S T A T E O F T E N N E S S E E
OFFICE OF THE
ATTORNEY GENERAL
425 FIFTH AVENUE NORTH
NASHVILLE, TENNESSEE 37243-0497

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Opinion No. 01-030

RU-486 — Abortion — Parental Consent and Informed Consent Statutes.

QUESTION

Does the administration of RU-486, known as mifepristone and marketed as Mifeprex, in order to facilitate the termination of a pregnancy fit the definition of "abortion" under Tenn. Code Ann. § 39-15-201(a)(1), which pertains to informed consent for abortion by women, or under Tenn. Code Ann. § 37-10-302(1), which pertains to parental consent for abortions performed on minors?

OPINION

The use of RU-486, as currently approved for use and labeling by the U.S. Food and Drug Administration, *can*, depending on when the drug is administered to a given individual, fall under the definition of "abortion" under Tenn. Code Ann.§39-15-201(a)(1), which pertains to informed consent for abortion by women, or under Tenn. Code Ann. § 37-10-302(1), which pertains to parental consent for abortions performed on unemancipated minors. However, last year the Tennessee Supreme Court found major portions of Tenn. Code Ann.§§39-15-200, *et seq.*, to be unconstitutional.

ANALYSIS

I.

The opinion request asks whether the administration of the drug RU-486 in order to terminate a pregnancy would fit the definition of an abortion as set forth under Tenn. Code Ann. §§ 39-15-201(a)(1) and 37-10-302(1). The aforementioned code sections govern, respectively, informed consent for women to obtain abortions and parental consent for minors to obtain abortions.

Tenn. Code Ann. § 39-15-201(a)(1), which governs circumstances which could constitute a criminal abortion, defines an abortion as:

> the administration to any woman pregnant with child, whether such child be quick or not, of any medicine, drug, or substance whatever, or the use or employment of any instrument, or other means whatever, with the intent to destroy such child, *thereby destroying such child before the child's birth.*

(Emphasis added). Therefore, this definition of abortion requires an intent to terminate a pregnancy and that the abortion attempt actually result in terminating the pregnancy before such act would come under the provisions of the section. Moreover, Tenn. Code Ann. § 39-15-201(c)(1) also specifies that a criminal abortion does *not* occur when performed:

> (D)uring the *first three (3) months of pregnancy*, if the abortion or attempt to procure a miscarriage is performed with the pregnant woman's consent and pursuant to the medical judgment of the pregnant woman's attending physician.

(Emphasis added).

Similarly, Tenn. Code Ann. § 37-10-302(1), which governs circumstances which require parental consent for abortions performed on unemancipated minors, defines an abortion as:

> the use of any instrument, medicine, drug, or any other substance or device with intent to terminate the pregnancy of a woman known to be pregnant with intent other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, or to remove a dead fetus.

The fundamental rule of statutory construction and interpretation is to ascertain and give effect to the intention of the legislature.[1] The legislative intent is derived primarily from the natural and ordinary meaning of the language contained therein, when read in the context of the whole statute.[2] A court must give effect to every word, phrase, clause and sentence of an act in order to discern legislative intent properly.[3] A statute should be construed so that no section will invalidate another.[4]

The plain language of both Tenn. Code Ann. § 39-15-201(a)(1) and § 37-10-302(1) is that

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[1] *Mercy v. Olsen*, 672 S.W.2d 196, 200 (Tenn. 1984).

[2] *James Cable Partners, L.P. v. City of Jamestown*, 818 S.W.2d 338 (Tenn. App. 1991).

[3] *Dingman v. Harvell*, 814 S.W.2d 362 (Tenn. App. 1991).

[4] *Id.*

abortion is defined as an act taken with the intent of "destroying such child before the child's birth" (§ 39-15-201(a)(1)) or with intent "to terminate the pregnancy of a woman known to be pregnant" (§ 37-10-302(1). Therefore, in either statute, the definition of abortion plainly means actions taken intentionally and purposefully in order to terminate a pregnancy.

II.

The synthetic drug RU-486, also known as mifepristone or by the brand name Mifeprex, was developed in 1982 by French researcher Dr. Etienne-Emile Baulieu. The drug began to be marketed in France as an abortifacient[5] in 1988. Since that time, the drug has also been approved for use in England, as well as Sweden and China. However, it was not until September, 2000 that the U.S. Food and Drug Administration ("FDA") approved RU-486 for use in the United States.

It has been noted scientifically that whether RU-486 should be classified as an abortifacient or a contraceptive depends on at what point in the process the drug interferes with potential birth.[6] In order to determine how its use in the United States, as approved by the FDA, should be classified, it is necessary to examine the process that is interrupted by the administration of RU-486. Fertilization occurs in the fallopian tube, whereby the fertilized egg forms a zygote. After approximately six days, the zygote reaches a place in the lining of the uterus where it begins the process of implantation, by which time the zygote has developed into a multi-celled blastocyst. The implantation takes another six to eight days to complete. As a result, implantation generally is accomplished approximately 12 to 16 days after fertilization, or 28 to 32 days from the beginning of the last menstrual period.

By the generally accepted medical definition, pregnancy begins at the completion of implantation of the embryo in the uterus. Termination of a pregnancy before this point is not classified as an abortion under generally accepted medical practice. Therefore, how RU-486 acts in a given situation, on a given individual, will depend on *when the drug is administered*, whether before or after implantation of the embryo in the uterine wall. RU-486 can block the naturally produced hormone progesterone, thus causing the expulsion of the uterine lining. If this expulsion occurs before implanation occurs, a pregnancy does not occur. Under such circumstances, the use of RU-486 can be classified as a contraceptive. If administered after the ovum has been implanted in the uterus, the use of RU-486 serves to cause an abortion.

III.

The introduction of new drugs for use in the United State is regulated by the FDA, which requires that an application for introduction of a drug be submitted to the agency and subsequently approved as to

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[5]*Blacks's Law Dictionary*, Seventh Edition, West Publishing Co, 1999, defines an abortifacient as "(a) drug, article or other thing designed or intended for producing an abortion."

[6]In researching the manner in which RU-486 acts, a number of legal periodicals were consulted. Most of the medical information provided in this paragraph and the subsequent paragraph was gathered from "RU-486: Legal and Policy Issues Confronting the Food and Drug Administration", Csilla Muhl, *Journal of Legal Medicine*, June, 1993.

indicated uses and appropriate labeling. 21 U.S.C. § 355. A pharmaceutical company filed a new drug application ("NDA") with the FDA for approval of the use of mifepristone, or RU-486, in March, 1996. The FDA eventually approved the drug in September, 2000 for use in the United States "for the medical termination of intrauterine pregnancy through 49 days' pregnancy." (FDA approval letter of September 28, 2000). This approval of RU-486 as of the September 28, 2000 approval letter allowed for the marketing of the drug from that date forward. 21 C.F.R. § 314.105.

Likewise, the FDA also approved proposed labeling for the drug as submitted by the manufacturer. 21 C.F.R. § 314.550. This approved labeling, which includes information as to indications and usage of the drug, provides that:

> Mifeprex is indicated for the medical termination of intrauterine pregnancy *through 49 days' pregnancy*. For purposes of this treatment, pregnancy is dated from the first day of the last menstrual period in a presumed 28 day cycle with ovulation occurring at mid-cycle.

(FDA approved labeling for mifepristone). (Emphasis added).

Thus, if, medically speaking, a pregnancy begins at the completion of implantation of the embryo in the uterus, which is usually 28 to 32 days from the beginning of the last menstrual period, and if RU-486 is approved for use by the FDA only through 49 days' pregnancy, then whether the use of RU-486 constitutes an "abortion" as defined under Tenn. Code Ann. §§ 37-10-302(1) and 39-15-201(a)(1) would be *determined on a case-by-case basis*, and would be based on *whether the drug is used before or after implantation of the embryo.* In other words, in order to constitute an "abortion" within the meaning of the two relevant statutes, the physician must administer RU-486 to a woman or minor who he or she knows is "pregnant", i.e. after implantation but before the 50th day of pregnancy.

Moreover, in terms of an "abortion" as defined under the abortion statute at Tenn. Code Ann. § 39-15-201(a)(1), the statute goes on to specify that a criminal abortion does *not* occur when performed during the first three months of pregnancy if done with the pregnant woman's consent by a licensed physician. Tenn. Code Ann. § 39-15-201(c)(1). Because RU-486 is only approved for use by the FDA through the first 49 days of pregnancy, then it must be used *well before the first three months of pregnancy* have passed, and, therefore, by the terms of the statute, its use as indicated would never constitute a criminal abortion.

IV.

There have been significant legal challenges to both the parental consent statute and the informed consent abortion statute. In *Planned Parenthood of Middle Tennessee v. Sundquist* (2000 WL 1303507), clinics and physicians challenged the constitutionality of certain provisions of Tenn. Code Ann. §§ 39-15-200, *et seq*. The Tennessee Supreme Court found most of the provisions of this section to be unconstitutional and, therefore, unenforceable. Furthermore, the Tennessee Supreme Court found that "the statutory provisions regulating abortion must be subjected to strict scrutiny analysis", and that, under the

Tennessee Constitution:

> the statutes at issue, Tenn. Code Ann. § 39-15-201(c)(2) (the second trimester hospitilization requirement), § 39-15-202(b), (c) (the informed consent and physician-only counseling requirements), § [39-15]-202(d)(1) (the mandatory waiting period requirement), and § [39-15]-202(d)(3) and (g) (the medical emergency exceptions) are unconstitutional because the statutes are not narrowly tailored to further compelling state interests.

(2000 WL 1303507, *23). Since these statutory provisions are unconstitutional, they cannot be applied to physicians administering RU-486 to adult women.

On the other hand, the United States Court of Appeals for the Sixth Circuit held, in a challenge to the constitutionality of Tenn. Code Ann. §§ 37-10-301, *et seq.*, the parental consent law, that the plaintiff was not likely to succeed on its constitutional claim and reversed an injunction by the federal district court which had prevented enforcement of the provisions. *Memphis Planned Parenthood v. Sundquist*, 175 F.3d 456 (1999). The Sixth Circuit held that the requirements to be met by a minor seeking judicial bypass of the parental consent requirement, as explained in Rule 24 of the Rules of the Supreme Court of Tennessee, were allowable and did not constitute an undue burden on the ability of a minor to pursue a judicial bypass. *Id.* at 462-465. As a result, all provisions of the parental consent act currently are in effect. Accordingly, if a physician administers RU-486 to a minor who the physician knows is pregnant, i.e., after implantation, then the physician must obtain the consent of one parent or judicial approval under Tenn. Code Ann. §§ 37-10-301, *et seq*., before administering RU-486.

PAUL G. SUMMERS
Attorney General & Reporter

MICHAEL E. MOORE
Solicitor General

JOHN W. DALTON
Assistant Attorney General

Requested by:
The Honorable David Fowler
Senator
304 War Memorial Building
Nashville, Tennessee 37243-0211