IN THE HIGH COURT OF JUSTICE **Claim CO/1402/20202**

QUEENS BENCH DIVISION

ADMINISTRATIVE COURT

APPLICATION FOR JUDICIAL REVIEW

BETWEEN:

Her Majesty the Queen

(on the application of CHRISTIAN CONCERN)

Claimant

-v-

Secretary of State for Health and Social Care

Defendant

Witness statement of Mr Kevin Duffy

I, Mr Kevin Duffy MScPH of [redacted]*, SAY as follows:*

Introduction

1. I am a former director of a major abortion provider, Marie Stopes International; my full credentials are set out further below.

2. Except where otherwise appears from the context, all facts and matters set out in this witness statement are within my own knowledge and are true. Where I refer to a fact or matter that is not within my own knowledge, I identify the source of my information.

3. References in square brackets in this statement are to pages in the agreed hearing bundle.

4. I have been instructed by the solicitors for the Claimant in this case to review the evidence served by the Defendant, and identify any incomplete or otherwise misleading information therein. I have reviewed:

    a. The witness statement of Ms Andrea Duncan **[265-277]**
    b. The witness statement of Dr Imogen Stephens **[278-292]**
    c. Documents at **[293-360]**

Credentials

5. I was employed by Marie Stopes International (MSI) from March 2013 to February 2017, after which I was engaged by MSI as an independent consultant on numerous assignments, the final one completing in February 2019.

6. For the first two years I was Deputy Regional Director and provided strategic guidance and technical support to Country Directors across ten countries in East and Southern Africa, helping to deliver quality, cost-effective sexual reproductive healthcare services and programmes.

7. In November 2014, I was appointed as the director responsible for the development and implementation of MSI's global clinics standard operating procedures manual (referred to internally as the centres channel success model). This provided detailed instructions to help ensure that all staff working in MSI clinics understood what was required for compliance with the organisation's global policies and guidelines. I developed this in close collaboration with many departments and teams across the organisation, including the medical development team and the international operations management team. The success model covered every aspect of a clinic's operation across the organisation's three strategic pillars: Scale and Impact, Quality and Sustainability.

8. From March 2017 until February 2019, I was engaged by MSI as an independent consultant to provide subject matter expertise and technical

support to country and regional management teams, across East and Southern Africa, and South Asia.

9. During these six years I travelled to fifteen of MSI's country programmes and conducted management review visits in more than 100 of its clinics.

The process of early medical abortion (EMA) – *Duncan*, paras 15-20 [268-270]

10. In her paragraphs 15 – 20, Ms Duncan explains matters related to the '2018 Approval' which permitted women to take the second pill, misoprostol, in their own home. This is consistent with my international experience in which it is routine practice for the woman to take the misoprostol at home. I do not have any client safety or quality of care concerns about such practice.

11. However, Ms Duncan's description of the final stage of the EMA process at the end of paragraph 20 is as follows: "*the woman attends the clinic to take the first pill and then returns home to take the second pill 24-48 hours later*". This omits to mention the other important steps are routinely included in this clinic visit:

12. Before the Covid-19 changes, it was routine for women presenting for an EMA to be clinically assessed for suitability, including an ultrasound scan and blood tests. Marie Stopes UK states on its website[1] that after the remote consultation the woman will attend a clinic and on that visit will have an assessment which covers the ultrasound scan, her general health, blood pressure check, blood tests, and tests for sexually transmitted infections (STIs). It goes on to say, "We will assess how many weeks pregnant you are using ultrasound scanning."

13. The RCOG guidelines[2] introduced as a consequence of the Approval of 'home' on 30 March 2020, to which Ms Duncan refers in her paragraph 11, list on its

[1] https://www.mariestopes.org.uk/abortion-services/what-to-expect/
[2] https://www.rcog.org.uk/globalassets/documents/guidelines/2020-04-09-coronavirus-covid-19-infection-and-abortion-care.pdf

page 11 changes to the care pathway to minimise Covid-19 exposure, including,

- Provide abortion care without routine pre-procedure ultrasound.
- Provide abortion care without routine pre-procedure blood testing.

14. These ultrasound scans are part of the routine processes primarily to ensure accurate assessment of the gestational age (GA). This is an essential step for providers, especially when the woman might be in some doubt about the timing of her last menstrual period (LMP). This is explicitly stated by RCOG in a flow-chart on page 4 of the guidelines, as referenced by Ms Duncan in her paragraph 14.

15. Certainty of GA is important because the new regulations limit EMA at-home to a maximum GA of 9.6 by the day on which the misoprostol is self-administered. Also, it is accepted that the efficacy of the medical abortion treatment reduces as GA increases, with an increase in potential side-effects experienced. BPAS notes this on its website.[3]

16. These new regulations mean that the assessment of GA is solely dependent upon the woman's accurate and honest recall of the first day of her LMP. The prior use of ultrasound scan was to overcome any lack of provider's confidence in the woman's recall.

17. The significance of this change, and the fact that the approval of 'home' means dispensing with a number of clinical tests, is not reflected in Ms Duncan's witness statement. As detailed further below, that information was also omitted from the Ministerial Submission at **[298-304]**, or other documents considered by the Secretary of State as part of the decision-making process.

[3] https://www.bpas.org/abortion-care/abortion-treatments/the-abortion-pill/abortion-pill-up-to-10-weeks/

Pre-existing evidence on approving homes as a class of place where EMA could be performed – page 8

18. In her paragraph 21, Ms Duncan states that "Home use of EMA has been routine in the USA since 2000", but she does not cite evidence to support this claim. I do not consider this to be so, especially given that the FDA in the USA has approved a Risk Evaluation and Mitigation Strategy (REMS) to ensure the safe use of Mifeprex (mifepristone).[4] This restricts how, where, and by whom mifepristone is prescribed and dispensed.

19. I am aware of a small trial called TelAbortion, which is being conducted by Gynuity Health Projects in the USA, across 13 states.[5] Up to April 22nd, 2020, this trial had sent abortion pills to 841 women, and 611 had so far confirmed completed abortions, ~73%. Before Covid-19, women participating in this trial needed to first obtain an ultrasound scan to confirm GA.[6]

20. The TelAbortion lead, Elizabeth G. Raymond, in response to the Covid-19 emergency, recently published a recommendation for a no-test protocol, in which it is proposed that EMA could be provided without the ultrasound or pelvic examination, and blood tests which are routinely performed to evaluate eligibility before the abortion pills are dispensed.[7] I'm not aware of the FDA or any other USA regulator having given approval for use of this protocol.

21. I noted that Raymond et al acknowledge the advice and guidance given by Patricia Lohr, Medical Director at BPAS. There are many similarities between this no-test protocol and the RCOG guidance for EMA during the Covid-19 pandemic, cited above.

[4] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information
[5] https://telabortion.org/
[6] https://www.nytimes.com/2020/04/28/health/telabortion-abortion-telemedicine.html
[7] E. G. Raymond, D. Grossman, A. Mark et al., Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond, Contraception, https://doi.org/10.1016/j.contraception.2020.04.005

22. In paragraph 22, Ms Duncan discusses a NICE review of abortion services by telemedicine. In the interests of balance, there are several other studies which might also have been included here. I suggest eg a paper published by BJOG at the end of 2018 reviewing a study of EMA at-home facilitated by telemedicine services at Women on Web.[8]

23. The key findings noted by the authors are that neither safety nor acceptability are affected by the increase in GA at the time of self-administration of the abortion pills, but there is an association for GA >9 with a higher risk, four-fold, of clinical visits by women and this risk continues to increase as their GA increases; more than one-in-eight women with GA >9 weeks made such a visit.

24. Other results worth noting for further investigation include:

    a) Even at ≤9 weeks GA, 45% of women reported that their rate of bleeding was higher than expected, increasing to 57% for those women >9 GA.

    b) One-third of all women, regardless of GA, reported that their rate of pain was higher than expected.

    c) Both of the above, might indicate a weakness in the guidance and information provided during the consultation and pre-counselling.

    d) The rate of surgical intervention needed to complete the abortion was much higher than expected. In the ≤9 weeks GA group this rate was 8.6% compared to a predicted 3%. For >9, the rate was 14.9% compared to a predicted 7%. One-in-nine women taking the abortion pills at home needed a surgical intervention to complete their abortion.

[8] Endler M, Beets L, Gemzell Danielsson K, Gomperts R. Safety and acceptability of medical abortion through telemedicine after 9 weeks of gestation: a population-based cohort study. BJOG 2019;126:609–618

e) The authors noted some uncertainty about the self-reporting of gestational age.

f) Provider organisations should carefully evaluate the clarity and effectiveness of the advice and guidance which they provide to women, and how well this prepares women for self-administration and self-management of the abortion process.

25. Apart from the legal status, there is no significant difference between the telemedicine service offered by WoW and that which is now permitted by the Approval of homes as a class of places on 30 March 2020. In both cases the assessment of eligibility is made remotely by the woman with guidance from a qualified provider, pills are delivered to the woman's home by post, she manages the self-administration of these at home, and afterwards the woman performs a self-assessment of the completeness of her abortion.

Ministerial Submission [298-304]

26. The submission to the Secretary of State is misleading, as it fails to inform the reader that the proposed Approval will entail a significant change to the routine clinical pathway, as explained in paras 10-17 above, especially the removal of the ultrasound scan for assessment of GA. The recommendation as written implies that it is only the places in which the mifepristone is being prescribed and administered which are being changed. This recommendation does not refer to the associated, necessary changes to the care pathway which RCOG was recommending. In particular:

27. Para 4: "*Women attend a clinic where they take the first pill (mifepristone), and then have the option of either returning to the clinic to take the second pill, or taking the second pill at home.*" This neglects to inform the SofS about the other important steps in the care pathway which are part of this clinic visit.

28. Para 6: "*all women must attend a clinic or hospital in person at least once, to take the first pill.*" No mention of the others steps in the pathway which can only take place at the clinic.

29. Para 9: "*The consultation would be equivalent to the current in person consultations.*" The in-person consultations were not just about the prescribing and administration of the first pill, mifepristone, but included several different steps in the clinical assessment of eligibility for EMA. This information was not provided in this approval request to the SofS.

30. Para 10: "*This proposal has been tested with abortion providers, the Royal College of Obstetricians and Gynaecologists (RCOG) and PHE and has received strong consensus support.*" The submission fails to mention that support by the RCOG assumes significant changes to the existing routine pathway, other than just the place where the mifepristone is administered.

31. Para 10: "*Home use for both abortion pills is supported by clinical evidence*". It is not clear what clinical evidence the authors of the submission rely on. As explained in paras 18-25 above, there was also considerable clinical evidence of various risks associated with the proposed process.

32. Para 10: "*telemedicine is supported by NICE abortion guidance.*" This misleadingly implies that the NICE guidance supports the proposal to limit all contact with the patient throughout the abortion process to telemedicine, which is not the case. NICE does recommend the inclusion of telemedicine in order to make services more accessible to women, but it does not suggest that this could be the only contact with the woman throughout her abortion care journey. Telemedicine is seen as part of it, but not all of it. I agree that telemedicine can be useful as part of the care pathway, eg for the initial consultation, and to facilitate the review of the client notes and approval of treatment by the doctor.

33. Para 20: "*RCOG are developing urgent guidance on managing access to abortion in the context of COVID-19 and we are working with them closely on*

this to ensure alignment of messaging." There is no mention that, if the proposal is approved, RCOG guidance would include significant changes to the pathway.

34. I acknowledge that the changes to the RCOG guidelines were not something the Secretary of State would need to approve. However, the approval of 'home' as a class of places for administration of Mifepristone could only be effective if the RCOG guidance as to the clinical pathway was significantly changed as explained above. It was misleading not to draw that to the attention of the Ministers.

Other documents

35. The significant changes to the clinical pathway and the RCOG Guidance which the Approval would entail were not identified in any of the other documents submitted to the Ministers and now provided to the Court. Most notably:

36. The letter from BPAS **[307]** states that the change of place will remove the requirement for a woman "*to attend a treatment unit for the sole purpose of ingesting the mifepristone tablets.*" This is misleading. As noted in my statement above and here on the BPAS website,[9] this clinic visit involves several other steps in the care pathway, not just the administration of the mifepristone.

37. In its fifth paragraph BPAS mentions that it has already been considering asking about a move to home-use of both drugs, but that this has now been overtaken by the Covid-19 emergency. This is consistent with my earlier statement related to Lohr's involvement in the No-Test protocol with Raymond et al. BPAS is not alone in this, the proposed move towards remote consultations enabling the removal/replacement of a clinic visit, and the subsequent self-administration of both abortion pills by the woman at home is part of the strategic plan for most provider organisations. The Gynuity TelAbortion trial, discussed earlier in this

[9] https://www.bpas.org/abortion-care/what-to-expect-on-the-day/consultation-appointment/

statement, is one example. Another is the SafeAccess hub, a collaborative development by MSI, IPPF, PSI, SAAF, and IPAS.[10]

38. The letter from Lucy Allan MP to Nadine Dorries MP **[341]** states: "*BPAS has explained that under the law, 500 women a day have to travel to abortion clinics to take a pill before self-managing the abortion at home. BPAS has stated that this is not clinically required*". There is no indication in the letter that in fact, the visit to the clinic was not just to take the mifepristone.

I believe that the facts stated in this statement are true.

Mr Kevin Duffy

18 May 2020

[10] https://www.safeaccesshub.org/