No. 20130259

In the Supreme Court of North Dakota

MKB Management Corp, d/b/a/ Red River Women's Clinic, **Tammi Kromenaker**, and **Kathryn L. Eggleston**, M.D.,

Plaintiffs-Appellees,

v.

Birch Burdick, in his official capacity as State Attorney for Cass County, and **Terry Dwelle**, M.D., in his official capacity as the chief administrator of the North Dakota Department of Health,

Defendants-Appellants.

On Appeal from the East Central Judicial District, Cass County
Hon. Wickham Corwin (No. 09-2011-cv-02205)

AMICUS CURIAE BRIEF OF 49 NORTH DAKOTA LEGISLATORS

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[1] Pursuant to N.D. Sup. Ct. Admin. Order 14, references within the tables refer to paragraph numbers.

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STATEMENT OF INTEREST OF *AMICI CURIAE*[2]

1. *Amici Curiae* are 49 legislators in the state of North Dakota who support HB 1297, the state's regulation of abortion-inducing drugs. *Amicus* Representative Grande was the official sponsor of the regulation.

2. *Amici* have a special interest in the outcome of this case. First, *Amici* have an interest in ensuring that a constitutional law enacted by the Legislature is upheld and enforced. Second, *Amici* have an interest in protecting the welfare of women seeking abortion in the state. As affirmed by the U.S. Supreme Court, this is an important interest that vests in the State at the outset of pregnancy.

3. *Amici* demonstrate herein that the trial court made reversible errors in interpreting and construing federal law. These errors of law led the trial court to render a decision irreconcilable with federal abortion jurisprudence. The trial court's errors of law must be reversed.

[2] No party's counsel has authored the brief in whole or in part. No party or party's counsel has contributed money intended to fund preparing or submitting this brief. No person other than *Amici*, their members, or their counsel has contributed money that was intended to fund preparing or submitting this brief.

ARGUMENT

4. HB 1297 ("the regulation") is a medical regulation designed to protect women from the dangerous unapproved use of abortion-inducing drugs. Specifically, it requires that the RU-486 regimen be administered in the way approved by the U.S. Food and Drug Administration (FDA). It does not ban the use of the RU-486 regimen; it simply requires that the regimen be administered in the way deemed safest by the FDA. Until 49 days gestation, either surgical abortion or abortion-inducing drugs are available. After 49 days, surgical abortion—deemed "very safe" by abortion providers[3]—is available. The Act imposes no obstacle to obtaining an abortion.

5. Defendants rightfully argue that a rational basis test applies. However, the trial court mainly relied on federal precedent and applied an "undue burden" standard. But even under the "undue burden" standard, the regulation should have been upheld, as demonstrated herein.

6. According to the U.S. Supreme Court, states have an interest in maternal health from the outset of pregnancy and are free to enact regulations designed to protect women from harm even in the first trimester.

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[3] *See*, *e.g.*, Planned Parenthood, *In-Clinic Abortion Procedures* (2011), http://www.plannedparenthood.org/health-topics/abortion/in-clinic-abortion-procedures-4359.asp. "In-clinic abortion procedures are very safe." *Id*.

Moreover, the Supreme Court has given state legislatures wide discretion to regulate abortion when there is medical uncertainty as to the safety of a procedure.

7. This is important here, where there is disagreement among the parties and their experts regarding the safety of administering abortion-inducing drugs off-label. Regardless of Plaintiffs' claims, they did not meet this Supreme Court-imposed burden of demonstrating that the State has no medical basis for enacting the regulation. The most Plaintiffs demonstrated is that there is disagreement—which places the regulation directly within the state's "wide discretion."

8. Comparing federal case law with the trial court's legal interpretations reveals that the trial court opinion is replete with legal and factual inaccuracies that completely undermine that court's decision and demonstrate that its framework for evaluating the regulation—and, therefore, its entire ruling—undervalued the state's interest in maternal health, is in error and must be reversed.

I. North Dakota has an interest in maternal health from the outset of pregnancy and rational medical regulations do not pose an "undue burden."

9. In both *Planned Parenthood v. Casey* and *Gonzales v. Carhart*, the Supreme Court affirmed *Roe v. Wade*'s "essential" holding, which specifically included "the principle that the State has legitimate interests from the outset of the pregnancy in protecting the health of the woman." *Casey*, 505 U.S. 833, 846 (1992); *Gonzales*, 550 U.S. 124, 145 (2007); (both citing *Roe v. Wade*, 410 U.S. 113 (1973)). *Roe* "was express in its recognition of the State's 'important and legitimate interests in preserving and protecting the health of the pregnant woman….'" *Casey*, 505 U.S. at 875-76. This principle must "coexist" with other principles outlined in *Roe*. *Gonzales*, 550 U.S. at 158.

10. Likewise, the Court concluded that some interpretations of *Roe* could not be "reconciled with the holding in *Roe* itself that the State has legitimate interests in the health of the woman," and such interpretations "contradicted the State's permissible exercise of its powers." *Casey*, 505 U.S. at 871, 872. The Court then "rejected both *Roe's* rigid trimester framework and the interpretation of *Roe* that considered all previability regulations of abortion unwarranted." *Gonzales*, 550 U.S. at 146. Such interpretations "led to the striking down of some abortion regulations which

in no real sense deprived women of the ultimate decision." *Casey*, 505 U.S. at 875. Those interpretations went too far. *Id*.

11. Instead of supporting such "zero tolerance policies" as had been applied to some abortion regulations, the Court utilized an "undue burden" standard, examining whether a regulation placed a substantial obstacle in the path of a woman seeking a previability abortion. *See Casey*, 505 U.S. at 877-78; *Gonzales*, 550 U.S. at 166.

12. *Casey* and *Gonzales* hold that a reasonable medical regulation enacted to protect women's health is not an undue burden. In fact, in *Casey* the Court expressly held: "As with any medical procedure, the State may enact regulations to further the health or safety of a woman seeking an abortion." *Casey*, 505 U.S. at 878. Regulations that have the effect of increasing cost and/or requiring a second appointment are not an undue burden. *See id*. at 885-87. Only those restrictions that are *unnecessary* and have the purpose or effect of presenting a *substantial obstacle* impose an undue burden.

13. Moreover, in upholding a previability ban on partial-birth abortion in *Gonzales*, the Supreme Court explicitly held that state and federal legislatures are given "wide discretion to pass legislation in areas

where there is medical and scientific uncertainty." *Gonzales*, 550 U.S. at 163.

14. After recognizing that the government "has an interest in protecting the integrity and ethics of the medical profession" and declaring that the state has a "significant role to play in regulating the medical profession," the Court held, "[w]here it has a rational basis to act, and it does not impose an undue burden, the State may use its regulatory power to bar certain procedures and substitute others, all in furtherance of its legitimate interests in regulating the medical profession…." *Id*. at 157-58.

15. Importantly, the Court concluded that "[p]hysicians are not entitled to ignore regulations that direct them to use reasonable alternative procedures. The law need not give abortion doctors unfettered choice in the course of their medical practice…." *Id*. at 163. In *Gonzales*, the medical uncertainty over whether the ban imposed a significant health risk provided sufficient basis to conclude in that facial challenge that the ban did not impose an undue burden. *Id*. at 164.

16. The Court also stated that its conclusion was supported by other considerations. First, alternatives to partial-birth abortion were available. *Id*. Further, the Court concluded that striking down legitimate abortion regulations if some part of the medical community is disinclined to follow

them is too exacting a standard to impose on legislatures. *Id*. at 166. The Court stated, "[w]hen standard medical options are available, mere convenience does not suffice to displace them; and if some procedures have different risks than others, it does not follow that the State is altogether barred from imposing reasonable regulations." *Id*.

17. Simply put, when there is uncertainty over the safety of a regulated procedure and there are other available procedures that are considered to be safe alternatives, as in this case, a law cannot be invalid on its face. *Id*. at 164-65. In fact, precedent *instructs* that such laws survive facial attacks, which should not be entertained in the first place. *Id*. at 163, 167.

II. The trial court misconstrued and misinterpreted federal precedent.

18. The states' ability to regulate abortion to protect maternal health is well-established. Yet the trial court ignored explicit provisions in *Casey* and *Gonzales* related to state interest in maternal health and the proper application of the "undue burden" standard.

19. The trial court acknowledged that the state interests recognized under both federal and state constitutions are coextensive and that Defendants justified the regulation as necessary to "protect women's health

and maintain medical standards." R. 251 at 8-9.[4] But at that point, the trial court's analysis utterly failed to give proper consideration to the state's interest in maternal health. For example, the court began its discussion of state interests and federal precedent with the following:

> *Roe* held that during the first trimester of pregnancy a woman…, must be permitted to decide free from any interference by the state. Only later in the pregnancy does the state have a sufficient interest to justify legislation designed to safeguard women's health or maintain medical standards.

Id. at 8 (citations omitted).

20. This claim—and a later statement by the court that *Casey* does not indicate when a state's interest in maternal health is entitled to consideration—is incorrect as a matter of law. *Id*. at 9. *Casey* and *Gonzales* hold unequivocally that states have "***legitimate interests from the outset of pregnancy in protecting the health of the woman***." *Casey*, 505 U.S. at 846; *Gonzales*, 550 U.S. at 145 (both citing *Roe*) (emphasis added).

21. The trial court also erroneously stated that *Casey* did not abandon the trimester framework. R. 251 at 9. This interpretation of *Casey* inexplicably disregards the plain language of *Casey* where the Supreme Court stated:

[4] All references to the record are represented with "R." and refer to the docket ID number below.

> **We reject the trimester approach**, which we do not consider to be a part of the essential holding of *Roe*…. A logical reading of the central holding in *Roe* itself, and a necessary reconciliation of the liberty of the woman and the interest of the State in promoting prenatal life, **require,** in our view, **that we abandon the trimester framework**….

Casey, 505 U.S. at 873 (emphasis added). To that end, the trial court's reliance on the trimester framework—and the weight it *failed* to give the state's interest in maternal health—is clearly erroneous.

22. Further, the trial court utilized a strict scrutiny standard which was also rejected by the Supreme Court. *See* R. 251 at 1, 9. But the Court has rejected judicial interpretations that considered all previability regulations of abortion unwarranted. *Gonzales*, 505 U.S. at 146. Those interpretations went too far. *Casey*, 505 U.S. at 875. However, this is the exact type of strict scrutiny standard that the trial court applied here.

23. The trial court's legal errors did not end with its failure to give proper weight to the state's interest in maternal health and rejection of Supreme Court precedent. Nearly every aspect of the trial court's treatment of federal precedent was flawed as a matter of law. For example, the trial court stated that "majorities" of the Supreme Court have concluded that "a woman has the right to choose an abortion, and to select from the medical options that are safe and effective." R. 251 at 5-6. This is completely false. The Court has never held that a woman has a right to use whatever

procedure she prefers. *See Planned Parenthood v. DeWine*, 696 F.3d 490, 514-15 (2012) (rejecting an "undue burden" challenge to Ohio's RU-486 regulation and noting that the Supreme Court has never stated that a woman has a right to choose a particular abortion method).[5]

24. Another example is the trial court's assertion that return trips to the clinic and "even a small increase in the cost" constitute an "undue burden." R. 251 at 30, 48. Conversely, the U.S. Supreme Court has unequivocally and repeatedly stated that regulations that have the effect of increasing cost and/or requiring a second appointment are not an undue burden. *See*, *e.g.*, *Casey*, 505 U.S. at 885-87.

25. The trial court also erred in stating that the "requirement for a health exception is something that the Supreme Court has repeatedly emphasized." R. 251 at 48. As already discussed, the Supreme Court has upheld a pre-viability ban that did not include a health exception. *See Gonzales*, 550 U.S. 124. Similarly, the trial court further ignored *Gonzales* when it claimed that laws prohibiting "any safe and effective method of abortion, used on a pre-viability basis, have uniformly been held to violate federal constitutional protections."

[5] The trial court cited a 2008 Sixth Circuit opinion in the same case, but ignored this particular statement of the Sixth Circuit. *See* R. 251 at 25 (citing *Planned Parenthood Cincinnati Region v. Strictland* [sic]).

26. While examples of the trial court's legal inaccuracies could continue, one final example must suffice. The trial court claimed that the *plurality* in *Casey* is the "last definitive word" from the Court on facial challenges. R. 251 at 46. Clearly, the trial court ignored the holding of the *majority* in *Gonzales* that ruled facial challenges are improper and should not be entertained in the first place.

27. The trial court's rulings of law are based on a misinterpretation and misconstruction of federal precedent, are clearly erroneous and must be reversed.

III. The trial court's findings of fact do not support its conclusions of law.

28. The trial court's legal inaccuracies undermine its factual conclusions and similarly require reversal. For example, ***the trial court concluded without documentation or record evidence that off-label administration of RU-486 is "extremely safe."*** The court based its flawed *legal* conclusion that there is "no justification for regulation or restriction" of RU-486 on its incorrect *factual* conclusion that off-label administration is safe. *Id*. at 10.

29. Its conclusion is flawed for a number of reasons. First, the trial court provided no record evidence for its conclusory statements. The court cited not a single peer-reviewed study to support its assertion that there is a

"wealth of solid medical evidence," *id*. 11, that off-label use is safer than the FDA-approved protocol. Conversely, the trial court possessed evidence demonstrating that eight women have died from bacterial infection following off-label administration, while not a single report of death from bacterial infection has followed the FDA-approved use. *Id*. at 17 (citing Ex. 6, which is FDA, *Mifepristone Postmartketing Events Summary through 04/30/2011* (July 2011)).[6]

30. Second, the "facts" cited by the trial court do not support its conclusions. For example, the trial court relied on the statistic that there have been 1.75 million medical abortions since 2000, but did not delineate how many of them were off-label and how many were administered according to the FDA-approved protocol. Further, the court concluded that there is a wealth of medical evidence "particularly regarding procedures commonly performed in the first trimester." *Id*. at 11. However, such procedures include surgical abortion. Chemical abortion comprises only one-fourth of abortion procedures performed in the first nine weeks. Guttmacher Institute, *Facts on Induced Abortion in the United States* (Aug. 2011). It is impossible to draw any sort of safety conclusion from the type

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6 http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf

of data utilized by the trial court when various procedures or protocols are not distinguished within that data.

31. Third, the trial court incorrectly claimed that there can be no controlled medical trials on the safety of off-label use because "adverse events are so rare" and, therefore, any clinical study designed to analyze the risks would necessarily require an unfeasible number of patient participants. R. 251 at 17. However, because the FDA and the drug manufacturer readily acknowledge that *nearly every woman* who uses the RU-486 regimen will experience adverse events—and many will experience more than one—the trial court's conclusion was clearly wrong. *See Mifeprex Final Printed Labeling*.[7]

32. Overall, the trial court relied on erroneous or speculative data because there are no peer-reviewed studies supporting Plaintiffs' claims that off-label use of the RU-486 regimen is safer than the FDA-approved protocol.

33. ***The trial court also used improper comparisons***. It began its discussion of "Studies and Statistics" by referencing morbidity and mortality statistics "applicable to childbirth and early surgical abortions" cited by

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[7] http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf

Plaintiffs' expert witness, Dr. Grossman. R. 251 at 15. Such a comparison has no bearing on this litigation. First, the state is not prohibiting abortion, so a comparison need not be made between risks of abortion and risks of childbirth. Further, the statistics involved a comparison to surgical abortion—a procedure not at issue in the case.

34. The court also made the unsupported conclusion that "[t]he alternative to safe and legal abortion is, of course, illegal abortion." *Id*. at 15. The court cited the World Health Organization for statistics on the number of women who die from unsafe abortions each year.[8] Again, the North Dakota regulation is not making abortion illegal. Comparing legal abortion to the absence of abortion bears no relevance to the case. Moreover, the quoted statistics made no distinctions between different abortion procedures and protocols. Without such a distinction, statistics and conclusions about general risks cannot be levied against a regulation of one particular procedure.

35. The trial court then concluded that "[i]f medical abortions are no longer legal, safe and available in North Dakota, it must be assumed some women will feel compelled to resort to self-help" and get drugs over

[8] The trial court did not cite the record when referencing these World Health Organization statistics. It appears that it is used purported facts that are outside the record.

the internet. *Id*. This unfounded assertion ignores the fact that the North Dakota regulation does not make chemical abortion illegal. Moreover, it is an undocumented assumption to conclude that women will resort to buying drugs over the internet—especially in light of the fact that surgical abortion (a safer and more commonly used procedure)[9] will still be available at Plaintiffs' clinic.

36. "By comparison," the trial court continued, "medical abortion [using Plaintiffs' off-label protocol] is an extremely safe and effective procedure." *Id*. at 15-16. Again, the trial court made an improper comparison (comparing self-abortion to off-label administration, rather than comparing FDA-approved to off-label administration), and again it failed to provide any documentation that the off-label protocol is safe.

37. Later in the opinion, the trial court claimed that childbirth is far more likely than abortion to result in death or significant complications. *Id*. at 18. Again, this is an irrelevant comparison and is not supported in by evidence in the record. The state is not prohibiting abortion or encouraging

[9] The trial court did not address the various studies demonstrating that surgical abortion is safer than chemical abortion. *See*, *e.g*., Niinimaki, *Immediate Complications after Medical compared with Surgical Termination of Pregnancy*, OBSTET. GYNECOL. 114:795 (2009); Jenson, *Outcomes of Suction Curettage and Mifepristone Abortion in the United States: A Prospective Comparison Study*, CONTRACEPTION 59:153-59 (1999).

childbirth; rather, the state is requiring one method of chemical abortion over another.

38. In sum, there is no medical data comparing the safety of the off-label regimen to the FDA-approved regimen. The trial court attempted to cloud this important fact by engaging in comparisons that had no relevance.

39. ***The trial court also improperly discredited Defendants' expert witness, Dr. Donna Harrison***. First, the court concluded that Dr. Harrison has conflicting opinions because she co-authored a Citizen Petition urging the FDA to revoke its previous approval of RU-486, and now supports the regulation requiring the FDA-approved regimen.

40. These opinions are easily reconciled. It is true that Dr. Harrison believes that the FDA-approved regimen poses risks for women. But she also believes that the off-label use of the regimen is even more dangerous; therefore, it is not conflicting for her to now support a law requiring what appears to be the less dangerous protocol. *See*, *e.g.*, R. 74 ("HB 1297 provides needed regulation to ensure, *as much as is possible*, the safety of women….") (emphasis added).

41. Further, the trial court provided no explanation for why the published studies Dr. Harrison proffered did not support her opinions—it simply dismissed them out of hand. Likewise, it presented no

documentation to back up its claim that Dr. Harrison's opinions were "at odds with solid medical evidence." R. 251at 14. It cannot be repeated often enough: the trial court claimed to rely on medical evidence in its opinion, but it cited not one scintilla.

42. As such, the trial court's conclusions are erroneous. It is Plaintiffs' position that is not supported evidence. Their expert, Dr. Grossman, presented only irrelevant medical data. The trial court cited no studies to support its conclusion that Plaintiffs' assertions are supported by medical evidence.[10]

[10] Further examples of the trial court's factual inaccuracies abound. For example, the court claimed that few of Plaintiffs' patients have complications, but ignored that one-fourth of the patients are lost to follow-up, leaving only a pool of 1,062 women to evaluate—which is not statistically significant. *See* R. 251 at 12. Further, the trial court claimed the FDA indicates no causal connection between off-label administration and death from bacterial infection, but this misconstrues the FDA's stance. *Id.* at 17. The FDA says causation has not been determined—which is completely different than claiming the FDA indicates no causal connection—and the FDA has, in fact, issued safety warnings noting that deaths have "involved the off-label dosing regimen." *See* FDA, Public *Public Health Advisory: Sepsis and Medical Abortion* (Mar. 17, 2006). Further, the court stated that once a drug is approved, the FDA "in no manner" restricts use, *id*. at 9 n.2, but this ignores the fact that RU-486 was approved under Subpart H—a code provision that specifically allows the FDA to place restrictions on drugs that "can be safely used only if distribution or use is restricted." 21 C.F.R. § 314.520. The FDA did, in fact, place restrictions on the Mifeprex regimen. *See* FDA, Approval Letter (Sept. 2000).

IV. Even under the "undue burden" standard, the regulation should be upheld.

43. While this Court should evaluate the regulation under a rational basis test, even under the "undue burden" standard the regulation should be upheld. Plaintiffs utterly fail to sustain their "undue burden" claim. First, North Dakota has an important and legitimate interest in protecting women from the harms of abortion, and this harm includes the documented harms associated with RU-486. *See Mifeprex Final Printed Labeling*, *supra*; FDA, *Mifepristone Postmartketing Events Summary*, *supra*.

44. Second, in enacting the regulation, the State properly exercised its wide discretion to advance its interest in protecting women. *See Gonzales*, 550 U.S. at 163. It is clear that, at most, Plaintiffs can demonstrate that there is a range of opinion on the safety of off-label use of RU-486—and, therefore, their claims fail under *Gonzales*. *Gonzales* makes clear that it is Plaintiffs' burden to prove that those deaths were *not* caused by RU-486. This is impossible for Plaintiffs to do, given the FDA's warnings against off-label use and the fact that all eight women who died from bacterial infection used an off-label administration.

45. Third, adequate alternatives exist for women who are past the 49-day gestational limit imposed by the FDA. Not only are these alternative surgical procedures available to women, but medical evidence indicates that

these surgical procedures are *safer* than chemical abortions. Plaintiffs are not "entitled to ignore regulations that direct [them] to use reasonable alternative procedures." *Id*. Plaintiffs do not have "unfettered choice in the course of [their] medical practice." *Id*.

46. Moreover, the regulation does not prohibit all "commonly used and generally accepted" methods of abortion and thus, as clearly indicated under *Gonzales*, it does not "construct a substantial obstacle." *Id*. at 164. Where standard medical options are available—as they are here—"mere convenience does not suffice to displace them." *Id*. at 166.

47. HB 1297 is a medical regulation promulgated within the State's wide discretion, aimed at protecting the health and welfare of women. There is no "undue burden."

CONCLUSION

48. The trial court's legal analysis and factual conclusions are fatally flawed and must be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of N.D.R.App.P 32 and N.D.R.App.P 29 because it contains only 3,983 words, excluding parts of the brief exempted by the rules. I relied on my word processor, Microsoft Word 2010, to obtain the count.

2. This brief complies with the typeface requirements of N.D.R.App.P32 because it has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in Times New Roman font, size 14.

I certify that the information on this form is true and correct to the best of my knowledge and belief formed after a reasonable inquiry.

s/ Don Grande
Counsel of Record for *Amici Curiae*

CERTIFICATE OF SERVICE

I hereby certify that on October 4, 2013, I electronically filed the foregoing *Amicus Curiae* Brief with the Clerk of the Court for the Supreme Court of North Dakota via email. Pursuant to N.D. R.App.P. 25, counsel below have been emailed the foregoing document.

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