STATEMENT OF GREGORY GARDNER

I, Gregory Gardner of [redacted] WILL SAY AS FOLLOWS:

1. I, Gregory Gardner have been instructed by Andrew Storch Solicitors representing the claimant, to prepare an expert independent witness statement.

2. My principal qualifications to act as an expert witness in this case include the following: I am a General Practitioner and a member of the Royal College of General Practitioners. I am an Honorary Clinical Lecturer in Clinical Sciences at the University of Birmingham and a final year medical student tutor. I am a GP Trainer and Educational Supervisor, and supervise candidates for specialist training in General Practice and the examination for Membership of the Royal College of General Practitioners.

3. I have been provided with the following material:
    a. Letter of instruction.
    b. The document 'Temporary approval for home use for both stages of early medical abortion'
4. My instructions were to advise on:
    a. What are the dangers to women self-administering Mifepristone and Misoprostol at home?
    b. To comment on any other relevant matter.

5 Background.

Preliminary to any discussion about the risks of taking Mifepristone and Misoprostol at home to procure an abortion should be reflection on the Covid-19 crisis. Self-isolation in itself may – at least for some women – heighten anxieties and change decision making capabilities. The risk of making a life-changing decision which is subsequently regretted may be higher than normal, so standards of care and counselling must be of an especially high standard.

Induced abortion is a medical procedure regulated by law. It is treated differently than other interventions because there is a possibility it may cause injury to the mother – either physical or psychological - and because unborn children need the protection of the law. There may also be risks to a mother's future children (see section below on preterm birth.)

There are dangers relating to medical abortion in general, including dangers in the way that communication between doctor and patient may be compromised by changes in the regulations, and dangers to the woman as a result of the relaxation of safeguards.

6 Assessment of risk.

Under current abortion regulations, an abortion can be carried out only if the risk to the mother's physical or mental health is greater if she continues with the pregnancy than if she were to have an abortion. The practitioner will therefore have to ask a number of questions in order to complete a risk assessment; this risk evaluation is a critical part of informed consent. Material risks have to be disclosed to the patient in line with the 'Montgomery' principles whereby 'a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.'(1)

I include below a shortened list of possible complications of medical abortion, which may be material to a decision to have a home abortion by means of taking both Mifepristone and Misoprostol.

7 Risks of physical complications:

<u>Infection.</u>

The Royal College of Obstetricians and Gynaecologists (RCOG) in their guidelines for abortion providers give a figure of 10% for infective complications after abortion.(2) Other studies give lower figures for diagnosed or presumed infection(3, 4) but there is a cohort of women undergoing abortion who may have undiagnosed infection. Abortion without antibiotic prophylaxis risks the later development of Pelvic Inflammatory Disease (PID) and puts a woman at increased risk of subsequent infertility.(5) The RCOG recommend screening for Chlamydia and other sexually transmitted diseases in all women having abortion.(2) This cannot be done other than by a face to face appointment.

The lack of provision for this under 'Temporary approval for home use for both stages of early medical abortion' regulations therefore increases the risk of personal injury to the woman.

A small proportion of women who have abortion may be susceptible to sepsis. Women need written information about sepsis warning signs which could be overlooked if the woman is alone.

Haemorrhage and subsequent Surgical Evacuation

A large registry-based study from Finland on medical abortion in 27,030 women noted a 15.4% incidence of haemorrhage in women aged over 18.(4) 10.2% of the adult cohort had an incomplete abortion and 13.0% required surgical evacuation. A second paper derived from the same dataset found the rate of haemorrhage to be eight times greater after medical than surgical abortion.(6)

A Swedish study which looked at all abortions from one hospital from 2008 to 2015 reported an overall complication rate of 7.3% in medical abortions under 12 weeks. The commonest complication was incomplete abortion.(7) The complication frequency was significantly higher among women < 7 gestational weeks who had their abortions at home. A significant finding of the study was that the rate of complications associated with medical abortions increased from 4.2% in 2008 to 8.2% in 2015, possibly associated with a shift from hospital to home medical abortions.

In Australia a case series of 947 women undergoing first trimester medical abortion resulted in an 11.1% combined total of either emergency department presentation or hospital admission for treatment of complications.(8)

These are high figures and contrast with lower figures for complications reported in systematic reviews of clinical trials on Mifepristone/Misoprostol.(9, 10) The higher figures are more reliable than those in clinical trials because this is ‘real world’ reported data.

8 Risks of psychological trauma

The psychological assessment of women by medical professionals prior to abortion is challenging. This is even more difficult when such assessments are done by phone or video link. Reflecting on a study which looked at pre-abortion counselling,(11) Coleman concluded that ‘women arriving at abortion facilities are not necessarily sure of their decision to abort and they benefit greatly from counselling with professionals who address several parameters of the abortion decision.(12)

In an exhaustive review of the literature Reardon makes the point that ‘Research has shown that women considering abortion have a high degree of desire for information on ‘all possible complications’, including rare risks.’(13) Included among ‘all possible complications’ must be questioning about suicidal ideation. About half the women who have abortions in England and Wales each year have had at least one abortion

previously. The incidence of repeat abortion is therefore high. Sullins found a compounding effect of repeat abortion on suicidal ideation and substance misuse.(14)

The American Psychological Association's report in 2008 identified fifteen risk factors which counsellors needed to ask about in an assessment of women at risk for post abortion psychological injury.(15) Included in this list are, 'Perceived pressure from others to terminate a pregnancy' and 'Perceived opposition to the abortion from partners, family, and/or friends.' Reardon notes that the list is one of the shortest that has been developed.(13) Other researchers have compiled more extensive lists of risk factors thereby making it highly unlikely that consultations done by phone or video link will be able to fully assess the risk of an abortion to a woman's psychological health.

9 Communication risks

The difficulty which the practitioner faces is that information obtained by phone/video/other electronic means may be incomplete. It will be virtually impossible to do a full risk assessment and communicate that risk back to the patient. The woman may not accurately report her last menstrual period and without having an ultra sound scan, there is a possibility of wrongly assessing the pregnancy gestation. In practice this risks women taking Mifepristone/Misoprostol at a later gestation thus risking heavier bleeding.(2)

A study of post-abortive women from Sweden in 2016 noted that 'one-third of the women stated that they lacked information in different areas like bleeding, pain, the abortion process, expulsion of the embryo, and the opportunity to see a counsellor. Lack of or insufficient information about bleeding was most frequently mentioned.'(16) This finding is important because home abortion instructions given by phone or video may lead to misunderstanding and therefore potential for harm. This would be especially true if the woman did not have English as a first language.

Informed consent implies not just a full risk assessment, but time allowed for reflection and change of mind. How does a doctor ensure that the woman actually takes the medical abortion tablets, at the right time and in the right way, rather than someone else – perhaps a woman at a later stage of pregnancy?

10 Relaxation of safeguards

In the data sheet for Medabon Combipack of Mifepristone with Misoprostol there are clear warnings about the use of these drugs in combination to procure abortion:

Because it is important to have access to appropriate medical care if an emergency develops, the treatment procedure should only be performed where the patient has

access to medical facilities equipped to provide surgical treatment for incomplete abortion, or emergency blood transfusion or resuscitation during the period from the first visit until discharged by the administering qualified medical professional.

The non-negligible risk of failure, which occurs in 4.5 to 7.8% of the cases, makes the follow-up visit mandatory in order to check that abortion is complete. The patient should be informed that surgical treatment may be required to achieve complete abortion.

The patient must be informed of the occurrence of prolonged vaginal bleeding (an average of about 13 days after mifepristone intake, up to three weeks in some women..……heavy bleeding may require surgical evacuation of the uterus. Bleeding is not in any way a proof of termination of pregnancy as it occurs also in most cases of failure.

The patient should be informed not to travel far away from the prescribing centre as long as complete expulsion has not been confirmed. She should receive precise instructions as to whom she should contact and where to go, in the event of any problems or emergency, particularly in the case of very heavy vaginal bleeding.

A follow-up visit must take place within a period of 14-21 days after administration of mifepristone to verify by the appropriate means (clinical examination, ultrasound scan, or beta-hCG measurement) that expulsion [of] the abortion has been completed and that vaginal bleeding has stopped or substantially reduced. In case of persistent bleeding (even light) beyond the follow-up visit, its disappearance should be checked a few weeks later. If an ongoing pregnancy is suspected, a further ultrasound scan may be required to evaluate its viability. Persistence of vaginal bleeding at this point could signify incomplete abortion, or an unnoticed extra-uterine pregnancy, and appropriate investigation/treatment should be considered.

During intake and for three hours following the intake, the patient should be monitored in the treatment centre, in order not to miss possible acute effects of misoprostol administration.

Since heavy bleeding requiring haemostatic curettage occurs in 0.2 to 1.8% of the cases during the medical method of pregnancy termination, special care should be given to patients with haemostatic disorders with hypocoagulability, or with anaemia. The decision to use the medical or the surgical method should be decided with specialised consultants according to the type of haemostatic disorder and the level of anaemia.

Before Medabon is given to a woman who has undergone genital mutilation (FGM) a physical examination must be performed by a qualified trained medical professional to exclude any anatomical obstacles to medical abortion.(17)

No consideration seems to have been given to any of these safeguards in the ‘Temporary approval for home use for both stages of early medical abortion’ regulations.

11 Safeguarding and the risk of coercion

Control over women’s reproductive autonomy by others is common and healthcare professionals need to ask specific questions about it.(18) A study of teenagers found that 10% reported some degree of coercion in making a decision to have an abortion.(19) It will be difficult if not impossible to verify by phone or video whether a woman is undergoing any kind of duress to have an abortion. There does not seem to have been any consideration given to this in the proposed change in policy. There will be women who need delicate counselling to discover coercion or other forms of abuse. Face to face consultation is needed – if necessary on more than one occasion. A phone call or video call to someone at home who may not have the ability to speak in complete confidence may cause important information to be hidden. Even where coercion may not be present, the relatively circumscribed nature of phone or video consultation creates a risk that important bits of information may be missed, thus compromising decision-making.

12 Longer term risks

Risks of future preterm birth.

Women having counselling for first trimester medical abortion should also be informed of the possible increased risk of preterm birth in a future pregnancy. A 50% increased risk of preterm birth after one medical abortion was noted in the most recent meta-analysis on this subject.(20)

Risks of breast cancer

Emerging data on the risk of breast cancer after medical abortion are concerning. A paper published in 2019 put the increased risk of premenopausal breast cancer at nearly four times and postmenopausal breast cancer risk at seven times (after adjustment) in women who had undergone one medical abortion.(21) Abortion consent forms need to mention these long term risks (see para. 9 above).

13 Self-regulation

The Care Quality Commission found examples of malpractice at Marie Stopes centres in 2016. Amongst these were pre-signing of consent forms, the flouting of infection control regulations and inadequate safety standards to monitor patients whose condition was deteriorating. In answer to a Parliamentary question in February 2020, it was reported that 121 facilities performing abortions (59% of the total) required improvement for safety.(22) Abortion providers have compromised on safety standards when those standards were higher than under the proposed new

regulations. It is likely that lowering safety standards will therefore lead to further compromises on safety.

14 Systemic Risks

The increased risk of complications when abortion is done at home (para. 7) potentially places health services under increased pressure at a time of already stretched capacity. In contrast, because of the nature of the current Covid-19 crisis, some GP practices are double triaging patients before referring them for a possible assessment at a 'hot clinic.' That is, the patient is assessed independently by two clinicians before a referral is made. The patient is further assessed by a third clinician before acceptance to the 'hot clinic' is made. This alternative would increase diagnostic accuracy and avoid added pressure, unlike the proposed changes.

15 Summary

The introduction of home abortions as proposed (notwithstanding the presence of a Covid-19 pandemic) is a policy that is more likely than not to depart from the essential tenets of duty of care through proper clinical assessment, thereby raising the risk of serious injury and harm being done to women self-administering Mifepristone and Misoprostol at home.

1. Montgomery v Lanarkshire Health Board [2015] SC 11 [2015] 1 AC 1430. In.
2. The care of Women Requesting Induced Abortion London: Royal College of Obstetricians and Gynaecologists; 2011.
3. Shannon C, Brothers LP, Philip NM, Winikoff B. Infection after medical abortion: a review of the literature. Contraception 2004;70(3):183-90.
4. Niinimaki M, Suhonen S, Mentula M, Hemminki E, Heikinheimo O, Gissler M. Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study. BMJ 2011;342:d2111.
5. Achilles SL, Reeves MF. Prevention of infection after induced abortion: release date October 2010: SFP guideline 20102. Contraception 2011;83(4):295-309.
6. Niinimaki M, Pouta A, Bloigu A, Gissler M, Hemminki E, Suhonen S, et al. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol 2009;114(4):795-804.
7. Carlsson I, Breding K, Larsson PG. Complications related to induced abortion: a combined retrospective and longitudinal follow-up study. BMC Womens Health 2018;18(1):158.
8. Mulligan E, Messenger H. Mifepristone in South Australia -- the first 1343 tablets. Aust Fam Phys 2011;40(5):342-5.
9. Raymond EG, Shannon C, Weaver MA, Winikoff B. First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review. Contraception 2013;87(1):26-37.
10. Chen MJ, Creinin MD. Mifepristone With Buccal Misoprostol for Medical Abortion: A Systematic Review. Obstet Gynecol 2015;126(1):12-21.
11. Vandamme J, Wyverkens E, Buysse A, Vrancken C, Brondeel R. Pre-abortion counselling from women's point of view. Eur J Contracept Reprod Health Care 2013;18(4):309-18.
12. Coleman PK. Negative abortion experiences: predictors and development of post-abortion psychological and relational adjustment scale. Issues Law Med 2018;33(2):133-162.

13. Reardon DC. The abortion and mental health controversy: A comprehensive literature review of common ground agreements, disagreements, actionable recommendations, and research opportunities. SAGE Open Med 2018;6:2050312118807624.
14. Sullins DP. Abortion, substance abuse and mental health in early adulthood: Thirteen-year longitudinal evidence from the United States. SAGE Open Med 2016;4:2050312116665997.
15. Report of the APA Task Force on Mental Health and Abortion. Washington DC: American Psychological Association; 2008.
16. Hedqvist M, Brolin L, Tyden T, Larsson M. Women's experiences of having an early medical abortion at home. Sex Reprod Healthc 2016;9:48-54.
17. Electronic Medicines Compendium (accessed 02 April 2020). 2020 [cited; Available from: https://www.medicines.org.uk/emc/product/3380/smpc
18. Rowlands S, Walker S. Reproductive control by others: means, perpetrators and effects. BMJ Sex Reprod Health 2019;45(1):61-67.
19. Ralph L, Gould H, Baker A, Foster DG. The role of parents and partners in minors' decisions to have an abortion and anticipated coping after abortion. J Adolesc Health 2014;54(4):428-34.
20. Saccone G, Perriera L, Berghella V. Prior uterine evacuation of pregnancy as independent risk factor for preterm birth: a systematic review and metaanalysis. Am J Obstet Gynecol 2016;214(5):572-91.
21. Yuan X, Yi F, Hou C, Lee H, Zhong X, Tao P, et al. Induced Abortion, Birth Control Methods, and Breast Cancer Risk: A Case-Control Study in China. J Epidemiol 2019;29(5):173-179.
22. Abortion: Clinics: Written question - 21971. In. https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2020-02-27/21971/; 2020.

EXPERT DECLARATION

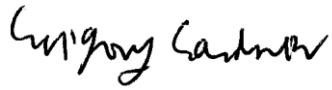
I declare the following:

1. That I understand that my duty in providing written reports and giving evidence is to help the court; and that this duty overrides any obligations to the party by whom I am engaged or, he person who has paid or I liable to pay me. I confirm that I have complied and will continue to comply with my duty.
2. I confirm that I have not entered into any arrangement where the amount or payment of my fees is in any way dependent on the outcome of the case.
3. I know of no conflict of interest of any kind, other than any which I have disclosed in my report.
4. I do not consider that any interest which I have disclosed affects my suitability as an expert witness on any issues on which I have given evidence.
5. I will advise the party by whom I am instructed if, between the date of my report and the hearing, there is any change in circumstances which affect my answers to points 3 and 4 above.

6. I have shown the sources of all information I have used.
7. I have exercised reasonable care and skill In order to be accurate and complete in preparing this report.
8. I have endeavored to include in my report those matters, of which I have knowledge or of which I have been made aware, that night adversely affect the validity of my opinion. I have clearly stated any qualifications to my opinion.
9. I have not, without forming an independent view, included or excluded anything which has been suggested to me by others, including my instructing lawyers.
10. I will notify those instructing me immediately and confirm in writing if, for any reason, my existing report requires any correction or qualification.
11. I understand that
    a. My report will form evidence to be given under oath or affirmation.
    b. Questions may be put to me in writing for the purposes of clarifying my report and that my answers shall be treated as part of my report and covered by my statement of truth.
    c. The court may at any stage direct a discussion to take place between experts for the purpose of identifying and discussing the expert issues in the proceedings, where possible reaching an agreed opinion on those issues an identifying what action, if any, may be taken to resolve any of the outstanding issues between the parties.
    d. The court may direct that following a discussion between the experts that a statement should be prepared showing those issues which are agreed, and those issues which are not agreed, together with a summary of the reasons for disagreeing.
    e. I may be required to attend court to be cross examined on my report by a cross examiner assisted by an expert;
    f. I am likely to be the subject of pubic adverse criticism by the judge if the court concludes that I have not taken reasonable care in trying to meet the standards set out above.
12. I have read Part 35 of the Civil Procedure Rules and Part 3.3 of the Criminal Procedure Rules, the accompanying practice direction and the Guidance for

the instruction of expense in civil claims and I have complied with their requirements.

13. I am aware of the practice direction



Gregory Gardner.

06/04/20