

REPUBLIC OF KENYA
IN THE HIGH COURT OF KENYA NAIROBI
CIVIL DIVISION
HCCC E399 OF 2010

**PETER & IDA (Suing as Legal Representatives of
the Estate of Jennifer - Deceased)
PLAINTIFFS**

**ARCHDIOCESE OF NAIROBI REGISTERED TRUSTEES
DR. LILLIAN
DR. MUCHAI.....
DEFENDANTS**

JUDGMENT

A. Introduction

1. The Plaintiffs instituted this suit seeking damages under the Law Reform Act and the Fatal Accidents Act arising from the death of the deceased, Jennifer, who died on 14.08.2008 while admitted at the 1st Defendant's hospital.

It is not disputed that the deceased was an expectant mother aged 40 years who presented with reduced fetal movement and was diagnosed with mild pre-eclampsia. She was admitted for monitoring and induction of labour. She was administered Cytotec orally at 3.00 am. Approximately thirty minutes later she collapsed and died despite resuscitation efforts.

The core dispute is whether the administration of Cytotec, particularly orally and while unregistered in Kenya, constituted negligence and whether it caused the death.

B. Issues for Determination

2. The overarching issue is whether the Plaintiffs have proved their case on a balance of probabilities.

More specifically:

- 1. Whether the Defendants owed the deceased a duty of care**
- 2. Whether the Defendants breached that duty**
- 3. Whether the breach caused or materially contributed to the death**
- 4. Whether the Plaintiffs are entitled to damages and if so, quantum**

C. Duty of Care

3. There is no dispute that the deceased was admitted and treated at the 1st Defendant hospital by the 2nd and 3rd Defendants. The doctor-patient relationship establishes a clear duty of care. A medical practitioner must exercise reasonable skill and care expected of an ordinary competent practitioner in similar circumstances. This element is satisfied.

D. Whether There Was Breach of Duty

4. The Plaintiffs allege negligence in:
 - **Use of Cytotec, which was not registered in Kenya**

- ***Oral administration of Cytotec instead of the vaginal route***
- ***Inducing labour despite mild blood pressure***
- ***Failure to manage blood pressure adequately***

Use of an Unregistered Drug

5. It is undisputed that Cytotec was not registered for use in Kenya at the time. The Medical Board reprimanded and punished the doctors for its use. However, a regulatory breach does not automatically amount to civil negligence. The question is whether its use fell below the standard of a reasonably competent gynecologist in 2008.

Evidence from DW2 and DW4 was that:

- ***Cytotec was widely used globally and locally, including at KNH***
 - ***It was readily available***
 - ***It had been used successfully in other patients***
 - ***Two patients used it the same day without incident***
6. The Court notes that off-label or unregistered use does not automatically establish negligence if such use is supported by accepted medical practice.

The Plaintiffs did not produce evidence of a statutory prohibition criminalizing its use, only that it was unregistered. Thus, the mere fact of non-registration, without more, does not conclusively establish breach of duty in negligence. The issue of registration of pharmaceutical products is, in essence, an administrative and regulatory function falling within the mandate of the relevant statutory authority.

Registration governs market authorization and regulatory compliance. It does not, in itself, determine the clinical appropriateness of a drug where evidence demonstrates that the drug was already in circulation and in active use within medical institutions in the country at the material time.

7. The evidence before this Court shows that Cytotec was available in the Kenyan market and was being administered in public referral facilities, including teaching hospitals. That state of affairs reflects a systemic regulatory lapse rather than an isolated clinical impropriety attributable solely to the treating physicians. A practitioner operating within an established medical environment, where a drug is openly procured, stocked and routinely utilized, cannot automatically be said to have fallen below the standard of care merely because the regulatory authority had not formally completed the process of registration.

Negligence in medical practice is assessed against the standard of a reasonably competent practitioner acting in similar circumstances. It is not measured by retrospective administrative irregularities unless it is shown that the practitioner knew, or ought reasonably to have known, that the drug's use was prohibited or inherently unsafe. No such evidence was placed before this Court.

Route of Administration

8. PW2 testified that Cytotec ought to have been administered vaginally and not orally due to its side effects. However, it is

necessary to examine the probative weight of that testimony within the proper context of medical specialization.

PW2 is a pathologist. His expertise lies in post-mortem examination and determination of cause of death. While he is undoubtedly a medical doctor, his area of specialization does not extend to obstetrics and gynecology, particularly the clinical decision-making involved in induction of labour. The administration route of labour-inducing agents falls squarely within the domain of obstetric practice.

9. In contrast, DW2 is a practicing gynecologist who directly managed the deceased, and DW4 is a gynecologist with over twenty years' experience. Both testified that oral administration of Cytotec was an accepted and commonly used method of induction in 2008, both locally and internationally. Their evidence addressed not merely theoretical pharmacology but practical obstetric application.

Where the Court is confronted with conflicting expert opinions, the weight to be attached depends on the expert's qualifications, area of specialization, and experience in the specific field in issue. The question before the Court is not the general pharmacological properties of the drug, but whether the mode of administration in obstetric practice fell below acceptable medical standards.

Under the **Bolam test**, a doctor is not negligent if acting in accordance with a practice accepted as proper by a

responsible body of medical professionals skilled in that particular art. The relevant “art” in this matter is obstetrics and gynecology, not pathology.

- 10.** The defendants testified that cytotec, although unregistered drug in Kenya, was widely used to induce labor. This evidence was not challenged by the Plaintiff nor was there any evidence that the drug was illegal in Kenya. The testimony of the pathologist on the the cause of death is acceptable because he is an expert to determine the cause of death but however, the issue as to whether the obstetric treatment could produce such effects falls on the gynecologists. On the issue of the choice as to whether administering cytotec vaginally instead of orally was unprocedural, it is a fact that is determined gynecologist and not a pathologist. The plaintiff did not call a gynecologist to rebut the evidence of two gynecologists called by the Defendant. The crucial question on this procedure can only be challenged by fellow gynecologists and not a pathologist and besides both vaginal and oral administration of the drug is acceptable in Kenya. In simple terms, the pathologist decides what killed the patient and a gynecologist decides whether the obstetric treatment could have caused the death of a patient. In this case the two gynecologists testified that the administration of cytotec does not cause coronary thrombosis. A decision of a pathologist that a drug and in this case cytotec triggered coronary thrombosis must be measured against the evidence of gynecologist and for the

court to believe it, it must be supported scientifically to mount a reasonable challenge against the evidence of a gynecologist.

Timing of death;

- 11.** The patient passed on 30 minutes after administration of cytotec does. This may raise suspicion that the drug might have caused the death but that alone is not enough and cannot rule out the possibility of coincidental death. There must be evidence to prove direct causation because coincidental death happens sometimes.
- 12.** The board reprimanded the hospital and the doctor who is a defendant in this matter. The decision of the board is persuasive and not binding to this court. The reprimand issued by the board may be in respect to non-regulatory compliance but does not prove negligence per se. In this matter the drug used had not been registered in Kenya. The plaintiffs did not produce the details of the board's deliberations for this court to probe it further since the board was composed of experts. Their opinions specifically as to whether cytotec was the cause of coronary thrombosis would have been important in this case. Doctors are normally judged based on the knowledge they possess at the time and not based on hindsight. This is because medicine is a progressive profession that does not rest or is not fully discovered and so it is better to judge a doctor for what he knew and what was available at the time so long as his action

was based on a widely acceptable practice bereft of negligence.

13. A professional is guided by the principle of contemporaneous law which means that he is judged based on the existing law and standard practice and not based on the later developments.

14. The Plaintiffs did not call an independent obstetrician or gynecologist to controvert the testimony of DW2 and DW4. Consequently, the assertion by PW2, whose specialization lies outside obstetric clinical management, cannot displace the evidence of two specialists practicing in the relevant discipline.

Accordingly, the Court is not persuaded that oral administration of Cytotec, in the circumstances prevailing in 2008, fell below the standard of care expected of a reasonably competent obstetrician. Breach on this ground is therefore not established on a balance of probabilities.

Induction Despite Mild Hypertension

15. Evidence shows the deceased had pre-eclampsia, albeit mild. PW2 acknowledged that induction was not wrong. Even he stated that the decision to induce was proper, save for the use of Cytotec.

Thus, the decision to induce labour cannot be termed negligent.

E. Causation

16. This is the most critical issue.

PW2 concluded that:

- ***Cause of death: coronary thrombosis***
- ***Pre-eclampsia was present***
- ***Cytotec aggravated the condition***
- ***Death occurred shortly after ingestion***
- ***The drug was a contributing factor***

DW2 and DW4 testified that:

- ***Coronary thrombosis is sudden***
- ***It cannot be predicted***
- ***Cytotec does not cause coronary thrombosis within 30 minutes***
- ***Side effect is low blood pressure, not high blood pressure***
- ***The deceased likely had undiagnosed arterial disease***

The Court must determine whether the Plaintiffs proved, on balance of probabilities, that Cytotec caused or materially contributed to the death.

17. The post-mortem cause of death was coronary thrombosis. That is a blood clot in the coronary arteries. No evidence was led showing Cytotec causes coronary thrombosis. Even PW2 did not conclusively state that Cytotec causes thrombosis, only that it aggravated high blood pressure. Further, PW2 admitted the deceased had high blood pressure and that pre-eclampsia was present.

18. DW4 gave expert testimony that 95% of heart attacks occur at childbirth and that thrombosis is sudden and unpredictable. The fact that death occurred 30 minutes after

ingestion is a temporal proximity. Temporal proximity alone does not establish causation.

19. The Plaintiffs were required to prove that:

- ***But for the administration of Cytotec, the deceased would not have died, or***
- ***That it materially contributed to the death.***

The evidence falls short of that threshold. The cause of death was coronary thrombosis. The link between Cytotec and thrombosis was not medically established with sufficient certainty.

Accordingly, causation is not proved on a balance of probabilities.

F. Standard of Proof

The burden remained on the Plaintiffs throughout. While the Board reprimanded the doctors, disciplinary findings are not binding on this Court and do not substitute proof of negligence and causation in civil proceedings.

The Plaintiffs have proved:

- ***The drug was unregistered***
- ***Death occurred shortly after ingestion***

They have not proved:

- ***That oral administration fell below an acceptable standard***
- ***That Cytotec caused coronary thrombosis***
- ***That the deceased would probably have survived absent the drug***

G. Conclusion on Liability

The Court finds:

- 1. Duty of care existed**
- 2. Breach of standard of care has not been established to the required standard**
- 3. Causation has not been proved on a balance of probabilities**

Accordingly, negligence is not established.

H. Quantum

20. Having found no liability, damages would ordinarily not arise. However, had liability been established, the Court would have considered:

- **Pain and suffering**
- **Loss of expectation of life**
- **Loss of dependency**
- **Special damages of Kshs 196,800 subject to strict proof**

Given the deceased was a lecturer, breadwinner and mother, dependency would have been substantial. But in the absence of liability, these do not arise.

21. Before taking leave of this matter, this Court cannot fail to acknowledge the profound tragedy that underlies these proceedings. A life was lost, a life that was carrying another life. The loss of a mother and her unborn child is immeasurably painful and deeply regrettable. Death in such circumstances naturally invites questions and a search for reasons. Yet, however much we may strive to understand or

attribute cause to every death, the law recognizes that not every unfortunate or devastating outcome is the product of negligence. Medicine, by its very nature, carries inherent risks, and even the most diligent care cannot guarantee preservation of life in every circumstance. While the passing of the deceased and her unborn child is a tragedy that should never be treated lightly or excused, this Court must remain guided not by sympathy, but by evidence and established legal principles. The law does not impose liability merely because an adverse outcome has occurred.

The Plaintiffs have also sought general damages for the loss of the unborn child. Having found that medical negligence has not been established against the Defendants, the Court must now consider the legal consequence of that finding in relation to this particular head of claim.

- 22.** The claim for loss of the unborn child is anchored on the alleged negligent acts and omissions of the Defendants. In law, a claim in tort for wrongful death, whether under the Law Reform Act or the Fatal Accidents Act, presupposes proof of actionable negligence or other wrongful conduct. Liability is the foundation upon which damages rest. Where negligence is not established, no compensatory damages can arise.
- 23.** The evidence before Court demonstrates that the fetus was alive at the time of admission and that its demise occurred following the mother's sudden collapse. There was no

separate or independent act directed at the fetus. The alleged loss of the unborn child is therefore inseparable from the alleged negligent management of the deceased mother.

- 24.** Having found that the Plaintiffs have failed to prove breach of duty and causation in respect of the mother's death, it necessarily follows that no liability attaches in respect of the unborn child. Damages cannot be awarded in the absence of established fault.

Further, it is worth noting that under Kenyan law, recovery under the Fatal Accidents Act is limited to dependants of a deceased person. An unborn child, unless born alive, does not acquire separate legal personality capable of founding an independent action in negligence. The claim herein was not framed as a statutory claim under specific legislation addressing prenatal injury, but rather as part of the negligence claim against the Defendants.

- 25.** In the circumstances, and in the absence of proof of actionable negligence, the claim for general damages for loss of the unborn child must fail.

Breach of duty of care for administering unregistered drug

- 26.** The evidence on record is that the drug used (cytotec) was unregistered in Kenya although this drug was ultimately registered after the unfortunate incident. I have already determined that though the drug was unregistered, it did not lead to the unfortunate death of a mother and unborn baby

as per the evidence adduced. The issue as to the actual cause of death is not the only issue for consideration in this suit because this court must address lack of adherence to statutory requirements that has clearly been breached by the defendants. The decision by the defendant to use unregistered drug attracts stringent responsibilities that must be met and the key one is to get a consent from the patient or in this case the Plaintiff who was the husband of the deceased. The deceased or her husband had a right to know that unregistered drug was going to be administered otherwise the administration of unregistered drug would violet the patient's autonomy and generally the acceptable medical standards. It would deprive the Patient's or her husband's right to know that unregistered drug was going to be used against the law to an extent that the patient could not make an informed decision. However, I hasten to note that an award under this limb must be pleaded and proved- it cannot be introduced in anyway even through submissions or be part of "other prayers that the Court may deem fit". This is because the defendant did not have the opportunity to testify as to whether consent was granted or not since the issue was not canvassed extensively during trial thus denying it a fair trial. The other instant where unregistered drug may be used is where there is no other alternative drug- and this is not the case here. The defendant was bound to justify its decision to use the unregistered drugs with the evidence that there was no alternative drug.

The conclusion;

27. The onset of the above is that administration of cytotec did not lead to the very sad death of the deceased and her unborn child. The defendants used unregistered drug to induce Labour without explanation of their decision like lack of alternative drug and were fined and reprimanded by the medical board. In other words, the defendants are the cause of this suit. The plaintiff had a right to seek a civil remedy for their actions or in other words the defendants triggered institution of this suit. The plaintiff was justified in filing this suit. It is settled that where a plaintiff files a suit and loses substantial prayers, courts have the discretion to award nominal damages not to compensate the plaintiff but to vindicate a grievance for a suit filed in order to recognize the fact that the suit was not without foundation or to justify the legitimate concern. In this case the medical board fined and reprimanded the defendants thus justifying an award of nominal damages. Having found that the plaintiff's suit was with foundation and cannot be regarded as an abuse of court process, the defendant must pay costs of the suit. To this end I award the Plaintiff the following:

- i. Nominal damages Ksh 100,000***
- ii. costs of this suit.***

DATED, SIGNED AND DELIVERED VIRTUALLY ON THIS 12TH DAY OF MARCH 2026.



**HON L P KASSAN
JUDGE**

**In the presence of;
Muhindi for the Plaintiff
Banji for 1st Defendant
Mungai for 2nd and 3rd Defendants
Carol - Court Assistant**

STAY GRANTED FOR 30 DAYS OF EXECUTION



**HON L P KASSAN
JUDGE**

ORIGINAL