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THE REPUBLIC OF UGANDA
IN THE HIGH COURT OF UGANDA AT KAMPALA
(CIVIL DIVISION)

MISCELLANEOUS CAUSE NO.429 OF 2019

- 1. CENTER FOR HEALTH, HUMAN RIGHTS AND DEVELOPMENT (CEHURD)
 - 10 2. COMMUNITY HEALTH AND INFORMATION NETWORK (CHAIN)
 - 3. UGANDA ALLIANCE OF PATIENTS’ ORGANIZATION (UAPO)::: APPLICANTS
- VERSUS

- 1. UGANDA NATIONAL HEALTH RESEARCH ORGANIZATION (UNHRO)
- 2. UGANDA NATIONAL COUNCIL FOR SCIENCE AND TECHNOLOGY (UNCST)
- 15 3. PROFESSOR SARAH KIGULI::: RESPONDENTS

BEFORE: HON. JUSTICE ESTA NAMBAYO

RULING

The Applicants, Center for Health, Human Rights and Development (CEHURD), Community Health and Information Network (CHAIN) & Uganda Alliance of Patients’ Organizations (UAPO), (hereinafter referred to as the 1st, 2nd & 3rd Applicants respectively) brought this application under **Article 50 (2) of the Constitution, Rule 7 of the Judicature (Fundamental & Other Human Rights and Freedoms) (Enforcement Procedure) Rules, and Section 98 of Civil Procedure Act**, against the Uganda National Health Research Organization (UNHRO), Uganda National Council for Science and Technology (UNCST) & Professor Sarah Kiguli, (hereinafter referred to as the 1st, 2nd & 3rd Respondents respectively), seeking for declarations and orders of this court that: -

- 1. The act of approving and clearing the Children’s Oxygen Administration Strategies Trial (COAST) protocol by the 1st & 2nd Respondents without ascertaining that it caters for the care needed for critically ill patients is a violation of the right to health and a threat to the right to life contrary to Articles 22 (1), 8A (1), 45 and Objectives XIV (b) and XX of the National Objectives and Directive Principles of State Policy of the Constitution of the Republic of Uganda, 1995 as amended.
- 2. The failure of the Respondents to follow the Health Service Commission Act, 2001 and the Guidelines for Research involving Humans as Research Participants on the

35 responsibility of health professionals in research and in the care and treatment for study
participants in the clearing, approval and conduct of the Children's Oxygen
Administration Strategies Trial (COAST) is an infringement on their obligations to respect
and protect the rights of children, the right to dignity and freedom from cruel, inhuman
and degrading treatment and a threat to the right to life contrary to Articles 20, 22 (1),
40 24, 34 (3), 34 (7) and 44 (a) of the Constitution of the Republic of Uganda, 1995 as
amended.

3. The failure by the 3rd Respondent to obtain a certificate of approval from National Drug
Authority prior to conducting the Children's Oxygen Administration Strategies Trial
(COAST) is a threat to the right to health and life contrary to 22 (1), 8A (1), 45 and
45 Objective XIV (b) and XX of the National Objectives and Directive Principles of State
Policy of the Constitution of the Republic of Uganda, 1995 as amended.
4. A Permanent injunction stopping the Children's Oxygen Administration Strategies Trial
(COAST) from being conducted in Uganda.
5. An Order for Uganda Medical and Dental Practitioners' Council (UMDPC) and National
50 Drug Authority (NDA) to investigate and file a report to this Honourable Court and the
parties within 1 (one year from the date of Ruling on the effects of the COAST in each of
the research sites and make recommendations of reparation.
6. An Order for Uganda Human Rights Commission (UHRC) and the Equal Opportunities
Commission (EOC) to make a human rights impact assessment of the COAST and file a
55 report to this Honourable Court and the Parties within 1 (one) year from the date of
Ruling.
7. An Order that this being a public interest litigation matter, each party bears its own costs.

The grounds for this application are premised on the affidavit of Nakibuuka Noor Musisi &
Regina Mariam Namata Kamoga but briefly are that: -

- 60 1. In 2016, the 1st & 2nd Respondents approved the Children's Oxygen Administration
Strategies Trial (COAST) protocol for clinical research involving children aged between 28

days and 12 years, admitted to hospital with respiratory distress complicated by hypoxia also known as Oxygen deficiency with the 3rd Respondent as the principal investigator.

65 2. This clinical trial started in 2017 and it is being conducted in sites including; Mulago National Referral Hospital, Mbale Regional Referral Hospital and Soroti Regional Referral Hospital and it is sponsored by the Imperial College, London in partnership with Joint Global Health Trials Scheme (Medical Research Council Department for International Development and Wellcome Trust; MR/L004364/1 and 102231, respectively.

70 3. The 3rd Respondent started conducting this clinical trial without first obtaining a certificate of approval from National Drug Authority (NDA) which is a requirement prior to conducting any clinical trial on pharmaceuticals in Uganda of which oxygen is listed as a pharmaceutical.

75 4. The Children's Oxygen Administration Strategies Trial (COAST) is an open, multi-centre, fractional Randomised Controlled Trial (RCT) of 4,200 participants, aged between 28 days and 12 years, admitted to hospital with respiratory distress complicated by hypoxia also known as oxygen deficiency.

80 5. The COAST is investigating the best oxygen delivery strategies to reduce mortality and morbidity in African children with respiratory distress complicated by hypoxia in hospital and the procedure is done by evaluating two link components of oxygen delivery to establish whether liberal oxygenation is superior to permissive hypoxia and to establish whether high flow oxygen delivery is better than low flow oxygen delivery.

6. During the course of the COAST, the children who are the study participants were critically ill paediatric patients with a diagnosis of severe pneumonia in addition to other diagnoses such as impending cardiac arrest, severe anaemia and others.

85 7. These children were randomly subjected to 2 (two) stratum where in stratum 1 (one) they were subjected to high flow oxygen arm or the low flow oxygen arm, stratum 2 (two) had study participants being subjected to permissive hypoxia as well as arms having high and low flow oxygen rates.

8. Several concerns were raised about the efficacy of the clinical trial particularly about the low flow oxygen arm and the permissive hypoxia arm where the study participants were given no oxygen at all which is below the recommended standards of care.

9. A number of the study participants were also not provided appropriate care for life threatening diagnoses that presented with the hypoxia and were largely only treated for the hypoxia which was detrimental to their health and lowered their chances of getting better.

10. That a team of intensivists formed a committee at Mulago National Referral Hospital to review 17 adverse report forms in the COAST and their report revealed that the number of study participants who died were 7.

11. Following these concerns, the 2nd Respondent halted the clinical trial in 2018 but it was ultimately restarted without addressing the concerns.

12. The Respondents did not follow the recommendations for research on human subjects as stated in the Declaration of Helsinki, the ICH Harmonized tripartite guideline for Good Clinical practice (E6 (R1), 1996), the National Drug Policy and Authority (Conduct of Clinical Trials) Regulations, 2014 and the National Guidelines for Research involving Humans as Research Participants.

13. The actions of the Respondents have resulted into violation of fundamental human rights of study participants as enshrined in the Constitution of the Republic of Uganda, 1995 as amended.

14. It is just and equitable that the declarations and orders sought in this suit be granted.

The Respondents filed their affidavits in reply opposing this application.

Brief facts

The brief facts of this case are that in 2016, the 1st and 2nd Respondents approved the 3rd Respondent as Principal Investigator in a study concerning children admitted to hospitals with severe pneumonia. The overall objective of the study was to reduce the mortality and morbidity

115 rates of children suffering from severe pneumonia. The study code named the Children's Oxygen
Administration Strategies Trial (COAST) covers children aged between 28 days to 12 years with
oxygen deficiency, (hypoxia) at Mulago National Referral Hospital and Mbale, Soroti and Jinja
Regional Referral Hospitals.

It is the Applicants' claim that during the course of the study trials, a number of the study
120 participants were not provided appropriate care for life threatening diagnoses that presented
with the hypoxia and were largely only treated for the hypoxia which was detrimental to their
health and lowered their chances of getting better. The Applicants are dissatisfied with
continuation of the COAST study on grounds that it violates the study participants right to health
and is a threat to their right to life, among other rights and have now filed this suit under Article
125 50 of the 1995 Constitution of Uganda, seeking for declarations, orders and a permanent
injunction stopping the COAST study from being conducted in Uganda.

Legal representation

Learned Counsel Kenneth Ssebabi represents the Applicants while the Learned Counsel
Muhumuza Phillip is for the 1st Respondent, Learned Counsel Specioza Tayebwa is for the 2nd
130 Respondent and Counsel Isaac Bakayaana is for the 3rd Respondent. Counsel have filed written
submissions as directed by this court.

Issues set down for determination are: -

1. **Whether the approval and clearance of the COAST protocol by the 1st and 2nd
Respondents without ascertaining that it caters for the care needed for critically ill patients
135 is a violation of the right to health and a threat to the right to life provided for under
Articles 22 (1), 8A (2), 45 and Objectives XIV (b) and XX of the National Objectives and
Directive Principles of State Policy of the Constitution of the Republic of Uganda, as
Amended.**
2. **Whether the clearance, approval and conduct of the COAST by the Respondents without
140 adherence to responsibilities of health professionals on care and treatment of study
participants laid out in the Health Service Commission Act, 2001 and Guidelines for
Research involving Humans as Research Participants is a violation of their obligation to**

145 respect and protect the rights of children, the right to dignity, freedom from cruel,
inhuman and degrading treatment and a threat to the right to life provided for in Articles
20, 22 (1), 24, 34 (3), 34 (7) and 44 (a) of the Constitution of the Republic of Uganda,
1995 as Amended.

150 3. Whether failure of the 3rd Respondent to obtain a certificate of approval from National
Drug Authority prior to conducting the COAST study is a violation of the right to health
and a threat to the right to health and life provided for under Articles 22 (1), 8A (1), 45
and Objectives XIV (b) and XX of the National Objectives and Directive Principles of State
Policy of the Constitution of the Republic of Uganda, as Amended.

4. Who is responsible for approval of clinical trials in Uganda?

5. Whether the Applicants are entitled to the remedies sought.

Preliminary objection

155 In his submissions, Counsel for the 2nd Respondent raised three preliminary objections that: -

- i. This matter is moot as it has been over taken by events.
- ii. The Applicants' affidavits do not comply with the requirements of the law.
- iii. The cause is incompetent for failure to add necessary parties

Submissions on the preliminary objections

160 On the objection that this application is moot and over taken by events, Counsel referred this
court to paragraph 9 of the 2nd Respondent's affidavit in reply and annexure PN5 thereto and
explained that the study trial was permanently halted by the Trial Steering Committee, its
sponsors and funders in February 2020 and as such, it is no-longer necessary to grant a
permanent injunction as sought by the Applicants. He relied on the case of *Kwesiga William &*
165 *Ors –v- Ssenyonga Haruna & 7 others SCCA No.43 of 2021*; where court held that;

*“A matter is deemed moot when it no longer has practical significance, is hypothetical or
academic; or where the decision arising there from will not have the effect of resolving the
controversy affecting the parties.”*

Counsel further relied on the case of *Julius Maganda -v- National Resistance Movement, HCMA*
170 *No. 154 of 2010 (unreported)*; where court noted that;

“Courts of law do not decide matters where no live disputes between the parties are in existence. Courts do not decide cases or issue orders for academic purposes only. Court orders must have practical effects. They cannot issue orders where the issues in dispute have been removed or merely no longer exist”.

175 He prayed that on the above grounds this application be dismissed.

In reply, counsel for the Applicant submitted that the COAST trial has never been officially stopped. That even if it was stopped, it does not erase the fact that human rights violations were occasioned during the conduct of the said trial. Counsel explained that under stratum 2 of the trial, the participants were subjected to permissive hypoxia as well as arms having high and low oxygen rates below the recommended standards which resulted into deaths, and as such, the children were denied their right to health and life. He relied on the case of *Patricia Asero Ochieng & 2 Ors. -v- Attorney General, High Court of Kenya Petition No. 409 of 2019 (2012) eKLR* and emphasized that the conduct of the COAST trial occasioned ethical and human rights violations that cannot be erased just because the trial is now alleged to be moot. He invited this Court to overrule the objection and hear this case on the merits.

Analysis

In their application, the Applicants seek for a number of orders and declarations. The above objection is specifically addressed to the prayer of a permanent injunction stopping the study from being conducted in Uganda. Counsel for the 2nd Respondent informed Court that the study has already been stopped.

I have looked at paragraph 13 of the 2nd Respondent’s affidavit in reply where the deponent, Peter Ibale Ndemere, (PhD) the Executive Secretary of the 2nd Respondent, states that; “implementation of the study has been halted by the study’s Trial Steering Committee pursuant to the directives of the 2nd Respondent and SOMREC, (School of Medicine Research Ethics Committee), premised on evaluation and monitoring.”

Annexure ‘PN6’ to the 2nd Respondent’s affidavit in reply, is a letter dated 16th /1/2020, by the Chairperson SOMREC, Assoc. Prof. Ponsiano Ocama. Prof. Ocama states in the last paragraph of his letter addressed to the 3rd Respondent that;

200 'the study recruitment should be halted immediately until the protocol has been amended as per the monitoring report dated May, 2019 and the UNCST letter dated 4th July, 2019 to the COAST Country PI.'

In the last line of this letter, he allows the study team to continue with follow – up and provision of care for the already recruited participants.

205 Annexure 'PN5' to Peter Ibale's affidavit in reply is another letter dated 22nd February, 2020, signed by the 3rd Respondent who is the Principal Investigator of the study together with the Chief Investigator of the study. Under the second last paragraph of their letter, they state that the accusers have now turned to using the media and court.

In the last paragraph of the letter, the 3rd Respondent and the Chief Investigator of the program state that; 'we hope that the Committee will permit expedite review of the amended protocol so
210 that we are permitted to continue on enrolment into COAST nutrition'.

My understanding of the statements in the annexures referred to above is that the study was only suspended/halted. There is no permanent injunction issued against the study as submitted by Counsel for the 2nd Respondent. Therefore, I find no merit in this preliminary objection and do hereby over rule it.

215 **Objection No. ii: The second objection is that the Applicants' affidavits do not comply with the requirements of the law.**

Counsel for the 2nd Respondent submitted that both deponents in the affidavits in support of the application are not medical professionals and lack experience in the medical treatment of hypoxic Children, or any demonstrable knowledge on what constitutes the appropriate medical
220 standard of care of such children. That their affidavits are based on their beliefs.

Counsel submitted that the Applicants' supporting affidavits without their knowledge, cannot on their own prove the allegations against the Respondents. That the evidence presented by the Applicants is hearsay gathered from a report of a meeting which the two deponents did not attend and yet none of the people who attended the meeting filed an affidavit to provide court
225 with firsthand information of the contents of the report. Counsel relied on *Order 19 Rule 3(1) of the CPR* and the cases of *Male Mabirizi –v- AG SCCA No. 7 of 2018; and AG and Anor –v- Human Rights Awareness and Promotion forum HCMA No. 482 of 2020* and prayed that the two affidavits in support of the application be expunged from record for failure to comply with the law in as far as they contain hearsay information.

230 In reply Counsel for the Applicants relied on a letter dated 4th July, 2019 by the 2nd Respondent to the 3rd Respondent stating that they observed that interruption of oxygen therapy to randomize participants and the abrupt reduction in oxygen flows at 48 hours post randomization as stated in the study protocol and confirmed during the monitoring visit are not standard practices, are unethical and may be associated with instant worse outcomes.

235 Counsel also relied on the minutes of the task force committee review of the trial study held on the 23rd April, 2018 (appendix V) where two concerns were raised by Dr. Nakwagala and the Mulago intensivists team members that the study design which included participants randomized to the no oxygen arm was unacceptable because participants in this study arm were being denied the standard care for respiratory distress complicated by hypoxia and; secondly that the study
240 team did not comply with the study protocol and that there were instances when the study team did not monitor participants adequately and there was no appropriate action taken when the participants' clinical progress was unsatisfactory.

Counsel submitted that indeed the COAST study that the 2nd Respondent approved and was carried out occasioned several ethical and human rights violations to the children and this fact
245 cannot simply be erased. He prayed that this court be pleased to overrule the objections so that the matter is heard on the merits and the declarations be granted as sought by the Applicants.

Analysis

*Order 19 rule 3 (1) of the CPR provides that affidavits shall be confined to such facts as the deponent is of his or her own knowledge to prove, except on interlocutory applications, on
250 which statements of his or her belief may be admitted, provided that the grounds thereof are stated.*

My understanding of the above provision of the law is that an affidavit must be sworn by someone who possesses knowledge of the facts stated in the affidavit, except in interlocutory applications. Where the affidavit contains personal knowledge and hearsay only averments
255 containing personal knowledge will be considered. The averments that are offensive must be expunged from the affidavit. *(See Rtd. Col. Dr. Kizza Besigye -v- The Electoral Commission & Another, Presidential Petition No. 1 of 2001.*

In this case, it is contended by Counsel for the 2nd Respondent that the facts deposed to by the deponents of the affidavits in support of the application were not in their personal knowledge
260 and as such, their depositions are hearsay and should be struck out.

I have looked at the affidavit in support of the application by Ms. Nakibuuka Noor Musisi. Ms. Nakibuuka states in paragraph 1 of her affidavit that she is a human rights lawyer by training and the Director of programs of the 1st Applicant. In paragraph 9 of her affidavit in support of the application, she states that;

265 *‘during the course of the COAST trial, the Children who are the study participants are critically pediatric patients with a diagnosis of severe pneumonia in addition to other diagnoses such as impending cardiac arrest, severe anemia and others.’*

There is no source of knowledge provided for this information attached. She then repeats the same thing in paragraphs 10, 11, 14, 15, 16, 17, 22, 23, 28 and 35; giving information without her
270 source of knowledge.

The second deponent, Regina Mariam Namata Kamoga is a teacher by profession, she holds a Master’s degree in Public Administration and Management; and a Post Graduate Diploma in Project Planning and Management. Ms. Namata makes her statements in paragraphs 7, 8, 9, 10, 11,12, 13, 14,15,17, 20, 23, 25, 26,27 and 28 on medical issues and the COAST study without any
275 source of knowledge. For instance, in paragraph 28 she states that;

‘that I know that the 3rd Respondent is responsible for the adequate and safe care of subjects during the trial and for ensuring that appropriate medical care and relevant follow –up procedures are maintained before and after the trial for a period that is dependent upon the nature of the disease and the trial and the interventions made.’

280 Ms. Namata does not work at Mulago and /or with the 3rd Respondent and has not indicated to this court how she came to get this information about the 3rd Respondent. Without any backup document, I would find that this, like the rest of the paragraphs cited above, is not within the deponents’ knowledge and as such inadmissible as evidence.

In paragraphs 12, 13, 18, 19 and 21, Ms. Nakibuuka Musisi refers to reports from Mulago
285 National referral hospital on COAST and reports of the review meeting. She was not one of the people who made these reports and none of the members who made the reports swore an affidavit. I find all the said paragraphs offending and are hereby struck out.

Having struck out the offending paragraphs, I find that the remaining paragraphs cannot support this application which I now dismiss from court.

290 **Costs.**

In *Wambugu –v- Public Service Commission 1972 (E.A.) 296*, court noted that;

295 *“It is a well settled principal that costs follow the event unless the court orders otherwise for good reason. The discretion accorded to the court to deny a successful party costs of litigation must be exercised judicially and for good cause. Costs are an indemnity to compensate the successful litigant the expenses incurred during the litigation. Costs are not intended to be punitive but a successful litigant may be deprived of his costs only in exceptional circumstances.”*

In this case, I am of the considered view that the interest of justice requires that the Court exercises its discretion to award costs to the Respondents and order that the Applicants pay costs to the Respondents.

300 I so order.

Dated, signed and Delivered by mail at Kampala, this 29th day of September, 2023.

Esta Nambayo

JUDGE

305 **29th /9/2023.**