2016 OK 17

ORIGINAL

IN THE SUPREME COURT OF THE STATE OF OKLAHOMA

OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members; and NOVA HEALTH SYSTEMS, d/b/a REPRODUCTIVE SERVICES, on behalf of itself, its staff, and its patients,

Plaintiffs/Appellees,

v.

TERRY L. CLINE, in his official capacity as Oklahoma Commissioner of Health; and LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision,

Defendants/Appellants.

No. 114,307

For Official Publication

COMBS, V.C.J., with whom GURICH, J., joins, concurring specially:

¶1 I concur with the majority's determination that H.B. 2684, ch. 121, 2014 Okla. Sess. Laws 375-80, does not violate the non-delegation doctrine of Okla. Const. art. 5, § 1 and is a permissible special law that does not violate Okla. Const. art. 5, § 59. However, although the Legislature has the authority to draw upon many resources in drafting and creating legislation, and the final language of

legislation may adopt in toto the FDA's final printed protocol, H.B. 2684 is not without some overreach.

¶2 Once again, those who do not practice medicine have determined to insert themselves between physicians and their patients, with the insistence they know what is best when it comes to the standard of care. It is undisputed that the FDA's final printed labeling does not restrict or control a doctor's practice of medicine or the use of medication once it is distributed. The FDA understands the role of physicians in adhering to the best possible standard of care. In the form of H.B. 2684, the Oklahoma Legislature has chosen to ignore this. While H.B. 2684 does not prohibit all medication abortions, it nonetheless binds Oklahoma physicians and their patients to the FDA's final printed labeling, regardless of whether evidence and the judgment of the medical community indicate it is not the best method for providing medication abortion.

¶3 As the majority notes, ninety-six percent of medication abortions do not follow the final printed labeling or the protocol used in the clinical trials on which the label's approval was based. *See Cline v. Oklahoma Coalition for Reproductive Justice (Cline II)*, 2013 OK 93, ¶21, 313 P.3d 253. Plaintiff Reproductive Services follows an off-label protocol endorsed by the American College of Obstetricians and Gynecologists (ACOG). ACOG determined that evidence-based medication

abortion protocols such as the one used here are superior to the FDA-approved regime in terms of efficacy and adverse effects.[1] Dr. Daniel A. Grossman, co-author of the ACOG Practice Bulletin Medical Management of First-Trimester Abortion, stated in his affidavit: "in my opinion, HB 2684 serves no valid, medical purpose and will harm women by forcing them to receive inferior medical care." *Affidavit of Daniel A. Grossman in Support of Plaintiff's Motion for Partial Summary Judgment*, p. 3 , R. Vol. 1, Tab 7, App. 2.

¶4 In *Cline II*, 2013 OK 93, this Court examined a prior statute requiring adherence to the FDA's final printed labeling for abortion-inducing drugs. We

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[1] *See* ACOG Practice Bulletin No. 143: Medical Management of First-Trimester Abortion (March, 2014), at pp. 2 and 11, Ex. B to Grossman Aff., R. Vol. 1, Tab 7. The Summary of Recommendations and Conclusions in the Practice Bulletin Provides in pertinent part:

> *The following recommendations are based primarily on good and consistent scientific evidence (Level A):*
>
> > Based on efficacy and adverse effect profile, evidence-based protocols for medical abortion are superior to the FDA-approved regimen. Vaginal, buccal, and sublingual routes of misoprostol administration increase efficacy, decrease continuing pregnancy rates, and increase the gestational age range for use as compared with the FDA-approved regimen.
> >
> > Regimens that use low doses of mifepristone (200 mg) have similar efficacy and lower costs compared with to [sic] those that use mifepristone at 600 mg.
> >
> > Women can safely and effectively self-administer misoprostol at home as part of a medical abortion regimen.
> >
> > Medical abortion also can be provided safely and effectively by nonphysician clinicians.
> >
> > Follow-up after receiving mifepristone and misoprostol for medical abortion is important, although an in-clinic evaluation is not always necessary.
> >
> > Misoprostol-only medical abortion regimens are significantly less effective than those that use a combination of mifepristone and misoprostol.

noted with disapproval the law's drastic interference in the role of physicians and agreed with the determination of the district court that restricting the use of abortion-inducing drugs to the regime in the final printed labeling "'is so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do.'" *Cline II*, 2013 OK 93, ¶27 (*quoting Okla. Coal. for Repro. Justice v. Cline*, No. CV-2011-1722, slip op., ¶7 (Dist. Ct. Okla. Cnty. May 11, 2012)). H.B. 2684 requires adherence to a protocol in contravention of prevailing medical standards; one that simultaneously shrinks the window in which medication abortion is accessible to the women of Oklahoma. This Court's above-quoted statement from *Cline II* remains apt. Further, the medical community should take heed: now that the Legislature has declared itself willing to dictate medical protocol and practice within this limited context, what areas of the practice of medicine are next?