UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

PRETERM-CLEVELAND, INC., et al.,	:	**Case No. 1:18-cv-109**
Plaintiffs,	:	**Judge Susan J. Dlott**
vs.	:	
LANCE HIMES, et al.,	:	**DECLARATION OF JUSTIN LAPPEN, M.D., F.A.C.O.G., IN SUPPORT OF PLAINTIFFS' MOTION FOR A TEMPORARY RESTRAINING ORDER AND/OR PRELIMINARY INJUNCTION**
Defendants.	:	

I, Justin Lappen, pursuant to 28 U.S.C. §1746, declare under penalty of perjury that the following is true and correct:

1. I am a maternal-fetal medicine specialist ("MFM") and a board-certified obstetrician-gynecologist ("OB/GYN").

2. I earned my medical degree at Johns Hopkins University in 2006, completed my residency training at the McGaw Medical Center of Northwestern University from 2006 to 2010, and completed my fellowship in Maternal-Fetal Medicine at MetroHealth Medical Center of Case Western Reserve University in 2017. I am also a fellow of the American College of Obstetricians and Gynecologists ("ACOG").

3. As an MFM, I specialize in the management of high-risk pregnancies. A specialization in maternal-fetal medicine requires an extra three years of training, beyond the standard residency period for an OB/GYN. My goal as an MFM is to help women and families through challenging

pregnancies—pregnancies that may be complicated by advanced maternal age, a medical condition, a fetal anomaly diagnosis, or more than one of these.

4. I am also an assistant professor of obstetrics and gynecology and of family medicine at the Case Western Reserve University School of Medicine. I have served as Associate Residency Program Director in Obstetrics and Gynecology and Assistant Director of a Ryan Residency Training Program in Family Planning. Additionally, I have served as Director of a Fellowship in Advanced Obstetrics in the Department of Family Medicine. Since 2010, I have trained hundreds of medical students, residents, and fellows.

5. I am actively engaged in research and have authored 26 manuscripts published in peer-reviewed journals, 29 presentations at national meetings, and 7 book chapters. I have participated in national consensus panels including the National Partnership for Maternal Safety committee on Vital Sign Triggers, a group sponsored by ACOG and the Society for Maternal Fetal Medicine ("SMFM") to reduce preventable maternal morbidity and mortality in the United States.

6. In addition to my hospital practice, I also perform abortions at Preterm up to 21 weeks, 6 days after the woman's last menstrual period ("LMP") (which is the same as 20 weeks postfertilization), a point in pregnancy that is prior to viability. I have worked at Preterm since 2010. I am therefore familiar with Preterm's services and patients. I have attached my curriculum vitae summarizing my educational and professional background and qualifications.

7. I have read the text of H.B. 214, which is set to go into effect on March 23, 2018. It is an affront to Ohio women and families.

8. When a woman receives a diagnosis of Down syndrome or another fetal anomaly, only she can decide how to proceed, along with her family, her pastor, her clinical team – whomever

she involves in this intimate decision process. Some women decide to continue the pregnancy, knowing that it is the right thing to do for them; others decide to terminate, knowing that that is the right decision given their lives, the needs of their existing children and other family members, their health, and a host of other factors that only they can weigh. My job is to inform, care for, and support my patients and their families, whatever decision they make. That means ensuring that my patients who decide to parent children with Down syndrome have the information and support they need to make this very personal and important decision. It also means ensuring that my patients who decide to terminate have access to the highest quality abortion care.

Facts about abortion

9. As a result of my study, training, and years of clinical experience, including my clinical practice at Preterm, I am familiar with the following facts and statistics about abortion.

10. Abortion is one of the most common medical procedures performed in the United States today. Approximately one quarter of the women in this country will have an abortion by age forty-five. Of those women, a majority (61%) have at least one child, and most (66%) plan to have a child or children in the future.

11. Abortion is virtually always safer than carrying a pregnancy to term. A woman is ten times more likely to die from carrying a pregnancy to term than from a first trimester abortion.

12. Women seek abortion for a variety of reasons, including familial, medical, and financial. For example, some women make the decision to terminate a pregnancy because it is not the right time in their lives to have a child or to increase the size of their families. Some women choose abortion because they have an underlying health condition that is caused by or exacerbated by continuing a pregnancy. Some may decide to end a pregnancy because it is the result of rape or

incest. Some women terminate a pregnancy after receiving a pre-natal diagnosis of fetal anomaly.

13. Most abortions are performed during the first trimester of pregnancy, at or before 14 weeks LMP; nearly 90% are performed in the first twelve weeks.

14. Many women who have abortions after the first trimester do so because of obstacles that prevented them from seeking the abortion earlier, such as financial difficulties and trouble accessing an abortion clinic. Others receive a fetal diagnosis that is not available until later in the pregnancy.

15. Women in Ohio may choose from two different types of abortion procedures: medication abortion and surgical abortion.

16. Medication abortion involves taking medications that cause the woman to undergo a process similar to an early miscarriage. In Ohio, medication abortion is available up to 70 days (10 weeks) LMP.

17. Surgical abortion, despite its name, is not a typical surgical procedure: it does not involve any incision. Rather, surgical abortion involves utilizing instruments to remove the products of conception from the uterus. In Ohio, surgical abortion may be legally performed until 21 weeks, 6 days LMP, which is the same as 20 weeks post-fertilization.

Facts about Down syndrome and Down syndrome Testing

18. In my MFM practice, I regularly counsel pregnant women about genetic and other fetal anomalies.

19. As a result of my training and practice in the field of maternal-fetal medicine, I am familiar with the following facts about Down syndrome and methods of testing for Down syndrome.

20. Down syndrome is the common name for a genetic anomaly, also known as Trisomy 21, that results from a trisomy—that is, an extra copy, whether full or partial—of the twenty-first chromosome.

21. There are various risk factors for Trisomy 21, such as advanced maternal age and having had a child with Down syndrome. But because Trisomy 21 results from a genetic event at the time of conception, there is no way to predict in advance of pregnancy whether a particular individual will have a fetus with Down syndrome.

22. Individuals born with Down syndrome may have a range of intellectual disabilities and medical conditions and therefore may require significant care stretching into adulthood. Individuals with Down syndrome may have one or more of the following medical conditions, and the severity of the conditions varies between individuals: intellectual disability; behavioral and/or psychiatric disorders that may interfere with function at home or school, congenital heart disease that requires one or more surgeries to repair, gastrointestinal disorders that may require surgical correction, hearing loss, endocrine disorders including diabetes and hypothyroidism, and bone and joint disorders including hip dislocation and instability of the cervical spine that may result in spinal cord compression. Given these associated medical conditions, individuals with Down syndrome require an organized, often multidisciplinary approach to care that extends from birth into adulthood. Testing during pregnancy cannot reveal whether a particular instance of Down syndrome will be severe or mild.

23. There are various screening and diagnostic tests available to determine the presence of any genetic, chromosomal, or structural anomalies, including Down syndrome. The typical approach to genetic screening in pregnancy includes the assessment for common fetal

aneuploidies—that is, an abnormal number of chromosomes—including Trisomy 21 (Down Syndrome), Trisomy 13, Trisomy 18, and aneuploidy involving the sex chromosomes (X and Y).

24. Screening tests cannot diagnose any particular anomaly, but rather indicate a likelihood or probability that one or more anomalies exist. These tests usually screen for a range of anomalies at the same time and may indicate a likelihood of more than one anomaly at once. By contrast, diagnostic tests diagnose the existence or non-existence of particular anomalies with near certainty.

25. ACOG, which is the preeminent professional association for OB/GYNs, recommends that all women should be counseled about prenatal genetic screening and diagnostic testing options as early as possible in the pregnancy, ideally at the first prenatal visit. ACOG recommends that all women, regardless of age, be offered the option of aneuploidy screening or diagnostic testing for fetal genetic disorders. ACOG also recommends that women with positive screening test results be offered further counseling and diagnostic testing.

26. There are multiple screening tests for aneuploidy used in pregnancy. First trimester genetic screening is available from 10 weeks 0 days to 13 weeks 6 days LMP and consists of an ultrasound measurement of nuchal translucency (a fluid-filled space on the back of the fetal neck) and the measurement of two hormones from the woman's blood. In the second trimester from 15 weeks 0 days LMP, a quadruple marker (or "quad") screening is available, which measures the levels of four different hormones in a woman's blood. These tests screen for Down syndrome, Trisomy 13, Trisomy 18, and anomalies of the brain or spinal cord. An additional screening test is an ultrasound examination. An ultrasound examination to assess the fetal anatomy is typically performed between 18 weeks and 20 weeks LMP and can often detect major physical anomalies in the brain and spine, skull, abdomen, heart, and limbs.

27. Another early screening test is a Non Invasive Prenatal Screening, or NIPS. Through a test of the woman's blood, NIPS evaluates cell free DNA in her circulation. Fetal cell free DNA can be isolated from her DNA as a mechanism to screen for genetic conditions or aneuploidy. NIPS is often combined with nuchal translucency screening in the first trimester. NIPS can be performed as early as 10 weeks LMP, and results are usually available within 7 days. Among other anomalies, the NIPS results indicate the probability of Trisomy 21.

28. If the screening indicates an increased probability of a fetal genetic condition or aneuploidy, it is my practice to offer patients a diagnostic test to confirm whether the anomaly that the screening test indicated is present. I also offer those patients counseling to help them understand the meaning of the screening test and to inform them of the risks and benefits of proceeding to a diagnostic test. This is consistent with the standard of care in my field and with ACOG guidelines.

29. There are two primary diagnostic tests that can confirm a diagnosis of Trisomy 21 or Down syndrome. The first is chorionic villus sampling (CVS), where a sample of cells is taken from the woman's placental tissue and analyzed. CVS is generally performed between ten and thirteen weeks LMP. The diagnostic accuracy of CVS for aneuploidy is greater than 99%.

30. The second diagnostic test is amniocentesis. Amniocentesis involves using a needle to extract amniotic fluid from the gestational sac, which is then analyzed for genetic abnormalities. Amniocentesis is generally performed beginning at 15 weeks gestation. The diagnostic accuracy of amniocentesis for aneuploidy is greater than 99%.

31. Many women will not receive a confirmed diagnosis of Down syndrome until well into the second trimester of pregnancy because amniocentesis, which tests for a wider range of conditions and is more widely available than CVS, is not available until 15 weeks LMP.

32. Although the available diagnostic tests provide a high level of certainty as to whether Down syndrome is present, there is no way to know before birth whether the Down syndrome will be mild, severe, or somewhere in between.

33. If the diagnostic test indicates Down syndrome (or another anomaly), the woman is again offered counseling to help her understand the condition and carefully consider her options, including whether to continue with the pregnancy.

34. When a patient is faced with an unanticipated screening result or diagnosis, including Down syndrome, my purpose is to provide comprehensive, objective, and individualized counseling to ensure she makes a well-informed and autonomous decision that is best for her and her family. In these challenging situations, I provide objective, compassionate, and non-directive counseling about options, including pregnancy continuation and termination, and I help women and their families navigate an unexpected and what may be a profoundly difficult situation. I provide patients with information that may help guide their decision-making, including resources regarding the specific diagnosis (which may include referrals to pediatric specialists, and advocacy or patient groups) and accurate, evidence-based information on pregnancy termination. If a patient is interested in gathering additional information, I typically refer her first to medical professionals—pediatricians and pediatric specialists. I also point her to non-medical resources including the National Down Syndrome Society and the National Down Syndrome Congress, as well as the Upside of Downs (which is a Northeast-Ohio based group). All of these organizations have excellent and informative websites and additional resources for patients seeking further information. This counseling complies with—and exceeds the minimum requirements of—Ohio law (Ohio Rev. Code § 3701.69(B)), which prescribes particular information that I must provide to patients who receive a prenatal or postnatal diagnosis of Down

syndrome. Importantly, I allow the patient's values, desires, and questions to guide our conversations.

Impact of H.B. 214 on My Patients

35. Providing ethical abortion care requires that I ensure my patients' decisions are informed and voluntary. In my experience, the overwhelming majority of my patients have arrived firmly at their decision for abortion after careful consideration of their options and what is best for their life, family, and circumstances, and so they are resolute in their decision. During my conversations with patients before, during or after abortion, some volunteer the reasons why they have pursued abortion and others do not. However, I do not ask them about the specifics of their path leading to their ultimate decision to pursue abortion. My primary responsibility is to assess for any lack of resolve or coercion, as I would not proceed with an abortion for any woman who is not certain of her decision or is being forced into it. I communicate with all of my patients that I am available to discuss any details of their decision if desired.

36. I am aware of a minority of my patients at Preterm who have terminated pregnancies after receiving a diagnosis of Down syndrome. (I cannot recall treating any patient who terminated a pregnancy based on a screening test alone.) This assertion is based, in part, on my conversations with patients, but for some patients may also be based on my review of their medical records. While it is not medically relevant for me to know whether there has been a Down syndrome diagnosis or screen in order to perform the procedure safely, we take a detailed medical history from patients prior to the procedure, and many will disclose the diagnosis during this time. In addition, most patients who come to Preterm for an abortion after a diagnosis are referred to us from another facility in Cleveland, somewhere else in Ohio, or even out of state, and this fact will usually be indicated in the patient's chart. These patients carrying pregnancies

with fetal anomalies typically come to Preterm only after undergoing extensive counseling with a specialist in Maternal-Fetal Medicine and a genetic counselor.

37. In my experience, which includes counseling women and families who receive diagnoses of various anomalies and providing care both for those who choose termination and for those who choose continuation of pregnancy, I do not feel it is possible (or appropriate) to generalize about the reasons underlying any woman's decision. The decision to terminate a pregnancy is motivated by diverse, complex, and interrelated factors that are intimately related to the individual woman's values and beliefs, culture and religion, health status and reproductive history, and resources and economic stability. In my experience, women make careful decisions that are most acceptable for their lives, families, and circumstances. The ability to make an informed and autonomous choice is of paramount importance, one that allows any individual woman to best direct her life in the present and future.

38. I am concerned that H.B. 214 will encourage women who have had Down syndrome testing and decide to proceed with an abortion to hide the test results from the physician and staff who will provide the abortion. This could have negative consequences for women who may prefer to discuss their reasons during the patient education session or who may wish to discuss the results with the physician who will perform the abortion.

39. As a Maternal-Fetal Medicine specialist, I also see many women with high-risk pregnancies. A "high-risk pregnancy" is one in which, because of advanced maternal age or a medical condition, there is an elevated risk of pregnancy complications and of resulting harm to the woman or the fetus.

40. Some women with high-risk pregnancies end up having complications that require an abortion in order to preserve their life or health. In some percentage of these cases, there is also a diagnosis of fetal Down syndrome.

41. There are numerous diagnoses that pose a substantial mortality risk in pregnancy, including pulmonary hypertension, maternal cardiac disease (cardiomyopathy, Eisenmenger's syndrome, or other congenital heart disease), or autoimmune diseases (lupus with nephritis or autoimmune hepatitis with cirrhosis). These are conditions that have mortality risks as high as 50% or have risks for progressive organ failure in pregnancy that could result in the need for transplantation.

42. The risk of fetal Down syndrome is independent of a woman's underlying medical conditions.

43. As I understand the meaning of H.B. 214, there is no exception allowing an abortion to proceed when it is necessary to preserve the life or health of the woman, if the Down syndrome diagnosis is also a reason for terminating the pregnancy. Therefore, if H.B. 214 goes into effect, I will be unable to provide an abortion necessary to preserve my patient's health if fetal Down syndrome is also a reason for her abortion.

44. If H.B. 214 goes into effect, I will be unable to provide abortion care to any woman who I know is seeking the abortion in part because of a screening test indicating Down syndrome, a diagnosis of Down syndrome, or any other reason to believe there is fetal Down syndrome. Instead, I will counsel her to travel out of the state, if possible, to have an abortion if desired. I believe that some of those women will ultimately be unable to obtain an abortion—for example, because they are unable to procure sufficient funds to travel out of state, or because the delay created by the law will push them past the point at which they can legally obtain an abortion.

45. I find the prospect of turning patients away to be both deeply upsetting and at odds with my professional obligation to act in their best interests. Women desire screening tests for chromosomal anomalies, genetic disorders, and anatomic abnormalities so they can make the most informed decisions about expanding their families. The ability to provide a genetic diagnosis but not provide comprehensive counseling and care, which includes pregnancy continuation and termination, disrupts my ability to practice evidence-based, individualized and compassionate medicine.

46. Moreover, H.B. 214 violates a fundamental principle of medical ethics, namely that of beneficence. By restricting a constitutionally-protected right to an abortion, H.B. 214 interferes with my ability to promote the welfare of my patients (beneficence), which is a central consideration in any physician-patient relationship. Forcing a woman to carry to term against her will, or to try to travel out of state for a medical procedure when my colleagues and I are fully capable of providing the safe, legal abortion she chooses, is a violation of this ethical principle.

47. My goal as an OB/GYN and as an MFM is to fully inform my patients of all relevant information affecting their pregnancies and to provide them with the best possible care. Because H.B. 214 would impose serious civil and criminal penalties on me if I provide abortion care to any woman seeking an abortion, in whole or in part, due to a test, diagnosis, or other reason indicating fetal Down syndrome, I am unable to meet this goal.

/s/ Justin Lappen
Justin Lappen, M.D., F.A.C.O.G.

Date Signed: February 15, 2018