# IN THE DISTRICT COURT OF SHAWNEE COUNTY, KANSAS DIVISION 7

HODES & NAUSER, MDs, P.A.;	)	
HERBERT C. HODES, M.D.; and	)	
TRACI LYNN NAUSER, M.D.,	)	
Plaintiffs,	)	
V.	) Case No	o. 11-C-1298
	)	
<b>ROBERT MOSER, M.D., in his official</b>	)	
capacity as Secretary of the Kansas	) ''	
Department of Health and Environment;	)	
STEPHEN HOWE, in his official capacity	)	
as District Attorney for Johnson County,	)	
Kansas; and DEREK SCHMIDT, in his	)	
official capacity as Attorney General for	)	
the State of Kansas,	)	
	)	
Defendants.	)	

# **DECLARATION OF TRACI LYNN NAUSER, M.D.**

TRACI LYNN NAUSER, M.D., declares the following statement to be true and correct under penalty of perjury under the laws of the State of Kansas;:

1. I submit this declaration in opposition to Defendants' Motion for Summary Judgment on the Plaintiffs' Claims under the Kansas Equal Protection Clause.

2. I am a board-certified obstetrician-gynecologist ("ob-gyn") licensed to practice medicine in the State of Kansas. I have been providing a full range of obstetrical and gynecological services, including first- and second-trimester abortions, for over sixteen years. I hold admitting and clinical privileges at a number of hospitals in the Kansas City area. I am also a Fellow of the American College of Obstetricians and Gynecologists ("ACOG"), the nation's leading association of medical professionals specializing in obstetrics and gynecology.

3. My father, Herbert Hodes, M.D., is also a board-certified obstetrician-gynecologist. Like me, he is licensed to practice medicine in Kansas, is a Fellow of the American College of Obstetricians and Gynecologists, and holds admitting and clinical privileges at a number of hospitals in the Kansas City area. He has provided a full range of obstetrical and gynecological services, including first- and second-trimester abortions, in Kansas for over forty years.

#### **Our Medical Practice**

4. My father and I own and operate a private medical practice, Hodes & Nauser, MDs, P.A. ("the practice" or "our practice"). The practice is located in Overland Park, Kansas, and is known as the "Center for Women's Health."

5. As part of our practice we provide a wide range of health care services in our office, including but not limited to obstetrical care, family planning services (short-term, long-lasting and permanent contraception, and emergency contraception), annual health examinations (including pap smears, cholesterol screening, osteoporosis screening and treatment), screening for and treatment of sexually transmitted infections, treatment of menopausal symptoms, evaluation and treatment of bladder control issues, breast evaluations and screening, infertility treatments, evaluation and treatment of interstitial cystitis, evaluation and treatment of chronic pelvic pain, simple management of endocrine disorders (hypothyroidism, hyperprolactinemia), treatment of menstrual irregularities, and gynecological procedures, including abortion surgeries.

6. We also provide hospital-based care when our patients need services in that setting. The services we provide in a hospital setting include but are not limited to antepartum care, vaginal and cesarean deliveries, postpartum care and gynecological surgeries. They also include occasional pregnancy terminations for patients who are suffering from medical complications that necessitate a hospital setting for their procedure.

7. We accept all major forms of health insurance in the area, including private insurance plans, Medicaid, and Medicare.

8. Our practice has offered abortion services in the same facility for over 30 years. The practice meets the applicable standards of care, the existing Kansas regulations governing providers of office-based surgery, and the clinical standards of the National Abortion Federation, a professional association for physicians and facilities providing abortions, of which we are members. Our practice is already subject to oversight and inspections by the Kansas Board of Healing Arts, the Kansas Department of Health and Environment ("KDHE") (to the extent it administers CLIA, the Clinic Laboratory Improvement Amendments, and OSHA, the Occupational Safety and Health Act), and the National Abortion Federation.

## **Provision of Abortion Services in Our Practice**

9. Dr. Hodes and I regularly provide pregnancy terminations in our practice. The vast majority of these procedures are performed in the first trimester of pregnancy. A small percentage of these procedures are performed after the first trimester but prior to 22 weeks LMP. Currently, we do not perform any abortion procedures after 22 weeks LMP. We have never performed post-viability abortions.

10. We perform both surgical and medical abortions in our practice. A surgical abortion is one in which medical instruments are used to evacuate the contents of a patient's uterus. These procedures are typically 5 to 15 minutes in duration.

3

11. A medical abortion is one in which medications that cause pregnancy termination are administered to a patient. Most commonly, we perform medical abortions early in pregnancy using mifepristone and misoprostol. Our patients take mifepristone in our office; it causes the pregnancy to stop developing. They take misoprostol forty-eight hours later at home; it causes the uterus to contract and expel its contents. Sometimes we perform medical abortions later in pregnancy using medications that induce premature labor. These abortions are sometimes called "labor inductions."

12. Dr. Hodes and I perform most abortion procedures in our office. On rare occasions, we perform abortion procedures in a hospital if, in our medical judgment, a patient has complicating factors that make a hospital setting more appropriate for her procedure. All of our labor induction abortions are performed in a hospital. Some Kansas hospitals do not permit abortion procedures on their premises under any circumstances. The others permit abortion procedures only in very limited circumstances.

13. Most surgical abortion procedures in our office are performed using only local anesthesia. We use minimal to moderate sedation for surgical procedures at 15 weeks LMP and later, and when a particular patient's needs make it appropriate. Medical abortions performed in our office do not entail the use of anesthesia or sedation.

14. In our practice, we perform a significant number of abortions in situations where the woman has a medical condition that complicates her pregnancy and/or the abortion procedure she seeks. If we were unable to provide abortion services to these patients, some of them would be unable to obtain those services in the region at all. This is because, to the best of my knowledge, Dr. Hodes and I are the only physicians in the region who can and will provide pregnancy terminations to women with certain complicating medical conditions.

4

15. In addition, we also perform a significant number of pregnancy terminations in our practice for patients who seek to end the pregnancy because the fetus has been diagnosed with a severe or lethal anomaly. For example, I sometimes provide abortions in cases where a patient's fetus is diagnosed with anencephaly, a condition in which a large part of the brain and skull are missing. A patient in that circumstance submitted an affidavit in support of Plaintiffs' Motion for a Restraining Order and/or Temporary Injunction against the Permanent Regulations and certain provisions of the enabling Act, using the pseudonym Jane Doe.

16. Many ob-gyns and perinatologists in the region primarily or exclusively refer their patients to our practice when the patient seeks a termination because of a complicating medical condition, fetal anomaly diagnosis, or for other reasons. To the best of my knowledge, these referrals are made based on the referring physicians' confidence in our extensive experience providing abortions, including to pregnant women with medical conditions and women who have received a fetal anomaly diagnosis, and in our ability to provide expert, high-quality abortion services to patients in these circumstances.

## Procedures That Are Medically Comparable to Abortion

17. The Regulatory Scheme singles out abortion providers for onerous regulations that go far beyond the standards of care for office-based surgeries. Those standards of care are reflected in the existing Kansas regulations governing *all* providers of office-based surgeries, K.A.R. §§ 100-25-1 to 100-25-5.

18. From a medical standpoint, however, there is no difference between the abortion procedures we perform in our office and numerous other procedures performed in physicians' offices, including our own. For example, the first-trimester abortions we perform in our office

are medically comparable to a whole host of other gynecological procedures that we and other Kansas ob-gyns perform in an office setting. These include dilation and curettage ("D&C"), endometrial ablation, tubal occlusion using the Essure method, diagnostic and operative hysteroscopy, loop electrosurgical excision procedure ("LEEP"), insertion and removal of intrauterine devices ("IUDs"), biopsy, and hymenectomy.

19. D&C may be performed for a variety of reasons including for diagnostic purposes, to treat abnormal uterine bleeding, or to complete a miscarriage. The techniques used to perform D&C are the same as those used to perform first- and early second-trimester surgical abortion.

20. As performed in our practice, endometrial ablation, tubal ligation and hysteroscopy are also comparable to first- and early second-trimester abortion in terms of technique, duration, complexity, and safety. Each involves dilation of the cervix with dilation rods, the introduction of instruments through the vagina and cervix, and the use of instruments in the uterus. LEEP does not entail entry into the uterine cavity, but it involves introducing a wire-tipped instrument into the vagina, applying electrical charge to the instrument, and using it to remove abnormal tissue from the cervix.

21. Typically, these procedures are performed using local anesthesia. Sometimes they are performed using minimal to moderate sedation, depending on the needs of the particular patient. Each of these procedures takes 5 to 15 minutes to perform. The length of recovery varies, depending in large part on the type of anesthesia or sedation used, but is typically short.

22. In my professional judgment, there is no medical basis for requiring that offices in which abortions are performed meet different regulatory standards than offices in which medically comparable procedures, including the gynecological procedures described above, are performed. Such disparate treatment is wholly irrational from a medical standpoint.

23. Indeed, the requirements of the Regulatory Scheme have nothing to do with the particulars of abortion. Rather, they govern topics that are as equally relevant (or, in most cases, irrelevant) to other medical procedures as they are to abortion. Thus, each of the requirements discussed below is no more necessary or useful in the context of an abortion than it is necessary or useful in the context of any other office-based surgery.

# Specific Requirements of the Regulatory Scheme

#### Staffing and Monitoring Requirements

24. A medical practice, just like any other business, can only stay afloat if it has an efficient distribution of labor: that is, if it distributes tasks among staff according to the level of expertise that each task demands. Requiring a physician to perform a task that can safely and appropriately be performed by a nurse makes no sense. It increases the cost of providing health care without adding any benefit to the patient, and it keeps the physician from performing tasks that only a physician can perform. Similarly, requiring a physician assistant or nurse to perform tasks that can be safely and appropriately performed by a medical assistant also makes no sense. Again, it raises the cost of providing health care, with no patient benefit, and it takes licensed personnel away from tasks for which their skills and experience are actually needed.

25. Licensed nurses command substantially higher salaries than medical assistants. It is already very difficult to hire licensed nurses in Kansas, due to a local and national nursing shortage. Further, in my experience, licensed nurses have little interest in employment that consists largely of lower-level duties that do not utilize their skills and training.

26. The Regulatory Scheme's staffing requirements are irrational, unjustified, and beyond what the standard of care requires, in Kansas or nationally, for ob-gyn practices and other practices that perform office-based procedures.

27. For example, K.A.R. § 28-34-135(m) requires a nurse or physician assistant to administer medication, even though it is accepted practice, and within the standard of care in Kansas and nationally, for ob-gyn and other practices, for a medical assistant to administer medications at the direction of a physician.

28. K.A.R. § 28-234-138(c) requires that both a physician and a licensed nurse or physician assistant be "available" to the patient throughout an abortion procedure regardless of whether sedation is used. I am not sure what exactly this provision requires. If it requires that a licensed nurse or physician assistant be in the room (or nearby and not attending to other patient care tasks) during a patient's abortion procedure, then it is burdensome and unnecessary in the context of a procedure involving no sedation. It is accepted practice and within the standard of care (in ob-gyn and other areas of medical practice) to have a physician, and no additional licensed health professional, "available" to a patient during a minor procedure in which only local anesthesia is given to a non-sedated patient.

29. K.A.R. § 28-234-138(f) requires that a nurse or physician assistant monitor the patient's vital signs "throughout the procedure." This requirement makes no sense in the context of short procedures that are performed without sedation. In that context, it is within the standard of care, and common practice, to take the patient's vital signs before the procedure, but not to monitor vital signs *during* the procedure. Given the lack of sedation and the brevity of the procedure, there is no medical reason to monitor vital signs in the midst of the procedure.

30. Similarly, K.A.R. § 28-34-139(a)(2) mandates that a physician assistant or licensed nurse monitor a patient's vital signs and bleeding after an abortion procedure. This requirement ignores the fact that medical assistants are trained to take patients' vital signs and check on patients after a minor procedure, and it is within the standard of care for a medical assistant to

carry out these tasks. Thus, it is perfectly appropriate for a medical assistant acting under the supervision of a physician or nurse in the facility to monitor a patient (*i.e.*, check her vital signs and monitor her bleeding), after an abortion procedure (or comparable medical procedure) involving no sedation. It is both unnecessary and burdensome to mandate that a physician assistant or licensed nurse carry out these tasks, especially given the difficulty we would face in finding a licensed professional willing to perform these tasks.

# Recovery Requirements

31. K.A.R. § 28-234-139(a) requires us to keep patients who have received abortions in recovery for a minimum of 30 minutes to 1 hour, depending on gestational age. The imposition of standardized minimum recovery times set by regulators is irrational, and not part of standard medical practice. Appropriate recovery times are determined by the exercise of medical judgment, and the time an individual patient will need in recovery depends on the type of anesthesia or sedation given, if any, the length and course of the procedure, and the patient's overall health condition. This is true not only for abortion, but for all outpatient procedures. I am aware of no other area of medicine in which physicians are prohibited from tailoring care to the specific needs of the individual patient.

32. A patient who has undergone a first-trimester pregnancy termination without sedation typically meets all discharge criteria and is ready to go home approximately 15 minutes after the procedure is over. Accordingly, for the vast majority of our abortion patients, the mandated recovery times would require us to keep the patient in "recovery" for twice as long as she needs, or more. Patients are discharged from our office when we have assessed that they meet our discharge criteria and are ready to go home. Discharging them before that point would be medically inappropriate because doing so would be unsafe; refusing to discharge them after that

point is medically inappropriate because doing so provides no medical benefit and may cause them unnecessary aggravation and stress after their procedure.

33. In addition to burdening our patients, such unnecessary recovery times would greatly impair patient flow (*i.e.*, the ability of a medical facility to schedule and see patients) in our practice. It is simply not practical in the context of modern medical practice to have patient rooms and staff occupied by patients who do not need them.

34. K.A.R. § 28-234-133(b)(7) requires a recovery area that has a "nurse station with visual observation of each patient in the recovery area." I am not sure what this provision requires, and whether it requires us to have a separate recovery room, rather than using the procedure room for recovery. If it does require a separate recovery room, then it is unnecessary and unreasonable. It is perfectly appropriate, within the standard of care, and far more private for the patient (whether she has undergone an abortion or another gynecological procedure), to recover in the same room in which her procedure was performed. Moreover, as with the other requirements discussed in this declaration, I cannot see any medical justification for imposing such a requirement exclusively on abortion patients and providers.

35. The reference to a "nursing station" in K.A.R. § 28-234-133(b)(7) is also unclear to me. I am concerned that it might be interpreted to require that a licensed nurse monitor the patient during recovery. As discussed above, a patient who undergoes a first-trimester abortion, or any other medically comparable procedure, without sedation, does not need to be monitored by a nurse after the procedure. Nor does such a patient require constant supervision after the procedure; it is within the standard of care for a medical assistant to check on her periodically instead. Many patients would prefer this, as well, especially those who have brought a loved one to be with them during and after the procedure and would prefer privacy.

# Board of Pharmacy Registration

36. K.A.R. § 28-234-135(n) requires that our practice be registered with the Board of Pharmacy if we maintain controlled drugs at the facility. To the best of my knowledge, the Board of Pharmacy has no authority to register physicians' offices such as ours. We tried to obtain an application to register our office with the Board of Pharmacy in June of 2011, but were told by the Board of Pharmacy that they have no mechanism for registering private physician's offices.

37. The November 2, 2011, letter sent to us by KDHE (attached hereto as Exhibit A), in response to our request that they consider an application for a waiver, states that we can register with the Board of Pharmacy by representing our facility as an ambulatory surgical center on the registration application. Given the various ethical and professional obligations which we must meet as physicians – as well as the fact that government and private actors opposed to abortion have historically scrutinized abortion providers in this State very closely, and even brought dubious legal charges against them – I am not at all comfortable misrepresenting the nature and legal status of our practice on such an application form.

38. Moreover, the application form referenced by KDHE requires identification of the pharmacist who will be in charge at the registered facility. We do not employ a pharmacist at our office and we have no need for one, given that physicians are allowed to maintain and administer medications themselves in their offices. Thus, even if there existed a mechanism for registering with the Board of Pharmacy (which does not seem to be the case), such registration would require us to unnecessarily hire a licensed pharmacist for our staff.

39. Under the Regulatory Scheme, if we eliminated abortion procedures from the services we offered, then we would not have to register with the Board of Pharmacy. But the controlled

drugs that we use in connection with abortion procedures are exactly the same as those we use in other gynecological procedures. The only drug that we use exclusively in abortion procedures is mifepristone, and it is not a controlled substance.

# Confidentiality of Patient Medical Records

40. K.A.R. § 28-234-144(c) gives representatives of KDHE seemingly unfettered access to the medical records of our patients. In my professional judgment, this intrusion on patient privacy is wholly unjustified, and is contrary to the level of privacy that patients expect and deserve in a medical office setting. I know of no other type of physician's office in the state that must give KDHE access to its complete patient medical records, and I can think of no reason why KDHE would need such access to the records of abortion patients.

41. Patient medical records are among the most private of documents. They contain highly personal information about the individual's health conditions, medical and psychological history, personal relationships, and prior treatments. Patients have a profound interest in maintaining the privacy of their medical records, and this interest is heightened in the context of an ob-gyn practice because the records contain details of the patient's sexual and reproductive history and treatment. Moreover, to the extent a patient's medical record contains information about a pregnancy termination, disclosure may not only cause the patient emotional harm, it may expose her to harassment and/or retaliation.

42. Unfortunately, as a physician (and as a Kansas resident who is familiar with former Attorney General Phill Kline's mishandling of abortion patients' medical records during an inquisition, which led to his disbarment), I am well aware that persons charged with protecting the confidentiality of medical records and patient information do not always do so. I expect that many of our patients, particularly those obtaining abortions, would experience substantial stress and anxiety if they learned that their identities and medical records would be open to such extensive review by KDHE employees.

# Requirements for the Administration of Abortion-Inducing Drugs

43. The Act requires that any "drug used for the purpose of inducing an abortion" must "be administered by or in the same room and in the physical presence of the physician who prescribed, dispensed or otherwise provided the drug to the patient." Act, § 10(a).

44. It is not customary for physicians to personally administer medications. Medications are typically administered by a nurse or other member of the staff, and the physician need not be, and usually is not, present in the room while medications are administered. It makes no sense from a medical or patient health perspective to require that a physician personally administer medications when other staff are perfectly qualified to do so, and when the physician's time, care, and expertise are needed by other patients for tasks only a physician can perform.

45. Further, there is nothing distinctive about the medications used in abortion procedures to warrant special treatment. As stated earlier, except for mifepristone, the medications used in abortion procedures are also used in a variety of other procedures, which are not subject to this requirement. And mifepristone does not entail a higher risk of allergy or other adverse reaction than other medications.

46. If this provision is construed to apply to misoprostol, it will also require medicalabortion patients to make an additional, unnecessary trip to our office for administration of a medication that they can safely take at home. In addition to its use in gynecological procedures, misoprostol is commonly prescribed to prevent gastric ulcers.

# Exclusion of Physician's Offices From Facilities That May Seek Waivers

47. It is my understanding that the Act allows hospitals and ambulatory surgical centers that provide abortions to obtain waivers from the requirements of the Regulatory Scheme when doing so would have no significant adverse impact on the health, safety, or welfare of patients, but does not allow office-based practices to obtain waivers in the same circumstance. This differing treatment makes no sense from a medical standpoint. A physician's office is a setting in which less complex and risky procedures are performed, as compared to those performed in an ambulatory surgical center. We have inquired to KDHE about the availability of waivers from the Permanent Regulations and have been told that no waiver requests from us will be entertained or granted. *See* Ex. A.

Dated: Overland Park, Kansas February 20, 2015

TRĂCI LYNN NAUSER, M.D