NOS. 23-235, 23-236

IN THE

Supreme Court of the United States

U.S. FOOD AND DRUG ADMINISTRATION, ET AL.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

and

DANCO LABORATORIES, L.L.C.,
Petitioners,

v.

ALLIANCE FOR HIPPOCRATIC MEDICINE, ET AL.,
Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

BRIEF OF AMICUS CURIAE DR. CALUM MILLER IN SUPPORT OF THE RESPONDENTS

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INTEREST OF *AMICUS CURIAE*[1]

Dr. Calum Miller BA BMBCh (Oxon) MA is a medical doctor in the United Kingdom. As a researcher at the University of Oxford, he has published over 30 academic papers, including more than 15 on the topic of abortion. He has published two academic papers on the risks of telemedicine abortion. Dr. Miller believes that telemedicine abortion poses considerable harms to women which were either irrationally ignored or not considered at all by the FDA, thus rendering their actions in removing safeguards illegal.

SUMMARY OF ARGUMENT

1. Telemedicine abortion – permitted by the FDA's 2021 decisions – bears a wide variety of risks for women.
2. Even in the most pro-choice European countries, concerns were raised by leading medical authorities and abortion providers about the safety of telemedicine abortion. The FDA acted irrationally in not heeding these concerns.
3. Pre-existing data consistently showed complication rates orders of magnitude higher than the Adverse Events Data relied upon by the FDA. These latter data relied upon by the FDA were obviously deficient to anyone vaguely familiar with the academic and

[1] *Amicus* states that no counsel for a party authored this brief in whole or in part, and no person other than the *amicus* and its counsel made any monetary contribution intended to fund the preparation or submission of this brief.

clinical data available on abortion. The FDA acted irrationally in relying on it.

4. The FDA relied on four published studies in endorsing telemedicine and mail order abortion; principally on one key study from the UK. These studies were fatally deficient in many respects, including in some cases not even replicating the conditions the FDA sought to approve. In addition, these studies themselves revealed safety concerns which the FDA entirely ignored. Moreover, basic familiarity with UK complications reporting suffices to undermine the conclusions of the key UK study used by the FDA. The study was irredeemably flawed in ways that should have been obvious to any reasonably informed investigator. Other widely-publicized UK data demonstrates a wide variety of safety hazards pertaining to telemedicine abortion. The FDA entirely ignored these data.

5. In ignoring evidence of safety concerns even in the studies they cited, the FDA acted in a way inconsistent with basic norms of rationality. Moreover, the FDA entirely failed to consider multiple important aspects of the problem, thereby directly and clearly violating the law.

ARGUMENT

I. Telemedicine abortion is plagued with safety risks.

From the beginning of the COVID-19 pandemic, serious safety concerns regarding telemedicine

abortion have been raised by leading healthcare professionals and politicians, including:[2]

1) Failure to verify gestation by physical examination or ultrasound can lead to women and girls aborting in the second or third trimester at home with no medical supervision. While the FDA held that gestational age can be reliably judged by the last menstrual period alone, this is untrue. The American College of Obstetricians and Gynecologists estimates that 40% of women estimate their gestational age inaccurately when using their last menstrual period alone. *See* American College of Obstetricians and Gynecologists. Methods for estimating the due date, (2017), available at https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date. This undermines the FDA's claim that "pregnancies can also be … dated using other clinical methods"—they can, but not *reliably*.

   Illustrating the dangers, a significant number of women and girls have given birth later than the medically and legally allowed age in the UK after telemedicine abortion, with at least one resulting in a live birth and subsequent infant death, with attendant legal

[2] *See* Calum Miller, Telemedicine abortion: why it is not safe for women, in Nicholas Colgrove, ed., *Agency, Pregnancy and Persons: Essays in Defense of Human Life* (2022), New York: Routledge, for more detail on each of these.

implications. *See* Calum Miller, *The safety of self-managed abortion: a death of good-quality evidence and a wealth of misrepresentation*, 38 Issues Law Med. 3, 12 (2023).

These abortions are profoundly dangerous: skilled birth attendance is one of the most basic factors preventing maternal death even in the developing world.

2) Failure to verify gestation also increases the risk of Rhesus disease, which is more likely to develop during pregnancies of increased gestation. Ordinarily, anti-D is given to women at risk to prevent Rhesus disease. However, in telemedicine abortion, testing is not done to identify women at risk, and anti-D is not given. Hence the woman is at risk of developing Rhesus disease, which can lead to serious problems for future children, including death. Some argue that Rhesus disease is unlikely before 12 weeks' pregnancy. However, a) if the gestational age is not verified it is impossible to be sure the pregnancy is below 12 weeks, and b) Rhesus antibodies have been known to develop prior to 12 weeks. *Id*. at 13.

3) Failure to perform ultrasound also means women may have undetected ectopic pregnancies, a leading cause of maternal death. This is doubly dangerous: not only does the ectopic pregnancy go undetected—thereby eventually causing major haemorrhage and maternal death—but the medical abortion disguises the symptoms by causing abdominal pain and bleeding. This delays presentation to emergency services—one of the leading factors

contributing to maternal deaths in ectopic pregnancies. *See* Health Services Safety Investigations Body, Investigation Report: The diagnosis of ectopic pregnancy, (2020), available at https://www.hssib.org.uk/patient-safety-investigations/the-diagnosis-of-ectopic-pregnancy/investigation-report/.

4) Screening for risk factors is insufficient, since many women with ectopic pregnancies have no risk factors. *See* Calum Miller, Telemedicine abortion: why it is not safe for women, in Nicholas Colgrove, ed., *Agency, Pregnancy and Persons: Essays in Defense of Human Life,* *293, (2022), New York: Routledge.

5) Abortion pills do not treat ectopic pregnancies.[3] *See* World Health Organization, *Safe abortion: technical and policy guidance for health systems*. 2nd ed. Geneva: World Health Organization, *35, (2012).

6) Failure to perform an examination also risks other contraindications going undetected. The World Health Organization, before its political U-turn to support telemedicine abortion, specifically highlighted such conditions as requiring screening for more complex care: multiple pregnancy, fibroids, pelvic tumours, molar pregnancies, anaemia, malaria, or reproductive tract/sexually transmitted infections. *Id*. at 34.

7) Routine sexually transmitted disease testing before abortions declines under telemedicine.

[3] Known maternal deaths from ectopic pregnancies after no-test abortions are detailed in Miller (2022) at 293.

UK data show that the number of women not receiving an offer of chlamydia screening doubled after telemedicine abortion was introduced, worsening what is already a serious public health problem. *See* Miller (2023) at 13.

8) The provision of reliable long-acting reversible contraception (LARC) also significantly decreases under telemedicine. In the UK, LARC use decreased from around a third to just 8.7% under telemedicine, according to one of the key studies the FDA cited. *See* John Joseph Reynolds-Wright, et al, *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic*, 47 B.M.J. SEX REPROD. HEALTH 246, 250 (2021). This puts thousands more women at risk of unintended pregnancy and subsequent health complications.

9) Most irredeemably, lack of in-person contact means that women are at significantly higher risk of being coerced into their abortions, or having domestic abuse go undetected. A quarter of abortions are forced on a woman by someone else,[4] and victims of abuse and trafficking are at particularly high risk for having abortions, often coerced. *See* Laura J. Lederer and Christopher A. Wetzel, *The health consequences of sex trafficking and their implications for identifying victims in healthcare facilities*, 23 ANN HEALTH LAW 61 (2014) and Silvia Motta, et al., *Domestic*

[4] *See* Miller (2022) at 288 for detailed statistics.

violence in a UK abortion clinic: anonymous cross-sectional prevalence survey, 41 J. FAM. PLANN. REPROD. HEALTH CARE 128 (2015).

10) Before telemedicine, private, in-person consultations were the key safeguard against coerced abortion and domestic abuse: this is the singular solution given to women in leading global abortion provider Marie Stopes International's Frequently Asked Question: "I'm being pressured into having an abortion—what should I do?"[5] *See* Miller (2022) at 290. Likewise, a survey of over 1,000 sexual and reproductive health providers from leading telemedicine abortion advocate, the Faculty of Sexual and Reproductive Healthcare, highlighted widespread concern, "in particular … about domestic abuse". UK Parliament, Written evidence submitted by The Faculty of Sexual and Reproductive Healthcare, (May 2020), *3, available at https://committees.parliament.uk/writtenevidence/4457/pdf/. They noted: "Without face-to-face consultations, opportunities to pick up on safeguarding issues, domestic abuse and teenage pregnancy are lost … we call [for] … gradual reinstatement of face-to-face consultations." *Id*. at 3,7. Survey data found 90% of female family doctors were concerned about coerced abortion via telemedicine.[6] *See* ComRes, SPUC – GPs polling, (2021) available

[5] Note that this is a 'frequently asked' question.

[6] *See* Miller (2022) at 288-290 for further examples of abortion providers themselves raising concerns about safeguarding issues with telemedicine abortion.

at https://comresglobal.com/polls/spuc-gps-polling/.

II. Grave concerns exist across Europe.

The UK and the Netherlands are two countries in Europe with the most liberal abortion laws, allowing abortion on demand (de facto) up to 24 weeks. Yet in both European countries, leading *pro-choice* medical professionals and politicians have strongly opposed telemedicine abortion for safety reasons. In most other pro-choice European countries, telemedicine was never permitted at all.

A. Deeply pro-choice medical organizations in the UK oppose telemedicine abortion.

Concerns in the UK arose from many sources. Days before the pro-choice UK government introduced telemedicine abortion, Health Minister Lord Bethell said: "We believe that it is an essential safeguard that a woman attends a clinic, to ensure that she has an opportunity to be seen alone … [this amendment] could remove the only opportunity many women have, often at a most vulnerable stage, to speak confidentially and one-to-one with a doctor about their concerns." Christian Concern, DIY abortions, (2024), available at https://christianconcern.com/cccases/diy-abortions/.

Pro-choice medical and safeguarding authorities likewise raised concerns. The National Network of Designated Healthcare Professionals for Children (NNDHP) is the umbrella body within the National Health Service for clinicians dedicated to protecting children from safeguarding risks. In March 2021, they called for an end to telemedicine abortion, and lamented that when it was introduced, "Pilots to

evaluate the changes were not undertaken, and no evidence has been found that pre-implementation assessments of safeguarding risks were undertaken". National Network of Designated Healthcare Professionals for Children (NNDHP), Early medical abortions: safeguarding young people (first position statement: March 2021), *1.

They noted: "Virtual consultations enable unseen and unheard coercive adults to influence the patient. This risk is best contained in face-to-face consultations… Without any face-to-face component, applications can be entirely fictitious, and enable a supply of pills for an unknown, unseen, coerced pregnant female victim of exploitation." *Id.*

They highlighted the risk of traumatic and dangerous late-gestation abortions, in some cases leading to live births: "Mid-trimester abortions are more traumatising than first trimester terminations… Some of the early medical abortions that the NNDHP is aware of have led to live births of very premature but potentially viable infants." *Id.*

This was followed by a second statement in April 2022, reiterating their pro-choice position but referencing the "deaths of live infants born unexpectedly as a result of an intended early medical abortion". National Network of Designated Healthcare Professionals for Children (NNDHP), Early medical abortions: safeguarding young people (second position statement: April 2022), *2. They called for a full review of abortion services which recognized "the significance of psychological consequences of unintended late abortions", and which considered "making providers responsible in

law for ensuring that home abortions for under 18s do not occur beyond 10 weeks." *Id*. at 1-2.

The Royal College of Paediatrics and Child Health (RCPCH), the official membership body for paediatricians in the UK comprising 20,000 members, raised similar concerns. In a 2022 parliamentary briefing, they emphasized their strong pro-choice position, but noted that the legalization of telemedicine abortion "leaves a glaring gap—children and young people". Royal College of Paediatrics and Child Health, Lords consideration stage briefing on home early medical abortion provisions in the Health and Care Bill, (Apr. 5, 2022), *1, available at https://www.rcpch.ac.uk/sites/default/files/2022-04/RCPCHBriefingHealthandCareBillPositiononHomeEarlyMedicalAbortion5April2022.pdf.

They supported an amendment to the law requiring that children and young people be seen face-to-face before an abortion for three reasons: 1) to make an overall assessment of physical and mental health; 2) to undertake a safeguarding assessment; and 3) to determine the gestation of pregnancy – implying this cannot be done reliably by telemedicine.

Leading pro-choice medical authorities taking a political position alongside pro-life critics is virtually unprecedented in the UK, where only 6% of the population oppose legal abortion. *See* YouGov, Where does the British public stand on abortion in 2023?, (Oct. 12, 2023), available at https://yougov.co.uk/politics/articles/47568-where-does-the-british-public-stand-on-abortion-in-2023. Yet the safety threats posed by telemedicine were so severe as to prompt this unprecedented intervention from two leading medical bodies. Two former

Presidents of the Royal College of Physicians and Surgeons of Glasgow also publicly opposed the policy. *See* Kieran Andrews, Zoom consultations for abortion pills should be stopped, (Oct. 30, 2021), available at https://www.thetimes.co.uk/article/zoom-consultationsfor-abortion-pills-should-be-stopped-wt0tqd6j5.

Given the reliance of the FDA on UK studies, and the alleged comprehensiveness of their review, it is extremely difficult to believe that they would have been unaware of the significant safety concerns raised by leading medical authorities in the UK, including the NNDHP's intervention in March 2021.

Because of these concerns and mounting evidence on complications, the pro-choice UK government subsequently announced a politically costly and embarrassing repeal of their own telemedicine abortion policy (but was overruled by a parliamentary vote).

B. Pro-choice medical authorities and abortion clinics in the Netherlands oppose telemedicine abortion.

More remarkable still is the attempt to introduce telemedicine abortion in the Netherlands, which was opposed not only by pro-choice medical authorities but by the federations of abortion doctors and clinics themselves. After Women on Waves asked for telemedicine abortion to be legalized, the Minister for Medical Care and Sport replied: "Abortion care … must be carried out carefully, safely and medically responsible. Providing medication by post does not fit with this view … I have not currently received any

signals from the abortion sector that require an adjustment to the current policy." Civil Court, The Hague, Netherlands; ECLI: NL:RBDHA:2020:3551 (2020), available online at https://uitspraken.rechtspraak.nl/details?id=ECLI:NL:RBDHA:2020:3551 (translated by Google).

Women on Waves litigated this decision, but were refused by the District Court of The Hague. In the judgment, it was noted that telemedicine abortion was opposed as dangerous by both StiSAN, the Federation of Co-operating Abortion Clinics in the Netherlands, and NGVA, the Dutch Society of Abortion Doctors. StiSAN wrote: 'There are no signals from the clinics that women cannot receive the care they want … None of the clinics have seen a decline in the numbers of clients … No signal has been received from the clinics that women are being influenced by this corona crisis." *Id*. They continued:

> StiSAN, but also NVGA, strongly advise against giving pills to women and girls for an early medical abortion … via any route other than the abortion clinic. For termination of pregnancy up to 10 weeks … first a decision-making interview on the basis of which decision-making can be made. In addition, the pros and cons of medical abortion are discussed and contraceptive measures are discussed to prevent a repeat abortion. This knowledge is not available among pharmacists or general practitioners. The gestational age must also be determined by making an ultrasound. Providing an abortion pill after 10 weeks can have far-reaching medical

> consequences for a client. Consider complications that could occur that would require referral to a hospital.

Id. Likewise, the NGVA voiced their opposition to telemedicine abortion, taking the side of the state. Consequently, the Court rejected Women on Waves' appeal and ordered them to pay court costs. *Id*.

The FDA and Danco accuse the Fifth Circuit of "second guessing" the FDA's scientific judgment. But when leading pro-choice medical professionals have blown whistles across Western Europe, the judiciary is wise to listen.

III. The FDA's adverse events data was clearly false.

The FDA relied first on adverse events data available through the FDA Adverse Event Reporting System (FAERS). The irrationality of relying on such data after removing the requirement for reporting of non-fatal adverse events has been well noted and expounded at length by the Fifth Circuit, among others. Danco's claim that "anyone *can* still report any other adverse events," Danco Br. at 50 (italics added), is obviously irrelevant. No one claims otherwise. The fact that it is entirely voluntary, time-consuming, and against the interests of the abortion industry and its supporters to report means that many adverse events will not be *reliably* reported, and this is borne out by the data and statistics which are—very obviously to any competent and informed observer—dramatic underestimates.

Even a basic familiarity with abortion complications literature reveals that the rates reported by the FAERS system and other studies the

FDA relied on were beyond credulity. The FDA gave a substantial amount of weight to the Aiken study. *See* Abigail R.A. Aiken et al., *Effectiveness, safety and acceptability of no-test medical abortion provided via telemedicine: a national cohort study*, 128 B.J.O.G. 1464 (2021).

For example, the major systematic review published by Endler, et al. in 2019 (and hence available to the FDA) studied telemedicine abortion across a wide variety of studies from different countries. *See* Margit Endler et al., *Telemedicine for medical abortion: a systematic review,* 126 B.J.O.G. 1094 (2019). In some of these studies, there was an in-person component, making them safer than the regime ultimately endorsed by the FDA. Yet even in these studies, surgical intervention rates were far higher than those reported by FAERS or Aiken. Almost all the studies required surgical intervention at least 5% of the time, and many required it in over 10% of cases. In one major study, the surgical intervention rate was 19.3% even for pregnancies under 9 weeks gestation, rising to 44.8% over 13 weeks. *Id.* at 1097. A 2020 systematic review on at-home abortion from the prestigious Cochrane Library concluded that "[t]he evidence for the safety of these interventions was very low." Cochrane Library, Self-administered versus provider-administered medical abortion, (2020), available at https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013181.pub2/full.

By contrast, the FDA report a mere 8 adverse events over a 20-month period from January 2020 to September 2021, including 5 adverse events during the period of non-enforcement (July 2020-January

2021; April 2021-September 2021). Pet. App. 57a. These numbers are plainly false to any competent authority. It is the height of absurdity to believe that there were a mere 5 adverse events among the hundreds of thousands of abortions during the non-enforcement period, when virtually every credible study on medical abortion—including the UK data, and the studies on which the FDA relied (see below)—demonstrate complication rates orders of magnitude higher than this. To rely on such manifestly unreliable data when explicitly aware of plainly contradictory data is not mere scientific disagreement; it is straightforward irrationality. Likewise for the evidence cited in Danco's submission before this Court, alleging that fewer than 0.1% experienced *any* adverse event. Danco Br. at 10. Every credible study on this topic demonstrates adverse events orders of magnitude higher. The FDA would be aware of such other studies and should have been aware of the UK data showing otherwise (described below), given their reliance on UK data. Thus, they acted irrationally in trusting the FAERS data in the face of a mountain of contrary evidence known to them.

IV. A review of published studies

A. The shortcomings of the studies used by the FDA

The FDA relied secondly on published academic studies purporting to show that telemedicine dispensing of mifepristone is safe—that is, dispensing the drug without any routine in-person contact between the patient and provider. Given the safety risks detailed above— and raised widely and publicly

across the Western world—it was incumbent upon the FDA to produce studies alleviating these concerns. They did not do so. For multiple safety risks, the cited studies did not even address them at all, thereby showing that the FDA "entirely failed to consider an important aspect of the problem" and hence broke the law and violated its duty to consumers. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)). For other safety risks, the cited studies considered them only in the most skeletal sense and were manifestly ill-designed to capture even remotely accurate data about them. For other safety risks still, the cited studies—and other data from the UK (see below)—*confirmed* the concerns that had been raised. Thus, the FDA also acted in a way that was clearly inconsistent with basic norms of rationality.

The FDA claims that these studies were "not inconsistent" with the safety and efficacy of mail-order mifepristone. Pet. App. 57a. This is a lower bar than necessary—and even then, they fail to clear it: the very data they considered did, in fact, reveal substantial safety concerns that were inconsistent with their conclusion. Other data available from Europe, described above, compounds these concerns. In light of the considerable public and political discourse surrounding telemedicine abortion, and the safety concerns raised by major medical authorities in the UK, it would have been difficult or impossible for the FDA to be simply unaware of these data and concerns. Hence, in accepting data that was inconsistent with their conclusions and interpreting it as supporting (or at least being consistent with) their conclusions, and in entirely ignoring data and

concerns raised by leading medical authorities in Europe, they acted irrationally.

The FDA cited four studies in their initial non-enforcement decision in April 2021. Janet Woodcock, Letter from Janet Woodcock to Drs. Maureen Phipps and William Grobman, (Apr. 12, 2021), available at https://www.aclu.org/wp-content/uploads/legal-documents/fda_acting_commissioner_letter_to_acog_april_12_2021.pdf. None of these studies—individually or taken together—come close to demonstrating the safety of telemedicine abortion. Indeed, they contain evidence to the contrary.

The first paper did not study telemedicine abortion in isolation at all. *See* Erica Chong et al., *Expansion of a direct-to-patient telemedicine abortion service in the United States and experience during the COVID-19 pandemic*, 104 CONTRACEPTION 43 (2021). Rather, it combined data from two separate experimental conditions, one set involving ordinary pre-abortion in-person screening, and a far smaller set waiving the ultrasound requirement. These datasets were not separated for comparison, making any conclusions about the safety of waiving the ultrasound requirement impossible. Moreover, it was not explained which in-person regulations were still preserved, nor by which clinics. Even despite these safeguards remaining in most of the patients, 6% required emergency room visits, and 7.8% other outpatient visits. 1% had serious adverse events. 17% were lost to follow up with no known outcome. Not only did this study fail to show convincing safety outcomes; for the overwhelming majority of patients it included, it did not even study the conditions the FDA sought to introduce. To rely on it was irrational.

The second study used a tiny sample of 330 patients, 12.2% of whom were lost to follow-up with outcomes unknown (18.5% of the most relevant population—those who didn't receive an ultrasound). *See* Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: practical experience with multiple care delivery models*, 104 Contraception 49 (2021). Of these, 139—nearly half—had already had an ultrasound prior to presenting, and a further 51 had a routine ultrasound. Only 75 patients were mailed the drugs, and of these, 71 were 'TelAbortion' patients, whom the authors describe as having an "ultrasound or pelvic examination performed before being mailed medications". *Id.* at 50. Hence it appears that virtually the whole sample had some in-person contact—whether ultrasound, physical examination, or in-person collection of drugs—prior to the abortion. Hence the study simply does not study the conditions the FDA sought to approve. To rely on it was therefore irrational. In any case, a significant proportion, 4.2%, required surgery, and 3.8% required an emergency room visit. Other details regarding adverse events were minimal.

The third study studied 663 Scottish women, explicitly conceding that "the study size … is still too small to detect changes in rare events." *See* Reynolds-Wright, et al, *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during the COVID-19 pandemic*, 47 B.M.J. SEX REPROD. HEALTH 246, 250 (2021). Already by the 14-day follow-up, 8.4% of the sample had been lost. 2.4% required emergency hospital visits, and a further 8.4% required an urgent clinic assessment, mostly for signs or symptoms of continuing pregnancy. Given the survey methodology, this

suggests that the relatively[7] low 2% failure rate they report was *subsequent* to further treatment, including emergency surgical intervention—thus hiding this large number of adverse events and emergency interventions. The need for urgent clinic appointments more than tripled compared to earlier studies showing a 2.7% rate. The researchers noted that this high rate of urgent clinic assessments could have been due to the researchers actively following up and encouraging women to attend who had potentially incomplete abortions. It follows that without that experimental setting active follow-up, still more women would have presented with urgent complications to the emergency department.

In this paper, only one patient had an ectopic pregnancy, far lower than the standard population rate of 1-2%. This made it impossible for the study to meaningfully study how telemedicine abortion affects the tens of thousands of women in the U.S. each year with ectopic pregnancies.

Only 71.3% of participants said they would use telemedicine again, suggesting that nearly a third were at least somewhat unsatisfied with the experience. These presumably included a significant number who had been coerced into abortion. The study found an enormous drop in LARC use, from one third prior to telemedicine to just 8.7% in the study conditions. This would put thousands of women at increased risk of future unintended pregnancy, with a huge public health impact.

The fourth and final study on which the FDA relied was that of Aiken, authored primarily by

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[7] Relative to other studies.

leading abortion advocates in the UK. *See* Aiken (2021).

This was by far the largest study, constituting almost the entire sample on which the FDA relied. This study appeared to study a genuine telemedicine protocol and found failure rates of 0.8% among the telemedicine cohort. The problems with this study, however, are manifold and indeed obvious.

The most obvious is that, even if the data were reliable, they demonstrated significant safety issues. For example, regarding the concern that telemedicine could lead to unattended second and third trimester abortions at women's and girls' homes, the study found that in the traditional in-person control cohort, this did not happen once in 22,197 abortions. By contrast, among the 30,021 abortions done under the telemedicine regime, this happened 11 times—putting a significant number of women and girls at risk. The FDA did not even comment on this finding, despite it being one of the most prominent concerns highlighted by medical authorities in the UK at the time.

Likewise, the study evaluated a number of women who had treatment for ectopic pregnancies *after* the abortion pills were taken—i.e., the ectopic pregnancy was not identified and treated prior to the attempted abortion. In the traditional in-person cohort, this happened only twice in 22,197 abortions. But in the telemedicine cohort, this happened ten times in 30,021 abortions—the rate more than tripling.[8] Again, the FDA did not comment on this alarming

[8] Miller (2022) at 293 provides further evidence.

finding. Even these were likely vastly underestimated, for reasons explained below.

B. The FDA irrationally relied on manifestly incomplete and flawed UK data.

It is widely known—and was at the time—that complications from telemedicine abortion in the UK were far higher than those reported in the Aiken study. The study reported 7 adverse events in around 30,000 telemedicine abortions, a rate of 0.02%. They reported that only 1.2% of abortions failed, requiring surgical management. However, objective data from the same country and the same period available at the time of the FDA's original letter clearly contradicted this, despite Aiken claiming that they had included 85% of all telemedicine abortions performed nationally between April and June 2020. An e-mail from a regional chief midwife in late May 2020 was leaked, detailing "an escalating risk around the 'Pills by Post' process." Christian Concern, NHS email leak reveals 'DIY' abortions killing and harming pregnant women, (July 31, 2020), available at https://christianconcern.com/ccpressreleases/nhs-email-leak-reveals-diy-abortions-killing-and-harming-pregnant-women/. In one region alone, this included:

> women attending [emergency department] with significant pain and bleeding related to the process through to ruptured ectopics, major resuscitation for major haemorrhage and the delivery of infants who are up to 30 weeks gestation. There was also … a woman [who] was found to be 32 weeks [pregnant]. … [T]here is a concern that the baby was live born. … it was clear … that the only reporting

> of incidents, to the [Care Quality Commission], from this sector are those that are significant, i.e. babies that are found to be a late [termination of pregnancy], as all the other outcomes are seen to be a complication of the process which could occur in any setting. There is therefore no data to compare current outcomes to. … The balance of risk both physically, mentally and for safeguarding is challenging especially without data.

Id. This letter thus highlighted a) the poor quality of data in the UK; b) the fact that only complications above a certain threshold—seemingly subjectively defined as 'significant'—were being reported; and c) within one region alone in just two months, there were a wide variety of extremely serious complications, medically and legally.

This leaked letter was well-publicized in the national press, and it seems very unlikely that it would be unknown to the FDA. *See* Tom Wells, Pills by post: murder probe launched into death of newborn after mum took 'pills by post' abortion drugs, *The Sun*, (July 30, 2020), available at https://www.thesun.co.uk/news/12273020/newborn-death-pills-by-post/. It is straightforwardly impossible to reasonably believe that if all these incidents[9] occurred before the end of May 2020 in one region alone, a study accurately capturing 85% of national abortions and their complications from April to June 2020 would only catch 7 adverse events.

[9] And perhaps others unknown to the chief midwife.

Aiken's study is simply not credible, and any reasonable observer would have recognized this.

This was not the only evidence available: in February 2021, the results of an investigation were published, based on Freedom of Information requests directly to hospital trusts. *See* Kevin Duffy, Hospital treatments for complications from early medical abortion, (Feb. 22, 2021), available at https://percuity.files.wordpress.com/2021/02/complications-from-ema-kd210211.pdf/. This showed at least 19 abortions occurring beyond the 10-week limit for telemedicine, with 4 beyond 24 weeks. Moreover, at least 36 women called emergency services every month for complications of medical abortion, and an estimated 495 women attended hospital with incomplete abortion each month—2.4% requiring surgery. This is double the rate reported by Aiken, even without including incomplete abortions not treated surgically. The report found a haemorrhage and sepsis rate of 0.75%, five times higher than the official statistics, and an order of magnitude higher than the rate reported by Aiken. (who reported no cases of sepsis at all).

A later FOI report from October 2021—preceding the FDA's December 2021 letter—found that 5.9% of women having abortion pills were subsequently treated at an NHS hospital, with 3.0% requiring surgery—nearly triple the rate reported by Aiken. *See* Kevin Duffy, FOI investigation into medical abortion treatment failure, (Oct. 27, 2021), available at https://percuity.files.wordpress.com/2021/10/foi-ma-treatment-failure-211027.pdf.

Another FOI report from November 2021 found that ambulance callouts relating to complications

from medical abortion had tripled in recent years, following the introduction of at-home abortion (prior to telemedicine abortion). *See* Kevin Duffy, Emergency ambulance responses three times higher for pills-by-post, *1, (Nov. 16, 2021), available at https://percuity.blog/2021/11/16/emergency-ambulance-responses-three-times-higher-for-pills-by-post/.

A further investigation found that ambulance callouts for medical abortion complications increased 64% after the introduction of telemedicine abortion. *See* Tom Evans, Ambulance dispatches and 999 calls responding to abortion pill concerns have risen by 64% since 2019, *GB News*, (Aug. 30, 2022), available at https://www.gbnews.com/news/ambulance-dispatches-and-999-calls-responding-to-abortion-pill-concerns-have-risen-by-64-since-2019-gb-news-investigation/359311. Given the discrepancy between these data and those of Aiken, the question arises as to why. There are a few reasons.

In general, it is known that abortion providers in the UK have been routinely criticized for poor reporting even of the most serious incidents. Evidence has emerged more recently from the same hospital regulators Aiken supposedly consulted (the Care Quality Commission) that abortion providers such as those Aiken approached for data fail to highlight and notify the relevant authorities of serious incidents—for example, 3 cases in one clinic where patients were sent five hours by train to complete a surgical abortion after taking the first abortion pill, with no documentation of even a discussion about the risks and mitigating them. *See* Care Quality Commission, BPAS – Middlesbrough, *11, (2021), available at

https://api.cqc.org.uk/public/v1/reports/beb7e1f3-b0f7-458e-bc2f-c74df1e76b87?20211104080100; Care Quality Commission, BPAS – Doncaster, (2021), available at https://api.cqc.org.uk/public/v1/reports/bc49d8d2-46df-4b00-8d9f-965383c0be81?20211104080100; Care Quality Commission, BPAS – Merseyside, (2021), available at https://api.cqc.org.uk/public/v1/reports/b1211e17-f487-48a2-acde-00007f702a50?20211102080239#.

A government report (Department of Health and Social Care, DHSC) from 2023 explained in detail just how unreliable the data on which Aiken relied is. *See* Department of Health and Social Care, Complications from abortions in England: comparison of Abortion Notification System data and Hospital Episode Statistics 2017 to 2021, *1, (2023), available at https://www.gov.uk/government/statistics/complications-from-abortions-in-england-2017-to-2021/complications-from-abortions-in-england-comparison-of-abortion-notification-system-data-and-hospital-episode-statistics-2017-to-2021.

They described the two primary datasets available: i) the Abortion Notification System (ANS), which collects complications noted on the HSA4 form, the form filled out for every abortion, including demographic details, the legal justification for the abortion, and so on; and ii) the Hospital Episode Statistics (HES), which collects data of hospital encounters in general, many of which are connected to abortion codes in the coding system. Since the HSA4 form requires abortion providers to document known complications, any complications known to abortion providers should be part of the ANS system.

Hence the ANS system is a good proxy for the data that Aiken used, which came directly from abortion providers.

Many abortion providers in recent history were prone to illegally pre-filling abortion HSA1 forms indicating the reason for abortion before the healthcare professional was even aware of the patient. *See* Department of Health, Guidance in relation to requirements of the Abortion Act 1967, *7-8, (2014), available at https://assets.publishing.service.gov.uk/media/5a7dcc2fed915d2ac884d9d9/20140509_-_Abortion_Guidance_Document.pdf.

This does not inspire confidence that abortion providers would reliably fill out the complications section, even if aware of the complication.

As the government report indicates, the ANS system dramatically underreports abortion complications. One main reason is that it does not even count the most common complication of abortion: incomplete abortion and need for emergency surgery, which is counted as a complication by the National Health Service elsewhere. *See* National Health Service, Abortion risks, (2020), available at https://www.nhs.uk/conditions/abortion/risks/.

Another main reason is that the HSA4 form is filled out and sent generally when the woman is discharged—if the abortion occurs at home, then it is sent without seeing the woman at all. Most complications of abortion take time to manifest (sometimes years, as in Rhesus disease) and would happen after the form is sent, and even if they do occur before, there is no reason why the abortion provider would know about it. This is illustrated by

the fact that complications reported in the ANS were fewer than 10% of those found in the HES system, which itself contains significant underreporting (see below).

A third major reason is that the NHS number is not required on abortion HSA4 forms, making it impossible to connect complications treated in hospitals with the woman obtaining the abortion. Abortion providers in the UK have routinely opposed including this number, despite the fact that it would help collect data on abortion safety and that such record-linkage is widely done in 'progressive' countries such as those of Scandinavia. Most abortion complications will never even come to the attention of the abortion provider because they will present instead to emergency services.

The DHSC report explicitly describes how complications post-discharge are unlikely to be recorded, *especially* when the abortion is done at home: "If the abortion provider is informed (of a complication), they would need to have documented the relevant HSA4 form identification number and contact DHSC to ask for the form to be returned to them or updated with the relevant information. In 2022 there was no evidence of this occurring." Department of Health and Social Care (2023) at 1. They note that even if the provider wanted the form back, they would have to have the relevant identification number, which is by no means guaranteed.

In general, therefore, the pattern is a) abortion providers are unaware of complications; b) even if they become aware, they may not be able to retrieve the form to document it; c) even if they could do so,

there is no evidence of willingness to do so. As the DHSC summarize, "In 2022 there was no evidence of this occurring"—over 200,000 abortions were performed in the UK that year. *Id*.

In summary, therefore, the data on which Aiken—and the FDA—relied was demonstrably unreliable. This should have been obvious given the complication rates reported which are far lower than any other study on this topic, but is even more obvious when considering where the data come from, and how unreliable the reporting systems are. It is more obvious still when considering better quality UK data available from exactly the same period—much of which was available to the FDA (for example, the Freedom of Information reports detailed above).

The second system used in the government report, HES, found a complication rate over 10 times higher than the data from abortion providers. Yet even this system underestimated complications considerably. One reason is that in the government report examining complications in the HES system, a wide variety of ICD-10 codes pertaining to incomplete abortion and other complications were excluded—even obviously relevant codes like O07.1 (failed medical abortion, complicated by delayed or excessive haemorrhage). Complications treated in emergency departments, as an outpatient, at the abortion provider, or even at home were also omitted.

The HES data did demonstrate, incidentally, that abortion complication rates dramatically increased as gestation increased, with an abortion rate 60 times higher after 20 weeks compared to the first 9 weeks. This should be interpreted cautiously given the underreporting described above, but it reflects the

unanimous consensus that abortions at later gestations are riskier, something that FDA/Danco inexplicably cast doubt on when trying to undermine traceability in this case.[10]

Despite these obvious causes for underestimation of abortion complications, the HES system still showed a complication rate over 10 times that of the ANS data, the latter of which approximates the data Aiken used. Hence it is demonstrable that Aiken's data were not merely somewhat inaccurate—they were worse than useless. This should have been obvious to anyone with even the remotest acquaintance with *either* a) UK abortion complications reporting or b) abortion complications research in general. The FDA, in relying on UK data so crucially, should have been thoroughly familiar with *both*.

Aiken explicitly conceded they could have suffered from underreporting, Aiken at 1471, but attempted to mitigate this with five central claims:

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[10] The UK data relied upon by the FDA clearly show a far higher complication rate for later abortions. J.A. 404-06. This data is deeply unreliable, as explained, but that argument is not open to the FDA, who relied almost entirely on it and should have heeded it. In any case, the positive correlation between gestational age and prevalence of abortion complications is a universally recognized fact, and indeed is often one of the main arguments used by abortion advocates for increasing access. Aiken explicitly notes: "Even small reductions in waiting time are significant—NICE noted that a reduction of 1 day resulted in annual savings of £1.6 million to the health services in England owing to reduced complications and fewer needing to opt for a surgical abortion." Aiken, at 1470. That the FDA would seem to cast doubt on this uncontroversial fact is astonishing.

1) Patients are more likely to report complications to their abortion provider than to NHS providers (hospitals, clinics, etc.).

2) Abortion providers therefore are likely to have a relatively comprehensive database of complications following abortion.

3) Abortion complication reporting systems within the NHS are "well defined," suggesting that the NHS has a cogent, consistent and comprehensive system for capturing abortion complications.

4) Under-reporting of complications is not more likely in the telemedicine cohort compared to the in-person cohort.

5) The regulators they consulted did not identify any additional complications that were previously unknown to the abortion providers.

In fact, however, claims 1-4 are categorically false. As described in this brief and as the data illustrate: 1) Patients are very unlikely to report complications to their abortion providers, and much more likely to report to hospitals, since they are seeking emergency care; 2) Abortion providers have a paltry database of abortion complications and report almost nothing compared to reputable sources; and 3) Reporting systems within the NHS are the opposite of well-defined; they are subjective, scanty, inconsistent, and unreliable in about every way—this is obvious to anyone with a basic familiarity with either those reporting systems or with abortion complications data more generally. The FDA should have had a basic familiarity with *at least one of those*, either of which would be sufficient to mandate complete scepticism

about the Aiken data. Moreover, as to Aiken's fourth claim, as the government report noted, there is a blindingly obvious mechanism by which under-reporting in the telemedicine cohort is worse than in the in-person cohort: namely, the abortion provider might witness the complication and document it on the form if they see the woman in person, but obviously will not do so if they never see the woman at all.

Finally, claim five is true, but this undermines the FDA's case further, since it demonstrates the extremely poor quality of NHS regulators' complication reporting.

In summary, anyone with the vaguest familiarity with the UK data—or any data at all—could see how dramatic the underestimation was in Aiken's study. Table 3 in the DHSC report demonstrates the wide range of complications which were captured in *neither* dataset.

V. The FDA violated the law and its duty.

The FDA thus violated the law and its duty in multiple respects. First, it ignored evidence before them—even cited by them—which revealed the same safety concerns raised by leading medical authorities and politicians.

However, even more clearly, it failed the basic standard and "failed to consider important aspects of the problem." *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.* at 43. Only a small number of the potential risks of telemedicine abortion were even considered by the FDA, however unconvincingly. The FDA failed in its duty to consider safety risks on almost every count.

1) Gestational age: Aiken found 11 babies born beyond the expected gestational age during telemedicine, compared to 0 prior. This clear discrepancy was ignored by the FDA. UK FOI data clearly show many women and girls subject to medical risks as a consequence.

2) Rhesus disease: No studies examined the development of Rhesus disease subsequently. Thus the FDA "entirely failed to consider an important aspect of the problem".

3) Undetected ectopic pregnancies: Aiken showed more than triple the rate of undetected ectopic pregnancies during telemedicine compared to the traditional regime. This was ignored by the FDA. UK documents demonstrate women suffering from ruptured ectopic pregnancies and major haemorrhage as a result of telemedicine abortion within a month or two of its approval.

4) None of the studies covered the variety of complicating factors highlighted by the WHO as reason for physical examination, and how these affected outcomes: multiple pregnancy, fibroids, pelvic tumours, molar pregnancies, malaria, pre-existing infections, etc. Hence the FDA neglected more "important aspects of the problem".

5) Sexually transmitted diseases: None of the studies examined STD screening rates and the impact of switching to telemedicine abortion on public health. Data from the UK show that the number of women not receiving an offer of chlamydia screening doubled after telemedicine.

6) Reliable contraception: Reynolds-Wright et al. found that LARC use decreased from around a third to just 8.7% after telemedicine abortion, putting thousands of women at risk. This clear evidence of negative public health impact was entirely ignored by the FDA.

7) Coerced abortion and domestic abuse: Perhaps the most serious safety issue, certainly the issue which was raised first and foremost by NNDHP, RCPCH and the UK government, was the risk of telemedicine for women undergoing coerced abortions and domestic abuse, for which in-person consultations are the best way to screen. None of the cited studies studied this at all. Hence one of the most—perhaps the most— important aspect of the problem was entirely neglected by the FDA.

In summary, the FDA ignored evidence of safety risks even within the papers it cited, it ignored a variety of other available data and literature and professional bodies raising concerns, and in multiple different respects, it entirely failed to consider "important aspects of the problem" wholesale. *See Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, at 43.

Thus, it acted clearly in violation of the law and its basic duties.

CONCLUSION

Data from Europe, primarily the UK, reveal that a) telemedicine abortion has caused high complication rates, including putting a significant minority of women at serious danger of losing their lives; b) the data on which the FDA relied was entirely untrustworthy, and—given other data widely available—this should have been obvious to any minimally competent investigator such as the FDA; c) leading medical authorities—including even two federations of abortion providers—raised serious concerns about telemedicine. Given the political salience of this topic, its broad media coverage, and the allegedly comprehensive review that the FDA undertook[11] (including an almost complete reliance on UK data specifically), the FDA would—if they indeed undertook such a comprehensive review—be aware of these concerns and would have appropriately responded to them.

Given that there is broad opposition to telemedicine abortion in the medical community—pro-life and pro-choice—while only those with significant political or financial vested interests are in favor, the Court should affirm.

Consequently, by annulling the FDA's decisions, the Court would not be second-guessing the careful and complex scientific judgment of experts, but merely recognising the patently ridiculous for the patently ridiculous. Contra FDA Br. 12, 39, 44; Danco Br. 3, 39, 50. The judiciary is well equipped and

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[11] "A thorough scientific review by experts within [FDA] who evaluated relevant information, including available clinical outcomes data and adverse event reports" J.A. 377. "FDA comprehensively reviewed the data." Danco Br. at 48.

competent to do so, and indeed must do so in order to fulfill its role. Scientific credentials should not, and cannot, be a free pass for the FDA to act in ways that are manifestly irrational, as they have been on myriad counts here.

Danco submits that "agencies are not required to have 'perfect empirical or statistical data' before acting", but that is not at stake. Danco Br. at 43. The data used by the FDA in this case were not imperfect; they were absurd.

Likewise, the argument that the FDA need act only "within a zone of reasonableness" is irrelevant, since it clearly did not do so. It ignored a wide variety of important aspects of the problem, relied on various studies which did not even vaguely resemble the conditions they sought to authorize, relied on obviously unreliable data contradicting the unanimous scientific record on mifepristone's complications, ignored most of that scientific record and relied on a highly selective set of unreliable studies, and ignored even significant evidence of safety risks within the studies it did cite. None of these can be put down to expert disagreement. They can only be put down to ideological chicanery or sheer incompetence. Neither is an adequate legal basis for the FDA's actions.

The Court should affirm.

Respectfully submitted,

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