day."

The Committee recommends that the two clauses be merged.

Insertion of a new sub-clause (9)

The Committee observed that no provision has not been made for a brain dead potential donor who is in an intensive care unit in a hospital that does not provide organ, tissue and cell transplant services.

The Committee recommends that a new sub-clause (9) be inserted to cater for brain death in an intensive care unit of a hospital.

**DONATION AND TRANSPLANT OF ORGANS, TISSUES AND CELLS
REMOVED FROM LIVING DONORS**

Clause 67 (4) states that, "The Council shall ensure that the donation is legal and justified by ensuring that the proposed donor—

- (d) understands that it is illegal to accept any financial or other inducement for the donation but that he or she may have any expenses or loss of earnings reimbursed.
- (e) understands that he or she may be compensated for any unanticipated harm resulting from the donation."

The Committee observed that the organs, tissues and cells are donated free of charge. Reimbursement for loss of earnings and compensation for any unanticipated harm resulting from donation may be construed to mean a payment for the organ, tissue or cell.

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The Committee recommends that:

Clause 67(4) (d) be amended to remove a provision for any expenses or loss of earnings reimbursed.

Clause 67(4) (e) should be changed to put a provision to the effect that a living donor understands that he or she may be compensated for justifiable expenses which should be approved by the Council.

AUTHORITY FOR REMOVAL OF HUMAN ORGANS, TISSUES AND CELLS

Clause 71 (4) states that, "The authority given under subsection (1) or subsection (2) or, as the case may be, subsection (3) shall be sufficient warrant for the removal, for therapeutic purposes, of the human organ, tissue or cell but no such removal shall be made by any person other than a registered medical practitioner from a designated transplant centre".

The Committee recommends that, if a potential donor dies without giving his/her consent, and the next of kin cannot be contacted, that body should not be used for donation purposes.

PROHIBITION OF DONATION FROM LIVING CHILD

Clause 72 prohibits donation of an organ, tissue or cell from a living child.

The Committee noted that medically, stem cells are drawn from bone marrow and peripheral blood, which regenerate and they do not cause any harm.

The Committee recommends that the clause be redrafted to cater for the following:

Prohibition of donation from a living child save for exceptional circumstances approved by the Council with the consent of parent/guardian.

Put provisions under which a living child may donate. The provisions include: stem cell therapy for minors who are twins or close siblings after approval by the Council

Prescribe a penalty of life imprisonment for a person who contravenes the provision .

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Clause 79 is about authority for removal of human organ, cell or tissue from a body sent for post-mortem examination for certain purposes.

The Committee noted that Clause 78(1) requires that a post-mortem shall be carried out on all cadaveric donors and shall be conducted at the same time as the harvesting of the organs to determine the cause of death and the suitability of the donor.

The Committee observed that harvesting organs, tissues and cells sent for post mortem could be abused and in cases of medico-legal nature, it may destroy evidence that might be needed at a later date. For instance, in cases of exhumation.

The Committee further observed that there is no requirement for certification of death by the Council before a post mortem is carried out. This could create a possibility of a person alleging that the organs are harvested from donors who are still alive. In addition, Clause 75 already takes care of how organs are harvested from the dead.

The Committee recommends that Clause 78 and Clause 79 be deleted.

PART XI-OFFENCES AND PENALTIES

PREVENTION OF ORGAN, TISSUE OR CELL TRAFFICKING

Clause 88 (2) (a) states that, "The prohibition under subsection (1) shall not prevent payments which do not constitute a financial gain or comparable advantage, in particular—

- (a) compensation for living donors of loss of earnings and any other justifiable expenses caused by the removal or by related medical examinations;

The Committee observed that the provision is silent on who approves the justifiable expenses. Compensation for loss of earnings can be abused and commercialised. It may be construed as payment for the organs, tissues or cells provided by the donor.

The Committee recommends that Clause 88(2) (a) should be amended to allow only justifiable expenses which should be approved by the Council.

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Clause 88 (2) (b) states that, "payment of a justifiable fee for legitimate medical or other related technical services rendered in connection with the transplantation; and (c) states that, "compensation in case of undue damage resulting from the removal of an organ, tissue or cell from a living person.

The Committee observed that the fee for legitimate medical and other technical services rendered in connection with transplantation may vary from time to time; hence it should be catered for in the regulations.

The Committee further observed that consent is sought before going for any surgical procedure and before consent is given, the donor must have received all the relevant information and explanations including any eventualities that may arise.

The Committee recommends that clauses 88(2) (b) and (c) be deleted.

OFFENCES BY BODY CORPORATE

Clause 91 provides for offences by body corporate.

The Committee observed that the clause does not prescribe penalties for body corporate.

The Committee recommends that a new sub-clause be inserted after 91(4) to prescribe a penalty not exceeding five hundred thousand currency points.

GENERAL PENALTY

According to Clause 92, "A person contravenes a provision of this Act or any regulations made under this Act, or any condition of the designation granted under this Act for which no punishment is separately provided in this Act is liable, on conviction, to a fine not exceeding ten thousand currency points or imprisonment not exceeding three years or both."

The Committee observed that the penalty and the prison sentence are not deterrent enough.

The Committee recommends the penalty to be increased to one hundred thousand currency points and the prison sentence to 12 years.

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CODE OF PRACTICE

Clause 97 (2)(k) authorises the Minister to issue a code of practice in relation to the import or the export of the body of a brain-dead person or organ, tissue or cell from a human body for use for a scheduled purpose.

The Committee observed that use of the words import and export may be misinterpreted to mean commercialisation of organs, tissues and cells yet the Bill prohibits the sale of organs, tissues and cells.

The Committee recommends that Clause 97 (2) (k) is amended by replacing the word, "import and export" with "sharing" where sharing means medically sanctioned transboundary movement of organs, tissues or cells from one organ bank to another in cases where there are agreements approved by the Minister.

AUTHORISED TRANSPLANTATION ACTIVITIES

Schedule 2 of the Bill lists authorised transplantation activities and they include: donation, transplantation, harvesting organs, tissues and cells.

The Committee observed that storage and distribution which are part of the organ, tissue and cell transplant activities were not provided for in Schedule 2.

The Committee recommends that storage and distribution be added to Schedule 2 of the Bill.

GENERAL OBSERVATIONS

INADEQUATE FUNDS PROVIDED UNDER CERTIFICATE OF FINANCIAL IMPLICATIONS

Rule 118 (1) of the Rules of Procedure of the Parliament of Uganda requires that a Bill introduced in the House shall be accompanied by a Certificate of Financial Implications (CFI) issued by the Minister responsible for Finance.

(2) The Certificate of Financial Implication issued under sub-rule (1) shall indicate the estimates of revenue and expenditure over the period of not less than 2 years after coming into effect of the Bill when passed.

(3) In addition to sub-rule (2) above, the Certificate of Financial Implications shall indicate the impact of the Bill on the economy.

The Certificate of Financial Implications tabled with the Uganda Human Organ Donation and Transplant Bill complied with the requirements of Rule

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118. It was tabled with the Bill, contained planned expenditure for a period of 5 years and included a statement on expected savings to Government.

However, the Committee noted that the funds proposed may not be adequate for implementation of human organ, tissue and cell transplant programmes. During the interface of the Committee on Health with the medical specialists, the Committee was informed that the following pillars are required for a functional organ, tissue and cell transplant programme:

- Skilled medical experts
- Infrastructure where transplant is done (sterile theatre, corridors and wards)
- Enabling legal framework
- Adequate funding for medicines and supplies required

The medical experts expressed concerns over the gaps in human resources and facilities (infrastructure and equipment) for functional organ, tissue and cell transplant in the country.

According to Clause 28 of the Bill, transplant is to be pioneered at Mulago National Referral Hospital. During the preparation of the budget for FY2022/23, the Director General of Health Services reported that Mulago National Referral Hospital has a gap of 86 super specialists of which 23 are for surgery. He said Ministry of Health requires Shs 15.72 billion to recruit specialists to fill all the vacant posts in the referral hospital. However, only Shs 2.658 billion has been provided in the CFI for regional transplant centres for a period of five years. Furthermore, only Shs 911 million has been provided for capacity building for a period of 5 years.

This will not be adequate for putting in place the requisite infrastructure, hire and train the required specialists.

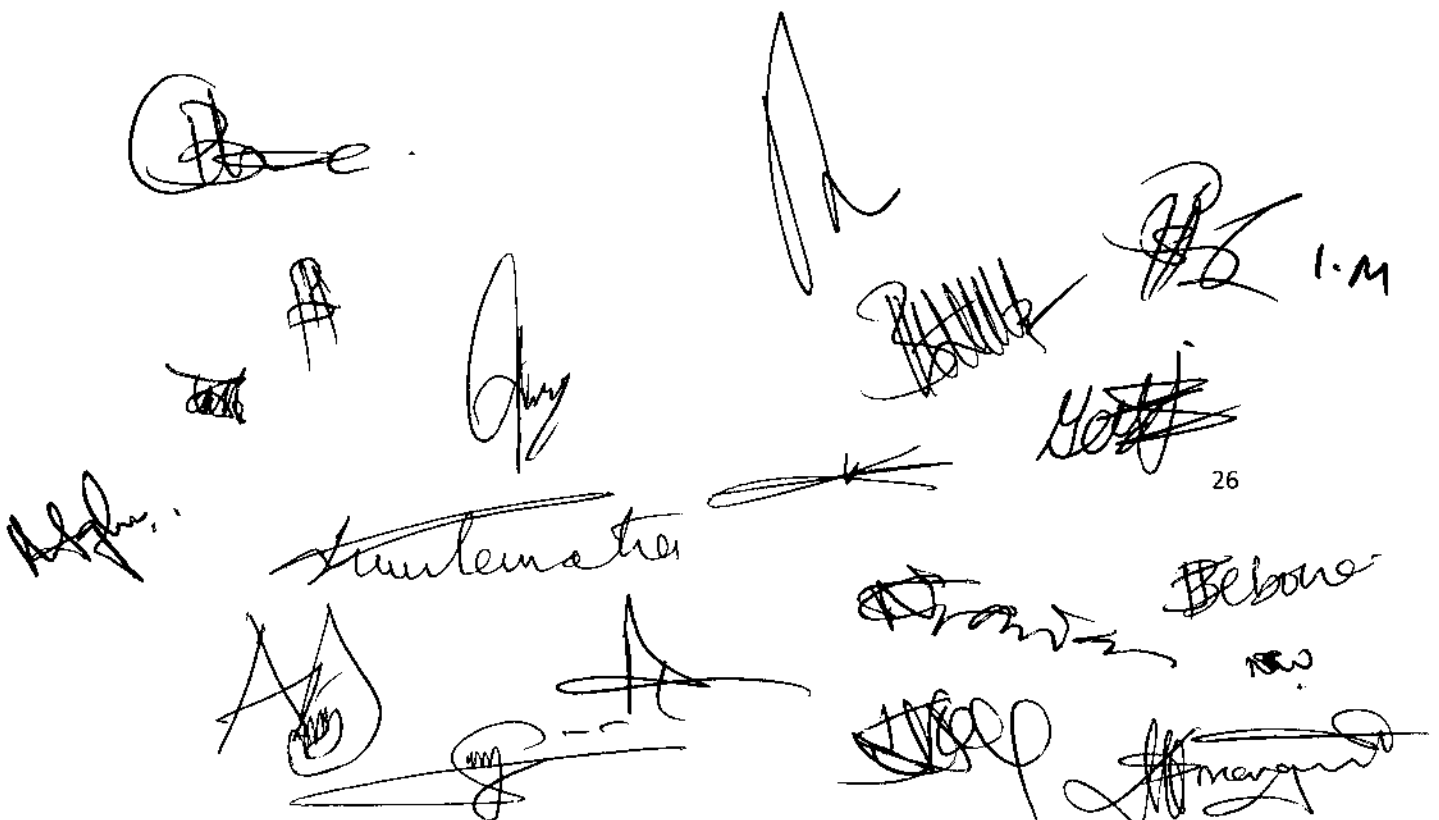
This programme requires a lot of publicity and communication for people to understand and be willing to donate their organs to those who are in need. However, only Shs 202 million has been provided for this activity for a period of 5 years.

The Committee recommends that Ministry of Finance, Planning and Economic Development should provide additional funding for successful implementation of the Uganda Human Organ Donation and Transplant programme once the Bill is passed.

8.0 CONCLUSION

The Organ Donation and Transplant Bill when enacted into law will cover a specialised part of medical care in the country which has hitherto been unregulated. The Bill presents an opportunity to streamline and strengthen the regulatory framework of medical practice in Uganda in matters of ethics and discipline in this sensitive and vital areas of medical practice.

Rt. Hon. Speaker and Hon. Members, I beg to move that the report of the Committee on the Uganda Human Organ Donation and Transplant Bill be adopted.



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PROPOSED AMENDMENTS TO THE HUMAN ORGAN DONATION AND TRANSPLANT BILL, 2021

1. CLAUSE 2: PURPOSE

a) Delete paragraph (c)

Justification

- *The clause would create an assumption that Mulago is ready and has met the standard criteria for accreditation and designation.*
- *Different types of organs can be harvested and yet Mulago may not be in position to offer the entire spectrum of transplant services yet the bill under clause 3 provides over 19 services to be offered and implemented, and other centers might be ready to commence operation before Mulago.*

b) Insert the word "accreditation" before the word "designation"

Justification:

- *To allow due process of accreditation and designation to take place*

c) Insert a new provision after paragraph (i) to read as-

"To provide for a framework for research and development."

Justification:

- *Research is a repository for knowledge and can be used for teaching purposes and for the development of new techniques, prevention and policy development.*

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Beano
RW

2. CLAUSE 3

Amend the provision-

- a) By deleting paragraph (c); and deleting reference to "blood" wherever it appears in the bill.

Justification:

- *Regulation of blood transfusion which is already on going in hospitals and health centers would affect the operations of the health centres. The current facilities where blood donation has been going on will fall short of the criteria for accreditation and this will affect current supply of blood. Therefore, it would be proper for "blood" to be regulated under a separate legal framework.*

- b) in paragraph (n), by substituting "cells" with "hair"

- c) by substituting paragraph "(s)" with the following-
"(s) any other organ, cell or tissue for the purpose of transplantation."

Justification:

- *To be all inclusive and accommodate emerging developments in science.*

3. CLAUSE 4 INTERPRETATION

- a) Substitute the definition of "tissue evaluation" with the following-

"Tissue evaluation" means the analysis of tissue for viability, abnormality, contaminants, compatibility and micro-organisms to determine its fitness for purpose"

Justification:

- *The current definition in the bill is narrow.*

- b) Insert the following new definitions:

"autograft" means tissue which is transplanted within the same person;

"allograft" means tissue that is transplanted from one person to another;

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“brain dead” means a condition where a person is on an artificial life support machine, with irreversible cessation of all functions of the entire brain, including the brain stem, confirmed by Electro-encephalogram (EEG) and independent team, and the person has no chance of revival;

“bone marrow” means the soft, spongy, gelatinous tissue that fills the medullary cavities, or the centers of bones, which is responsible for the production of red blood cells, white blood cells and platelets;

“A retrieval team” means an intensive care team that is capable of handling a patient on life support;

“stem cells” means undifferentiated cells originating from adult or embryonic tissue that can turn into specific cells, as the body needs them;

“stem cell transplant” means a medical procedure performed to replace bone marrow that has been damaged or destroyed by disease, infection, or chemotherapy”.

Justification:

- *for clarity*

4. CLAUSE 6:

Delete clause 6

Justification:

- *The type of assistance and support which the Minister is supposed to offer is not clear. The ambiguity posed by the provision can therefore be easily subject to abuse by wrong elements.*

5. CLAUSE 7.

Amend the provision as follows-

- a) Amend the cross heading and the headnote to read as-
“Uganda Human Organ Donation and Transplant Council”

Justification:

- *For clarity and uniformity*

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Bebone Amanya
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- b) Amend sub clause (5) by substitution the words "Uganda Medical and Dental Practitioner Council" with the words "**relevant health professional councils**"

Justification:

- To accommodate all the other professional bodies.

6. INSERTION OF A NEW CLAUSE AFTER CLAUSE 7.

Insert a new clause after clause 7 as follows-

"Composition of the Council"

The Council shall compose of-

- (1) The Director General
- (2) Persons who are qualified in, and have had experience and shown capacity, and are representatives in the following specialized fields;
 - (i) Surgery;
 - (ii) Law;
 - (iii) Intensive Care;
 - (iv) Anesthesia;
 - (v) Financial Management;
 - (vi) Bioethics; and
 - (vii) Investigative Specialist.
- (3) The chairperson who shall be appointed by the Minister from among the members.
- (4) The Executive Director, who shall be, the secretary to the council and shall be an ex-officio member of the council, without a right to vote.

Justification:

- To establish the governing body of the council.

7. CLAUSE 9 DISQUALIFICATION FROM APPOINTMENT TO THE COUNCIL

Amend the provision as follows-

- a) Redraft paragraph (d) to read as-

"(d) is serving on any other statutory council or Board in the health sector"

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Justification:

- To avoid conflict of interest.
- b) Insert a new paragraph after Paragraph (d) to read as follows-

“(e) is directly involved in the organ, cell or tissue transplant service.”

Justification:

- to avoid conflict of interest.

8. CLAUSE 11.

Delete sub clause (4)

Justification:

- To avoid unfairness and possible abuse of powers by the appointing authority.

9. CLAUSE 28. DESIGNATION OF TRANSPLANT CENTRES.

Amend the provision as follows –

- a) By deleting sub clause (1)

Justification:

- Consequential amendment
- b) In sub clause (2) by deleting the words “Notwithstanding sub section (1)”
Redraft the provision to read-

“The Minister may, in consultation with the Council, by statutory instrument, designate a hospital as an organ, tissue or cell donation and transplant centre.”

Justification:

- Consequential. Sub clause (1) which the provision makes reference to was deleted.

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10. CLAUSE 29. APPLICATION FOR DESIGNATION AS A TRANSPLANT CENTRE.

Amend the provision as follows-

a) By substituting sub clause (1) to read as-

“A hospital that wishes to be designated as a transplant center under section 28 shall apply to the council for accreditation and designation.”

Justification:

- *For quality assurance before the transplant centres are designation.*

b) by inserting 3 new sub clauses after sub clause (4) to read as follows-

“(5) A hospital designated as a transplant center shall be accredited annually for suitability to offer services and issue an accreditation certificate which expires by 31st of December of every Calendar Year.”

Justification:

- *To ensure compliance and for quality assurance.*

“(6) Notwithstanding the provisions of sub section (3), the person aggrieved by the decision of the Council may appeal to the Minister within 30 days from the date of decision of the Council.

Justification:

- *To provide for timeline*

“(7) The Minister shall dispose of the appeal within 30 days for the date of receipt of the appeal”

Justification:

- *For Justice to be served to the applicant after all due process is considered.*

“to operate specific transplant service for which the Hospital is qualified”.

Justification:

- Each hospital should be assessed against standards by the council. The Minister therefore should designate a Hospital for example as a Renal Transplant Center, or a Multi- organ Transplant center for Renal and Liver if it meets both requirements. A blanket designation as a “Transplant center” should be avoided.

13. CLAUSE 32. EXISTING CENTERS

- a) Amend sub clause (2) (a) by inserting the word “accreditation” before the word “designation”

Justification:

- Consequential

14. CLAUSE 33.

- a) Delete sub clause (4) and (5)

Justification:

- It usurps the powers of the Medical Council

- b) Delete the second sub clause (2)

Justification:

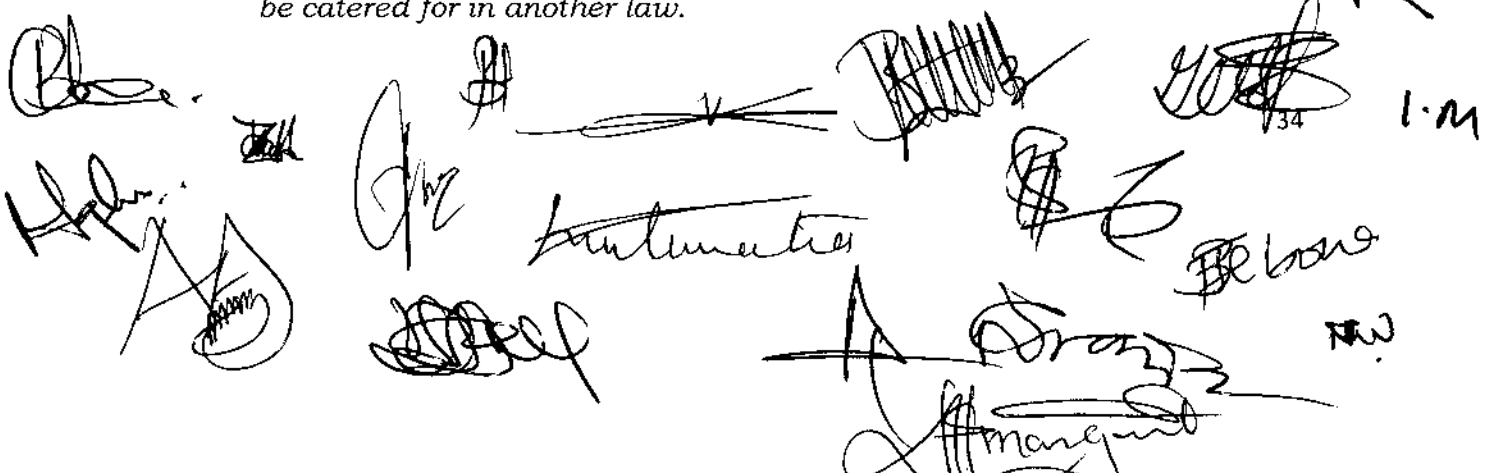
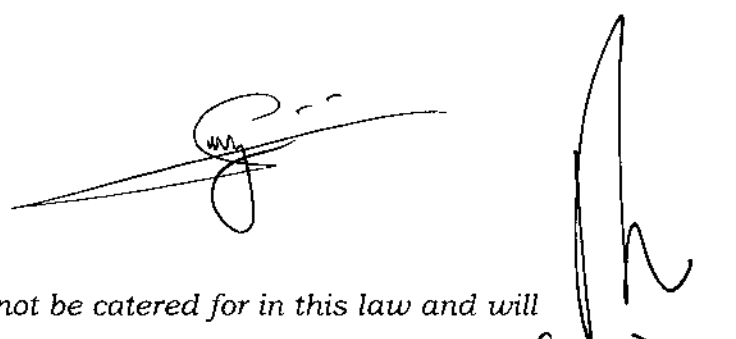
- To avoid repetition.

15. CLAUSE 34

Delete sub clause (7)

Justification

- Accreditation of blood services cannot be catered for in this law and will be catered for in another law.



16. CLAUSE 35

Clause 35 is amended-

(a) in sub clause (1), by inserting immediately after the word "procedures" the words "and shall conform to regulations made under this Act";

(b) In sub clause (3), by inserting immediately after the word "shall", the following words "in consultation with the Council".

Justification

- For standardization of policies and procedures
- To provide for checks and balances.

17. CLAUSE 37

Amend the provision as follows-

a) In sub clause (1) by substituting the word "protocols" with the word "guidelines"

Justification:

- For uniformity and consistency with other piece of legislation.
- b) In sub clause (4) by inserting at the end of the provision the words "as may be approved by the council"

Justification:

- To act as quality control measures

18. CLAUSE 40.

Substitute "Transport" with "Transplant"

Justification:

- To correct a typing error

19. CLAUSE 42

Substitute sub clause (3) with the following-

"The Minister may, in consultation with the council, by regulation, prescribe additional requirements for recall procedures."

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Justification:

- *To cater for any eventualities that might arise*

20. CLAUSE 53

Clause 53 of the Bill is amended in sub clause (3) by substituting the word "importation", the word "sharing";

Justification

- *To change the terminology used to refer to exchange of organs with other international transplant organizations rather than export of organs which connotes commercialization of organs, tissues and cells.*

21. CLAUSE 54. TRANSPLANTATION ACTIVITY

Amend the provision as follows-

- a) **In sub clause (1) by** deleting the words 'approved by the council'

Justification:

- *This is a function of Uganda Medical and Dental Practitioner Council.*

- b) In sub clause (4) by inserting at the end of provision the words "as may be prescribed by their respective professional bodies"

Justification:

- *The provision should clearly provide for the person who determines the professional and ethical standards.*

- c) in sub clause (5) by deleting the word "neurological" appearing before the word "team"

Justification:

- *The independent team is inclusive of other professionals*

- d) Amend sub clause (8) by substituting the cross reference "(6)" with "(5)"

Justification:

- *To streamline the cross referencing*

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e) Redraft sub clause (9) to read as follows-

“(9) where a person has been declared and confirmed brain dead in accordance with sub section (5), in an Intensive Care Unit of a hospital which is not a designated transplant centre, a retrieval team shall be dispatched by the Council to retrieve the potential donor to a transplant centre.”

Justification:

- for clarity

22. CLAUSE 67

Amend the provision as follows-

a) In sub clause (4)(d) by deleting all the words appearing after the word “donation” and

Redrafting sub clause (4) (d) as follows-

“understands that it is illegal to accept any financial or other inducement for the donation **of the organ**,”

b) In sub clause (4) (e) to read as follows-

“understands that he or she may be compensated for justifiable expenses which should be declared to and cleared by the Council within reasonable time.”

Justification:

- To guard against commercialization of organs, tissues or cells

23. CLAUSE 71

Amend the provision as follows-

a) In sub clause (3) by delete the words “of the removal”;

b) In sub clause (6) by deleting the word “the” appearing at the beginning of line three.

Justification:

- To correct grammatical error

c) In sub clause (7) by-

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By deleting the words "of age" appearing after the words "eighteen years"

Justification:

- *To correct grammatical error*

d) substituting the words "any of the parents" with the words "any close relations"

Justification:

- *To avoid creating a lacuna in the law.*

24. CLAUSE 72.

Substitute the provision with the following-

"72. Prohibition of donation from a living child

- (a) Donation from a living child is prohibited save for exceptional circumstances approved by the Council, with the consent of a parent or guardian.
- (b) A person who contravenes the provision of this section commits an offence and is liable on conviction to imprisonment for life.
- (c) For the purpose of this section, exceptional circumstances mean haematopoietic stem cell, allograft and autograph to a twin or sibling."

Justification:

- *There are circumstances that warrant donation by a living child such as donation for bone marrow transplant for conjoined or identical twins where one twin can be allowed to donate to the other based on sound medical assessment.*

25. CLAUSE 73.

Delete clause 73

Justification:

- *The provision presumes that a child has capacity to consent. It is trite law that a person under the age of 18 years is legally considered to be*

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a child and that as a child he or she automatically does not have the capacity to consent.

26. CLAUSE 74.

Amend the provision as follows-

- a) In sub clause (1) by substituting the words "sound mind" with the words "mental capacity";

Justification:

- For consistency with the terminology used in the Mental Health Act, 2018, which outlawed the use of the word "unsound mind" and instead adopted the use of the words "mental incapacity".

- b) Delete sub clause (2)

Justification:

- The Provision lacks clarity, and besides the content of sub clause (2) is catered for under sub clause (1)

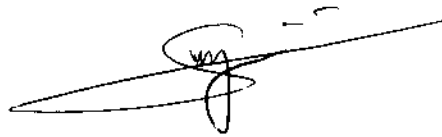
27. CLAUSE 75

- a) Amend sub clause (1) by deleting the words "brain dead or"

Justification:

- For clarity

- b) Delete sub clause (4)



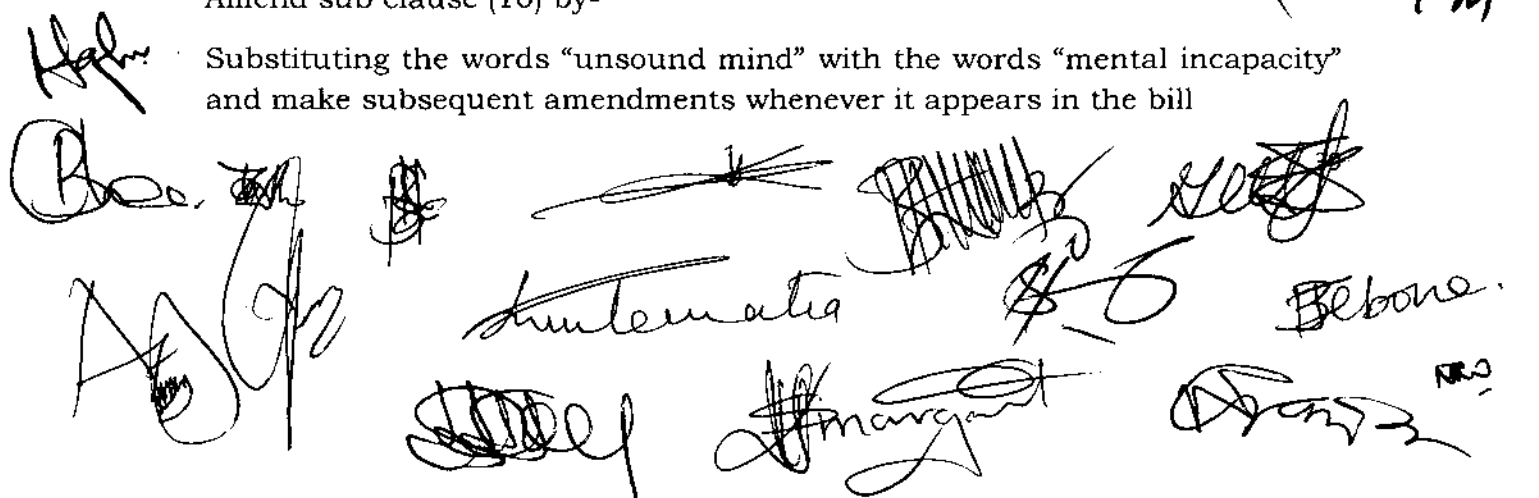
Justification:

- It is likely to be manipulated/abused. The time taken to secure a court order may go beyond the time of viability of the organ, tissue or cell.

28. CLAUSE 76. NOMINATED REPRESENTATIVES.

Amend sub clause (10) by-

Substituting the words "unsound mind" with the words "mental incapacity" and make subsequent amendments whenever it appears in the bill



Justification:

- *Consequential amendment.*

29. CLAUSE 78

Delete sub clauses (3), (4), and (5)

Justification:

- *harvesting organs, tissues and cells sent for post mortem could be abused and in cases of medico-legal nature, it may destroy evidence that might be needed at a later day; for example, in cases of exhumation.*

30. CLAUSE 79.

Delete

Justification:

- *Because there is no requirement for certification of death before post-mortem by the council, which would create a possibility of persons alleging that organs were harvested from a patient who was still alive, and in any case, clause 75 already takes care of how organs are harvested from the dead.*

31. CLAUSE 88

- a) Amend sub clause (1)(c) by inserting the word “unjustifiable” immediately before the word “financial”

Justification:

- *Sometimes use of money is required for purposes of organ, cell or tissue transplant.*
- b) Amend sub clause (2) as follows-
- *in paragraph (a) by deleting the words “loss of earnings” and inserting the words “as may be approved by the council” at the end of the provision.*

Justification:

The bottom section of the page contains numerous handwritten signatures and scribbles. Some legible words include "Amendment" and "Bebone". There are also some numbers like "40" and "1-11" and a small "RSO" at the bottom right.

- Use of the words "loss of earnings" can easily be abused and commercialized; and use of the words "as may be approved by the Council" is to ensure quality control.

(c) Delete paragraphs (b) and (c)

Justification:

- Paragraph (b) shall be catered for in the regulations, and paragraph (c) is deleted because Consent is sought before going for any surgical procedure and the consent explains any eventualities may arise.

(d) Redraft sub clause (6) as follows-

"(6) A person who contravenes this section commits an offence and is liable to life imprisonment."

Justification:

- To provide for a more deterrent penalty.

32. CLAUSE 91.

Amend the provision by inserting a new sub clause after sub clause (4) to read as follows-

"(5) A body corporate that commits an offence under subsection (1) is liable, on conviction, to a fine not exceeding **five hundred thousand currency points.**"

Justification:

- Body corporates should be prescribed a more stringent penalty

33. CLAUSE 92. GENERAL PENALTY.

Amend the provision by substituting for the words "ten thousand currency points" with "one hundred thousand currency points or imprisonment not exceeding twelve years, or both"

Justification:

- To prescribe a more deterrent penalty.

34. CLAUSE 96. REGULATIONS

Amend sub clause (2) as follows-

Amendments

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Belone

Margaret

- a) In paragraph (a) by inserting the words "accreditation and" before the word "designation"

Justification:

- *The transplant center must first be accredited before designation.*
- b) In paragraph (f) by inserting the word "National" before the word "waiting list";
- c) By deleting paragraph (s);
- d) By inserting four new paragraphs after (o) to read as follows-
- "fees to be charged by the council"
 - "recall procedures"
 - "look back procedures"
 - "procedure for sharing of organs"

Justification:

- *To be more inclusive*
- e) Inserting a new provision after sub clause (3) to read as
- "For the purpose of this section, "Sharing of organs" means medically sanctioned movements of a body organs, tissues or cells from one organ bank to another.

Justification:

- *for clarity*

35. SCHEDULE 2.

Insert number (4) after "(3)" to read as-

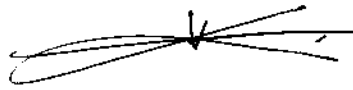




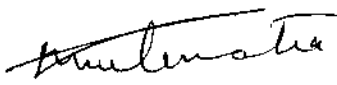

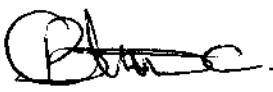
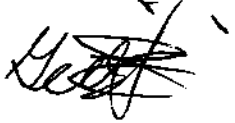
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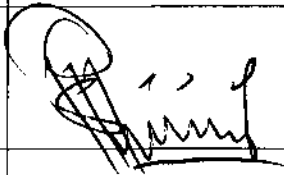
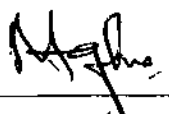
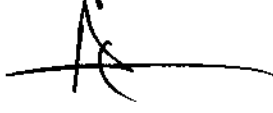
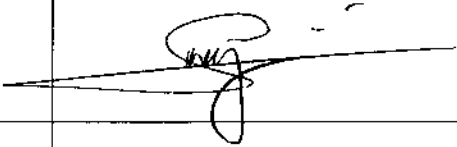


Justification:


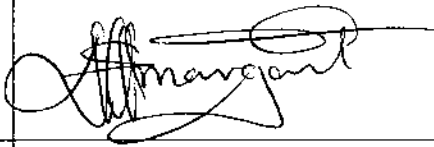


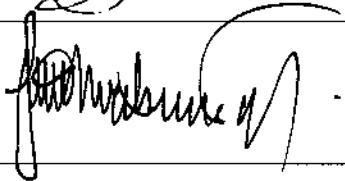
- *To be all inclusive. Storage is one of the components of transplant activities*

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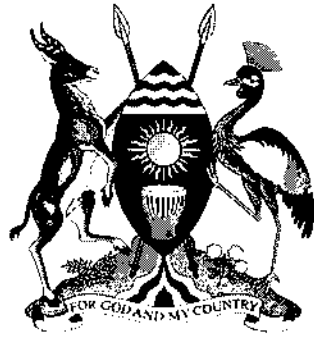
**COMMITTEE ON HEALTH - ENDORSEMENT OF THE REPORT ON THE
UGANDA HUMAN ORGAN DONATION AND TRANSPLANT BILL, 2021**

S/NO	NAME	SIGNATURE
1.	Hon. Dr Charles Ayume - Chairperson	
2.	Hon. Ssebikaali Yoweri - Vice-chairperson	
3.	Hon. Ninkusiima John Paul	
4.	Hon. Namukuta Brenda	
5.	Hon. Nakazibwe Hope Grania	
6.	Hon. Lematia Ruth Molly Ondon	
7.	Hon. Laker Sharon Balmoyi	
8.	Hon. Bebona Babungi Josephine	
9.	Hon. Chelain Betty Louke	
10.	Hon. Dr Bhoka Didi George	
11.	Hon. Atwijukire Dan Kimosho	

12.	Hon. Otingiw Isaac Ismail	
13.	Hon. Ayebare Margaret	
14.	Hon. Rutahigwa Elisa	
15.	Hon. Dr Ruyonga Joseph	
16.	Hon. Sekyanzi Benard Kirya	
17.	Hon. Eng. Irene Muloni Nafuna	
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19.	Hon. Dr Nandagire Christine Ndiwalana	
20.	Hon. Dr Kagabo Twaha Mzee	
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22.	Hon. Nanyondo Veronicah	
23.	Hon. Dr Kamara Nicholas	

24.	Hon. Dr Lulume Bayiga Michael	
25.	Hon. Col. Dr Victoria Nekesa	
26.	Hon. Auma Kenny	
27.	Hon. Makokha Margaret	
28.	Hon. Nakato Mary Annet	
29.	Hon. Dr Opio Samuel Acuti	
30.	Hon. Bahireira Tumwekwatse B Sylvia	
31.	Hon. Zawedde Victorious	
32.	Hon. Nebanda Florence Andiru	
33.	Hon. Rwaburindore Tarsis	
34.	Hon. Batuwa Timothy Lusaala	

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MINORITY REPORT ON THE HUMAN ORGAN DONATION AND TRANSPLANT BILL, 2021

SEPTEMBER, 2022

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1. INTRODUCTION

Rt. Hon. Speaker and colleague Members of Parliament, on behalf of members of the committee on Health who have signed on to this Minority Report, I would like to state from the onset that we are proud of the immense effort and work that went into the majority report which took care of many of our views and positions and indeed the law is timely to enable Ugandans take advantage of advancement in human science and medicine and will go a long way to save lives and prolong living.

On 5th July 2022, the Minister of Health tabled in Parliament the Uganda Human Organ Donation and Transplant Bill, 2021, and the same was referred to the Committee on Health in accordance with Rule 129(1) of the Rules of Procedure of Parliament.

The Bill intends to provide a legal framework that would enable carrying out of organ transplants in Uganda. The object of this Bill is to establish a legal framework for the regulation of organ, cell and tissue donation and transplantation in Uganda. The law aims at protecting the dignity and identity of every person and guarantee, without discrimination, respect for his or her integrity and other rights and fundamental freedoms with regard to donation and transplantation of organs, tissues and cells of human origin.

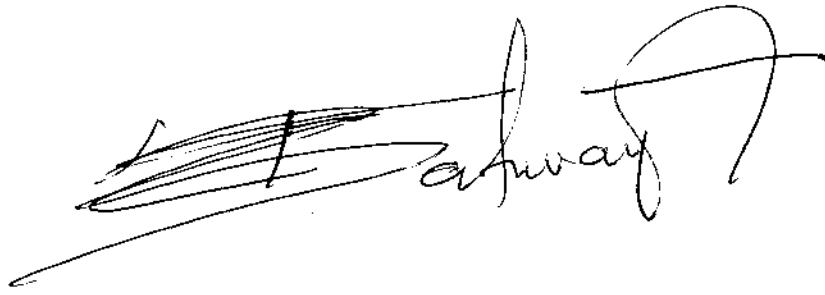
Pursuant to Rule 205 of the Rules of Procedure of the Parliament of Uganda, we hereby present dissenting opinion from the opinion of majority of the Committee.

1. AREAS OF DISSENT

We dissented with majority of the Committee on the following:

- a) Need to arrange close relations in order of ascendance for purposes of establishing who should be contacted first where consent is needed.
- b) Powers of the Minister over the Council which compromises the independence of the Council;
- c) Proposed competencies for members of the Council that leaves out critical professions and cadres that should be on the Council
- d) Tenure of the Human Organ Donation and Transplant Council
- e) Accreditation and licensing of multiple centers for organ harvesting
- f) Accreditation and licensing of multiple centers as organ banks
- g) Exporting organs
- h) Inclusion of a mechanism to protect vulnerable populations and migrant workers





3.0: DISSENTING OBSERVATIONS

3.3: Powers of the Minister over the Council which compromises the independence of the Council.

We disagreed with the majority committee on the powers of the Minister to direct the Council and the requirement as provided in the Bill to have the Council comply with the directives as a must, yet the same law provides for the independence of the Council.

Recommendation: Amend Clause 5(1) to give room to the Council to consider the directives and guidance of the Minister without talking them up by force.


3.4: Proposed competencies for members of the Council

Clause 8 of the Bill guides on the key qualifications and competencies of the people who should be members of the Council. The key competencies listed excludes a Pharmacist who are persons with expertise on drugs to guide on policy and oversight matters at the council level. Drug supply and management, drug costs, drug safety, drug interaction, drug dosing are highly technical aspects of organ transplant that need oversight and policy frameworks. Transplant patients have to take immunosuppressant medications for life which come at costs that need to be managed and currently estimated at UGX 36,000,000 per year, are exposed to drug safety concerns arising from organ replacement even where cross matched, dose adjustments due to organ variations and drug interactions for recipients with multiple ailments on a cocktail of drugs. The structure further excludes a Social Scientist on the committee, a resource needed to address the strong socio-cultural issues in Uganda's setting. The council as prescribed in the bill is a full time council with day to day responsibilities.

Recommendation: Amend Clause 8 to include a person trained as a social scientist and a pharmacist to be part of the Council.

3.5: Tenure of the Human Organ Donation and Transplant Council

We disagreed with the majority of the members on the issue of the tenure of the Council. The Bill, in Clause 10, proposes that the tenure of the Council shall be three years renewable once. We are convinced, guided by evidence available, that independence of council members is affected when they have to work for renewal of their appointments.





Recommendation: Amend Clause 10 to provide for the tenure of office to be one term of six years non-renewable.

3.6: Accreditation and licensing of multiple centers for organ harvesting

Clause 28 provides for the Council to designate a hospital as an organ transplant or donation center. We disagreed with the majority report in as far as the majority agree with the proposed law seeking to liberalize the harvesting of organs to various centers that would have satisfied certain criteria as shall be provided for by the Minister on advice of the Council. We maintain that the harvesting and banking of organs should be under the direct management and control of the Council in the different approved centers and hospitals should only be accredited to do transplanting.

Recommendation: Amend provisions of the Bill to ensure that organ harvesting is under the direct control of the Council. Specifically, Clause 28 (1) should be amended as suggested under the recommended amendments on Page 7.

3.8 Qualification for designation as transplant centres

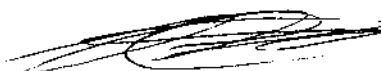
Clause 30 provides for the qualification for designation as transplant centres. We disagreed with the majority in regard to the need for the provision of a Pharmacy and a blood storage unit as one of the requirements for the transplant centre. The transplant centre will need drugs for immunosuppression during and post organ transplant. It will also require blood and other medical supplies. Whereas the clause provides for other requirements prescribed by regulation by the minister it is imperative that the minimum requirements is stipulated in the principal Act for the avoidance of doubt.

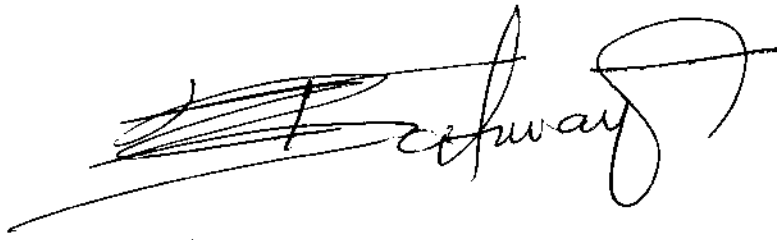
Recommendation: Amend clause 30 to include a Pharmacy and blood storage unit.

3.3 Prevention of organ, tissue or cell trafficking

Clause 88 provides for the prevention of organ, tissue or cell trafficking. Cases of vulnerable persons who have been exported abroad for labor are awash with allegations that their organs are harvested without their consent. There have been media reports of persons who are mentally incapacitated and street children being taken abroad for illegal harvesting of their organs under the disguise of medical treatment and adoption respectively. Provisions under this cause do not cater for illegal organ harvesting that is done on vulnerable Ugandan citizens and investigations being medical in nature maybe out of reach of the affected victims.

Recommendations: amend clause 88 to provide for the Minister to prescribe regulations to safeguard vulnerable persons exiting the country from exploitation and medical investigation assistance for victims of illegal organ donation.





Proposed amendments to the Uganda Human Organ Donation and Transplant Bill, 2021.

Proposed Amendment 1

Clause 5(1): Amend Clause 5 (1) by deleting the words, "... **and the council shall comply with those directions**" at the end of the clause sentence.

Justification: Clause 5(1) seems to be in conflict with clause 5(2) in as far as sub-clause 1 gives powers to the Minister to give directions and mandates the council to comply and sub clause 2 purports to guide that the directions shall not adversely affect or interfere with the independence of the council.

Proposed Amendment 2

Clause 8: Amend Clause 8 by adding the words, "**Pharmacist and social scientist**" after the word "management" at the end of the clause sentence.

Justification: The processes surrounding organ harvest and transplant, both before, during and after involve a lot to do with social behaviors and cultural adjustment. There is a lot of work to do around sensitization of the community, counselling of the donors and **donees** and cultural re-adjustment. If indeed the reasoning behind the listing of competencies required for members on the Council is to ensure successful organ donations and transplants, then the input of a social scientist on that Council is of much value.

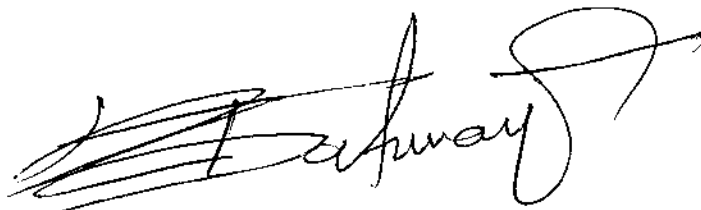
Secondly, Drug supply and management, drug costs, drug safety, drug interaction, drug dosing are highly technical aspects of organ transplant that need oversight and policy frameworks. Transplant patients have to take immunosuppressant medications for life which come at costs that need to be managed and currently estimated at Ugx 36,000,000 per year, are exposed to drug safety concerns arising from organ replacement even where cross matched, dose adjustments due to organ variations and drug interactions for recipients with multiple ailments on a cocktail of drugs. A Pharmacist, who is an expert on drugs therefore needs to be included.

Proposed Amendment 3

Clause 10: Amend Clause 10 by replacing the text with the following text, "**A member of the Council shall hold office for a non-renewable one term of six years.**"

Justification: The Organ Council can only play their role if independent. Clause 10 proposes the tenure of office for the council members to be three years renewable once. The period of three years is too short to guarantee the independence of the chairperson and the council members. The fact that they are eligible for reappointment makes it worse arguably because some of them could execute





their duties not necessarily in a manner that ensures justice, but in a way that pleases the appointing authority so as to secure a reappointment. This is exacerbated by the provision to have the members of the Council appointed by the Minister. The experience in other related bodies like Human Rights Commissions has shown that short and renewable tenures of such bodies compromise their independence. In the case of *Incal v Turkey*, the European Court held that among the concerns that made the independence of the judges in issues questionable was that their term of office was only four years and subject to renewal.

The argument that giving members of the Council a long term of six years presents challenges as they may behave any way, they want does not hold water since Clause 11 provides for termination of appointment of a Council Member.

Proposed Amendment 4

PART IV: Change title of Part IV as suggested thus; DESIGNATION OF ORGAN, TISSUE AND CELLS DONATION, TRANSPLANT CENTERS AND APPROVAL OF BANKS

Justification: The title does not capture the organ harvesting and donation bit.

Proposed Amendment 5

Clause 28 (1): Replace Clause 28(1) with the following text, "***The Council shall establish and run organ, tissue and cells donation and harvesting centers in areas and regions as the council shall deem it necessary.***"

Justification: The Committee agreed to delete Clause 28(1) since it would be discriminatory to legislate Mulago in the law, it should also apply like others. We therefore propose to have that clause provide for the provision to create organ donation and harvesting as preserve of government. Whereas organ, cells and tissue transplant can be liberalized and left to hospitals and other health care facilities, harvesting of the same should be the preserve and control of the government. This is because having multiple harvesting centers creates challenges of quality control and may fuel trafficking in organs which this law intends to curb.

Secondly, the law and World Health Organization (WHO) guiding principles emphasize that there should be no trade in organs and organs should be given to recipients free of charge which implies that governments should be in control of these organs. Unless the Council harvest these organs, it will be difficult to have control over the same yet Clause 53 of the same Bill suggests that it's the Council that shall have powers to allocate organs, tissues and cells to people on the waiting list. How shall the Council ensure allocation of organs it does not own? It will also create challenges where an organ harvested by one health facility/hospital is





required by a recipient in another hospital. What would be the motivation of private health care facilities and hospitals to invest in harvesting organs which they don't own?

Further, when hospitals both private and public are designated by the Minister as Human Organ Donation and Transplant facilities, there in lies a risk of conflict of interest. This conflict of interest envisaged to manifest in a way that; a patient in the Intensive Care Unit (UCU), on ventilation, is looked at as in imminent death rather than critically sick. Under the presumption that death is about to happen, focus may be shifted to addressing the demand of the organon recipients waiting list.


The law is liberalizing organ donation and transplant programs to include private hospitals. In the face of internationally recognized challenges of organ trafficking and transplant tourism as pronounced in the Istanbul Declaration, 2008; we should not only rely on restraining provisions in this proposed law but have systems and mechanisms that compel compliance and avert the above challenges. We therefore contend that all harvesting programs should be done by Government through the Council, and the harvested organs be distributed to designated hospitals whether public or private, in accordance with the waiting list provided for in Clause 53, for the purpose of transplanting.

We also note that this proposed law pronounces itself through many provisions on donations programs and transplant programs being nearly free of charge. However, the law does not expressly state whether the surgical procedures to effect harvesting and the consequent transplant will be free as well. We are alive to the subsisting financial burden of undergoing a surgical procedure in the premium private hospitals in this country. Unfortunately, these will be two surgical procedures (harvest and transplant) to address the therapeutic benefit of the recipient. The cost is foreseen to be discriminative. Yet, healthcare should be one of the benefits to be derived from the tax citizens pay. When government takes on the responsibility of harvesting; the hospital bill will to a great extent be manageable especially in private facilities; among other benefits of ensuring that whoever is on the waiting list gets a desired organ, tissue or regardless of his or her financial status. Since citizens are willing to donate their organs free of charge, in a cost sharing arrangement, let the Government also take over the responsibility of investing in harvesting of the organs for the benefit of all.

Proposed Amendment 6

Clause 28 (2): Delete the words "**donation and**" in the clause

Justification: This is to make it clear that designation of hospitals can only be in respect of transplanting not donation and harvesting.





Proposed Amendment 7

Clause 29: Add sub-clause 5, **"A hospital whose application is rejected as per Section 4 above shall continue implementing the recommendations of the Council until the Council is satisfied and the decision of the Council in this respect is final and not appealable."**

Justification: This is important to solve the vacuum created by the current arrangement of the law and to avoid unnecessary and costly litigation and dragging of the Council to the Courts of law.

Proposed amendment 8

Clause 30 Insert immediately after sub-clause f, a new sub-clause with the following text, a Pharmacy and blood storage unit.

Justification: The transplant centre will need drugs for immunosuppression during and post organ transplant. It will also require blood and other medical supplies. Whereas the clause provides for other requirements prescribed by regulation by the minister it is imperative that the minimum requirements is stipulated in the principle act for the avoidance of doubt. There is further no legal definition of a fully-fledged hospital in this country. The medical and dental practitioners act cross referenced in the bill only defines health unit which includes a private hospital, clinic, nursing home, maternity centre and other government units of the same nature.

Proposed Amendment 9

Clause 34: The sub-title should be amended by replacing the word "approval" with the word **"Establishment."**

Justification: In line with the proposed Amendment to have organ harvesting and storage a preserve of government, the banks should be established by the Council which shall then distribute the organs to hospitals only when they are to be used.

Proposed Amendment 10

Clause 34 (1): Replace the current text in the Bill with the following text; **"The Council shall establish banks for purposes of this Act."**

Proposed Amendment 11

Clause 34(2): Amend Clause 34(2) by replacing the current text in the bill with the following text; **"All organ, tissue and cells banks shall be operated by the Council in areas as the council may deem necessary."**

Proposed Amendment 12

Clauses 34 (3, 4, 5 and 6) Delete sub-clauses 34 (3), (4), (5) and (6)





Justification: The sub-clauses were drafted from the angle of organ, tissue and cells banks being managed by various hospitals. Where the banks are being managed by the Council, these provisions are redundant and not necessary.

Proposed Amendment 13

Clause 38(1): Amend Clause 38(1) by substituting the words "approved by the Minister" with "created."

Justification: This is to align with the change to have organ, tissue and cells banks established by the Council not as approved by the Minister.

Proposed Amendment 14

Clause 38 (4): Delete the clause

Justification: This is to align with the change to have organ, tissue and cells banks established by the Council.

Proposed Amendment 15

Clause 38 (5): Amend the text by substituting the word "approved" with "establishment of"

Justification: This is to align with the change to have organs, tissue and cells banks established by the Council and provide guidelines for the establishment of banks as shall be managed by the Council.

Proposed Amendment 16

Clause 46: Amend the clause by substituting the word "approved" with the word "established."

Justification: This is to align with the change to have organ, tissue and cells banks established by the Council.

Proposed Amendment 17

Clause 47: Amend the clause by substituting the word "approved" with the word "established."

Justification: This is to align with the change to have organ, tissue and cells banks established by the Council.

Proposed Amendment 21

Clause 49(2): Amend the clause by substituting the word "approved" with the word "established."





Justification: This is to align with the change to have organ, tissue and cells banks established by the Council.

Proposed Amendment 22

Clause 51 (1): Amend the clause by substituting the word "approved" with the word "established."

Justification: This is to align with the change to have organ, tissue and cells banks established by the Council.

Proposed Amendment 23

Clause 53(2): Delete clause 53(2).

Justification: Whereas the spirit of provision 53(2) is logical, and humane; and aware of our weaknesses in ensuring compliance, we are convinced that the need to protect our law from provisions that can be exploited to benefit organ traffickers; by far outweighs the need to pay attention to international relations.

Proposed Amendment 24

Clause 53 (5): Amend Clause 53(5) to add, "...or any other discriminatory ground" after "financial standing" to cater for discrimination on any other basis that may not be envisaged now.

Justification: Clause 53 (5) attempts to lay down grounds upon which one should not be discriminated. The list seems to be exhaustive as it does not provide room for any other ground that may not be foreseen by the law. Amending as proposed will ensure that any other form of discrimination is taken into consideration and it would be up to courts to interpret whether the act or omission qualifies to be branded as discriminatory.

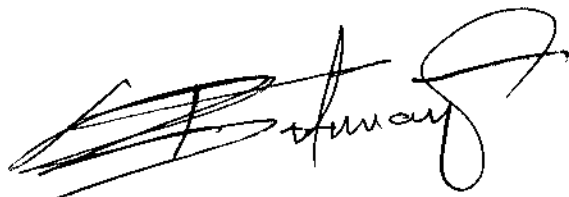
Proposed Amendment 27

Clause 86 (1): Amend the clause and delete the words, "**other than reimbursement of donation related expenses...**"

Justification: Clause 86(1) creates a window for monetary compensation or any other form of compensation for donation-related expenses. Leaving any opening for monetary compensation is likely to be abused and commercial dealings in organs and tissues will be disguised as reimbursements. The provision should be amended to completely prohibit any form of monetary or any other reimbursement. The only support a donor should expect is medical facilitation to ensure they have recovered fully to function normally.

Proposed Amendment 28





Clause 88(2): Delete Clause 88(2).

Justification: Just like in Clause 86(1), it should be clear to all donors that no monetary compensation is expected beyond medical treatment to re-instate them into a situation they were in before the operation. In short, at no single point in time should a living donor expect payment into his or her account for donating an organ.

Proposed Amendment 29

Clause 88: Insert two new sub-clauses immediately after clause (5) as follows:

New Sub-clause 1

"The Minister may by regulations prescribe measures to safeguard and protect vulnerable persons including the mentally incapacitated, street children, the unemployed, and others; from being exploited through the illegal removal of their organs as they exit the country for labor, adoption, medical treatment or other purposes."

New Sub-clause 2

"The Council shall make provisions for handling of medical complaints from victims or persons affected by organ trafficking including medical care such as rehabilitation services in a designated facility and medical investigations in an approved facility"

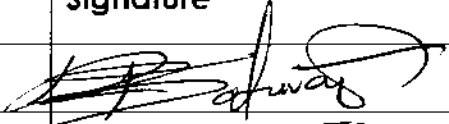
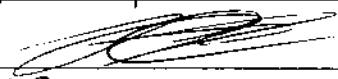
Justification: Cases of people who have been exported abroad for labor are awash with allegations that their organs are harvested without their consent. There have been media reports of persons who are mentally incapacitated and street children being taken abroad for illegal harvesting of their organs under the disguise of medical treatment and adoption respectively. This law should therefore make provisions to strengthen screening at the ports of entry via the port health facilities for any specified group of persons before exiting the country and upon return and put in other measures to safeguard them. This will help prevent but also improve detection. It will also ensure that persons affected by organ trafficking or the victims whether happening within or abroad have access to medical care for various purposes including rehabilitation or investigations due to the trauma they have undergone. Investigations should further be done only in approved facilities to avoid falsification of evidence considering syndicated nature of this crime. The human body in organ trafficking serves as the scene of crime.



CONCLUSION.

Rt. Hon. Speaker, resources have been allocated to the Committee members and two benchmarking trips to Turkey and India have been arranged this month. Our suggestion is that the committee report would be enriched with knowledge and experiences derived from the exposure from those two countries where such a law and practice is in place. Undertaking the bench marking trips after we have passed the law is like putting the cart before the horse. We therefore request you, Rt. Hon. Speaker and Honourable Colleagues, to consider and support the Minority Report.

MEMBERS OF THE COMMITTEE ON HEALTH WHO SIGNED THE MINORITY REPORT ON THE HUMAN ORGAN DONATION AND TRANSPLANT BILL, 2021.

SN	Name	Signature
01	Batuwa Timothy Lusaly	
02	Dr. Bayarasa Michael Kalene	
02	Dr. Samuel Opio Aziti	