IN THE HIGH COURT OF MALAWI
ZOMBA DISTRICT REGISTRY
CRIMINAL APPEAL NUMBER 36 OF 2016
(Being Criminal Case Number 95 of 2016 before the Second Grade Magistrate Court Sitting at Machinga)
Between:

THE REPUBLIC **RESPONDENT**

AND

[redacted] **APPELLANT**

EXPERT AFFIDAVIT

I, Dr Ruth Margaret Bland of The Knowes, Auchans Road, By Houston, Renfrewshire, PA6 7EF, UK, make OATH and STATE as follows:

1. **THAT** I am a medical expert and I have extensive experience in conducting research in the field of HIV transmission.

2. **THAT** I swear this affidavit on behalf of the Appellant.

3. **THAT** all matters of facts deposed to in this affidavit are true and correct, and save where the context indicates otherwise, are within my personal knowledge and belief. To the extent that I rely on information received from others, I believe that such information is true and correct. I respectfully submit that I am by my training and experience duly qualified to express the view and opinions that I express in this affidavit.

4. **THAT** this affidavit addresses medical and scientific evidence relating to the risk of HIV transmission through breastfeeding, specifically relating to maternal ART, HIV transmission and breastfeeding.

4.1. My qualifications and experience are as follows:

QUALIFICATIONS AND EXPERTISE

5. **THAT** I hold the qualifications of a Bachelor of Science from the University of St Andrews (BSc) (Hons), a Bachelor of Medicine from the University of Glasgow (MB ChB), a Doctor of Medicine from the University of Glasgow (MD), and Fellowship of the Royal College of Paediatrics and Child Health, UK (FRCPCH). I obtained my MD degree from Glasgow University in 2007, on "Infant feeding practices in rural South Africa and recommendations to prevent postnatal transmission of HIV".

6. **THAT** I am currently a Consultant Paediatrician at the Royal Hospital for Children, Glasgow, UK. I am also an Honorary Associate Clinical Professor in the Institute of Health and Wellbeing, University of Glasgow, and an Honorary Associate Professor in the School of Public Health, University of Witwatersrand, South Africa.

7. **THAT** I have worked in the field of paediatrics and child health for over 20 years. I spent 10 years in the West of Scotland as a clinical paediatrician, completing my specialist training at the Royal Hospital for Sick Children, Glasgow, UK. I then lived in KwaZulu-Natal, South Africa for 13 years, where I worked at the Wellcome Trust-funded Africa Centre for Population Health (www.africacentre.ac.za), initially as a clinical scientist and latterly as the Clinical Research Lead. In the latter role I oversaw the clinical research agenda for the Centre, including HIV, TB, biology of transmission of HIV, and child development and growth.

8. **THAT** I have considerable expertise on mother-to-child transmission of HIV and infant feeding and I have a particular interest in the early origins of health and disease, particularly the role of breastfeeding in later health:

   8.1. I was a co-applicant and project leader of the Vertical Transmission Study, a large community-based intervention cohort designed to investigate the impact of exclusive breastfeeding on the postnatal transmission of HIV from mothers to children, which was completed in September 2006. I was primarily responsible for implementing the home-based counselling intervention to support exclusive breastfeeding in over 2,000 HIV-infected and uninfected women. The results of the study were published in The Lancet in 2007 (Coovadia et al, Lancet 2007), have been disseminated widely, and contributed to changes in the World Health Organisation guidelines on infant feeding and HIV published in 2007.

   8.2. I was contracted as a consultant by the World Health Organisation in 2005 to develop a training course in infant and young child feeding (Infant and Young Child Feeding: A Counselling Course) which has been used in many regions globally.

   8.3. I developed a course on HIV and Nutrition for Children and Adolescents for the WHO, the first field test of which took place in Malawi in August 2009.

   8.4. I have been invited to several expert World Health Organization workshops: Global Consultation on complementary feeding, Geneva (2001); Workshop to design an assessment tool for documenting infant feeding practices, Botswana (2001); meeting to discuss new research related to HIV and infant feeding and implications for training

materials, Geneva (2004).

8.5. My ongoing research addresses the long-term benefits of breastfeeding in HIV-exposed and unexposed children in rural South Africa.

9. **THAT** my curriculum vitae is attached at **"B1"**.

CONCEPTS AND DEFINITIONS

10. **THAT** the Human Immunodeficiency Virus (HIV) is a virus that attacks the body's immune system, specifically the CD4 or T-cells. These cells help the body fight infection and disease. Left untreated, HIV reduces the body's CD4 cells, making a person more susceptible to opportunistic infections.

11. **THAT** antiretroviral therapy (ART) is the use of a combination of three or more drugs for treating HIV infection.

12. **THAT** the term vertical transmission refers to the transmission of HIV from a mother living with HIV to an infant, whether in utero, peripartum (during and immediately after delivery), or postnatally (following delivery) through breastfeeding.

13. **THAT** the term exclusive breastfeeding refers to feeding an infant on breastmilk only, and giving the infant no other fluids or solids. Exclusive breastfeeding is recommended by the World Health Organization for infants for the first six months of life except in exceptional circumstances.

14. **THAT** the term mixed breastfeeding refers to feeding an infant on breastmilk and other fluids or solids (e.g. breastmilk plus formula milk; or breastmilk plus porridge).

15. **THAT** the term replacement feeding refers to an infant, who receives no breastmilk, being fed on a suitable breastmilk substitute, usually in the form of commercial infant formula, during the first 6 months of life.

16. **THAT** the term WHO refers to the World Health Organization.

RECOMMENDATIONS FOR BREASTFEEDING AMONGST WOMEN LIVIGN WITH HIV

17. **THAT** breastfeeding is one of the foundations of child health, development and survival, particularly where diarrhoea, pneumonia and undernutrition are common causes of mortality among children younger than five years, as is the case in Malawi.

18. **THAT** HIV can be transmitted from mother to infant during pregnancy, delivery, or after birth through breastfeeding.

19. **THAT** the World Health Organization (WHO) in its latest 2016 "Guidelines: Updates on HIV and Infant Feeding: The Duration of Breastfeeding and Support from Health Services to Improve Feeding Practices among Mothers Living with HIV" (See attached at **"B2"**) strongly recommends that mothers living with HIV should breastfeed their children for at least 12 months and may continue breastfeeding for up to 24 months or longer while on ART. This recommendation is similar to the general population. The Guidelines further recommend:

19.1. "In settings where health services provide and support lifelong ART, including adherence counselling, and promote and support breastfeeding among women living with HIV, the duration of breastfeeding should not be restricted."

19.2. "Mothers known to be HIV-infected (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first six months of life, introducing appropriate complementary foods thereafter and continue breastfeeding."

19.3. "National and local health authorities should actively coordinate and implement services in health facilities and activities in workplaces, communities and homes to protect, promote and support breastfeeding among women living with HIV."

19.4. "Even when ARV drugs are not available, mothers should be counselled to exclusively breastfeed in the first six months of life and continue breastfeeding thereafter unless environmental and social circumstances are safe for and supportive of replacement feeding. In circumstances in which ARV drugs are unlikely to be available, such as acute emergencies, breastfeeding of HIV-exposed infants is also recommended to increase survival."

20. **THAT** the Malawi 2014 "Clinical Management of HIV in Children and Adults: Malawi Integrated Guidelines for Providing HIV Services in Antenatal Care, Maternity Care, Under 5 Clinics, Family Planning Clinics, HIV Exposed Child / Pre-ART Clinics, and ART Clinics" are guidelines published by the Ministry of Health for healthcare providers in public and private facilities in Malawi. These are attached at "**B3**". Amongst others, these Guidelines provide the following:

20.1. The provision of lifelong antiretroviral treatment (ART) for pregnant and breastfeeding women with HIV, regardless of their CD4-count / clinical stage is a prong in the strategy for the prevention of mother to child transmission (PMTCT) of HIV ("Option B+").

20.2. "Health workers should not actively discourage pregnancy [in women living with HIV] as the risk of transmitting HIV to the baby is less than 5% if the mother starts ART as early as possible [and] is fully adherent to ART throughout pregnancy and breastfeeding".

20.3. Breastfeeding is universally approved irrespective of the mother's HIV-status:

20.4. "Feeding recommendations are the same for all infants, regardless of HIV exposure or HIV infection status".

20.5. Feeding recommendations include giving "only breast milk up to age 6 months" and stopping "breastfeeding around age 24 months".

20.6. "Replacement feeding (formula) is not recommended unless women are unable to breastfeed."

21. **THAT** the Infant and Young Child Nutrition Policy and Guidelines (attached at "**B4**") similarly promote breastfeeding as the primary feeding option while emphasising the importance of providing mothers with full information on risks and options and support in their choices:

21.1. The Policy states that "exclusive breastfeeding shall be protected, promoted and supported as a primary feeding option for all infants in all populations regardless of the HIV status of the children or their mothers."

21.2. "All mothers who are HIV positive shall be given full information on all possible infant feeding options and be allowed to make an informed choice."

21.3. "Confidentiality and support of feeding choice shall be maintained at all times as standard management of infant feeding for mothers who are HIV positive."

EVIDENCE ON THE IMPORTANCE AND SAFETY OF BREASTFEEDING

22. **THAT** the recommendations cited above are founded in evidence that supports the promotion of breastfeeding amongst women living with HIV in order to ensure the HIV-free survival of infants exposed to HIV.

23. **THAT** in southern Africa, child mortality rates are among the highest in the world. In these settings, the use of commercial breast-milk substitutes and other replacement feeds among infants not exposed to HIV is associated with significantly increased morbidity and mortality.

24. **THAT** the evidence for the long-term benefits of longer duration of breastfeeding for both maternal and child health outcomes, including child development and prevention of non-communicable diseases, highlights the relevance of supporting breastfeeding in high- and low-income settings alike.

RISK OF HIV-TRANSMISSION THROUGH BREASTFEEDING

25. **THAT** without antiretroviral preventive interventions, the risk of HIV transmission after birth has varied between 15 and 45 percent, depending on maternal risk factors and whether breastfeeding is practised. These estimates were based on HIV transmission without ART. (Maternal risk factors include high HIV maternal viral load, low maternal CD4 count). The estimates also varied depending on whether the infant received no breastmilk, any breastmilk, or exclusive breastmilk.

26. **THAT** many factors increase the risk of transmission of HIV after birth, including the state of the mother's immune system, how recently the mother has become infected with HIV, and whether the child is exclusively breastfed or not (exclusive breastfeeding carries a lower risk of HIV transmission than mixed breastfeeding).

27. **THAT** while breastfeeding, treatment with ART reduces the HIV viral load in the body of a woman living with HIV. When effectively managed with ART, this suppressed viral load will

reduce the likelihood of transmission of HIV through breastfeeding.

28. **THAT** the WHO updated the guidelines on HIV and infant feeding in 2016, in the light of new scientific evidence relating to HIV transmission and maternal ART. Systematic reviews were commissioned by the WHO for this update, and included a review on 'Postnatal HIV Transmission rates at age six and 12 months in infants of HIV-infected women on ART initiating breastfeeding: a systematic review of the literature', authors: Lana Chikhungu, Stephanie Bispo and Marie-Louise Newell

29. **THAT** in the systematic review above, six studies provided estimates of HIV transmission rates through breastfeeding in women on ART. These studies were conducted in Malawi (Jamieson), South Africa (Coovadia), Kenya (Thomas), Tanzania (Kilewo), Mozambique (Marazzi) and India (Alvarez-Uria). A pooled analysis for these studies reported a pooled transmission rate through breastfeeding at 6 month of 1.08% (95% Confidence Interval 0.32% to 1.85%). In all these studies the infants received breastmilk from birth for at least 6 months.

30. **THAT** further evidence supporting the use of ART in breastfeeding women was presented by Taha at the 21st International AIDS conference in Durban, July 2016 The findings were from the PROMISE study, conducted at 14 sites in Malawi, India, South Africa, Tanzania, Uganda, Zambia and Zimbabwe among 2431 HIV-infected women and their 2444 infants. Rates of HIV transmission to infants were extremely low: 0.3% at 6 months of age and 0.6% at 1 year of age, with high rate of infant survival (99% at 12 months of age). The conclusion of the study was that ART regimens during breastfeeding essentially eliminate HIV transmission by breastmilk to their infants.

31. **THAT** the above studies included infants who received breastmilk for at least 6 months from birth. The duration of breastfeeding is a major determinant of postnatal transmission. The likelihood of an HIV-infected woman, who is on ART, with a suppressed viral load, transmitting HIV to an infant after one breastfeed would be extremely low (less than 0.3%).

CONCLUSIONS

32. **THAT** in my expert opinion in the appellant's case the risk of HIV transmission to the child after a single exposure to her breastmilk whilst she was on ART would be infinitesimally small.

Ruth M Bland

Dr Ruth M Bland

24th November 2016