IN THE SUPREME COURT OF FLORIDA

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DEPARTMENT OF HEALTH, JOHN) LAGWUNOBI, M.D., SECRETARY,)in his official capacity, and)	
AGWUNOBI, M.D., SECRETARY,) in his official capacity, and)	Case No. SC04-2186
in his official capacity, and)	Lt. 4D02-4485
FLORIDA BOARD OF MEDICINE	
i Lokubri bornab or medicine,)	
)	
Appellants,)	
vs.)	
)	
PRESIDENTIAL WOMEN'S CENTER,)	
MICHAEL BENJAMIN, M.D., NORTH)	
FLORIDA WOMEN'S HEALTH AND)	
COUNSELING SERVICES, INC., ET AL.,)	
)	
Appellees.)	
)	

BRIEF OF AMICUS CURIAE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, FLORIDA SECTION IN SUPPORT OF APPELLEES

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STATEMENT OF INTEREST OF AMICUS CURIAE American College of Obstetricians and Gynecologists, Florida Section (ACOG-FS)

The American College of Obstetricians and Gynecologists, (hereinafter "ACOG") is a voluntary, nonprofit membership organization of physicians specializing in obstetric and gynecologic care. ACOG was founded in 1951 and is the nation's leading group of professionals providing health care to women. ACOG has over 47,000 members, which represent approximately ninety-two (92%) percent of all board certified obstetricians and gynecologists practicing in the United States. ACOG's local chapter, the ACOG Florida Section (hereinafter "ACOG-FS") has 2,383 members located in the State of Florida.

ACOG-FS's interest in this case arises from its commitment to providing the highest possible quality health care to women. As part of its dedication to good medical practice, ACOG-FS has a responsibility to ensure that its members' patients are able to seek and obtain appropriate and personalized medical care without undue interference, and that its members are in a position to carry out their duty to provide care and treatment according to their best clinical judgment in accordance with applicable professional and ethical standards. ACOG-FS is concerned with preserving the sanctity of the physician-patient relationship and ensuring that physicians are able to exercise their best professional judgment in carrying out their

individual patient's wishes and decisions in the manner most suited to the patient's particular health needs.

SUMMARY OF THE ARGUMENT

Personal decision-making with respect to medical treatment issues is protected by the privacy clause of the Florida Constitution. The physician-patient relationship is an integral part of that decision-making process. The state can only intrude or interfere with that relationship in furtherance of a compelling state interest and, even then, only if the intrusion is narrowly tailored in the least intrusive manner possible. The legislation at issue in this case does not satisfy this compelling interest test.

The Act in question impermissibly requires physicians to uniformly provide patients with standardized information that the physician may not believe is appropriate to the circumstances of a particular patient. The Act's requirements are contrary to the fundamental principles of informed consent.

The Act is also unacceptably vague. It creates a basis for disciplinary action against the professional license of a physician without providing fair notice of the conduct proscribed by the statute and without providing adequate standards for enforcement of the statute.

ARGUMENT

I. The Act Is an Unconstitutional Intrusion upon the Physician-Patient Relationship

Article I, Section 23 of the Florida Constitution provides that "every natural person has the right to be let alone and free from governmental intrusion into his private life except as otherwise provided herein." This Honorable Court has recognized that this privacy right encompasses personal decision-making as it relates to medical treatment:

[T]he concept of privacy encompasses much more than the right to control the disclosure of information about oneself. . . . [It implies a] fundamental right of self-determination subject only to the state's compelling and overriding interest. For example, privacy has been defined as an individual's 'control over or the autonomy of the intimacies of personal identity' or as a 'physical and psychological zone within which an individual has the right to be free from intrusion or coercion, whether by government or by society at large.'

In re Guardianship of Browning, 568 So.2d 4, 9-10 (Fla. 1990)(quotation cites omitted).

The privacy clause of the Florida Constitution as it relates to government intrusions on health care decisions was explained in *In re Dubreuil*, 629 So.2d 819, 822-23 (Fla. 1993), wherein this Honorable Court held that "a health care provider's function is to provide medical treatment in accordance with the patient's wishes and best interests, not as a "substitute parent" supervening the wishes of a competent

adult. . . . A health care provider cannot act on behalf of the State to assert the state interests in these circumstances."

In *In Re T.W.*, 551 So.2d 1186, 1192 (Fla. 1989), this Honorable Court also recognized that the state constitutional right to privacy "is clearly implicated in a woman's decision of whether or not to continue her pregnancy." That decision reiterated that Florida's privacy right "is a fundamental right which we believe demands the compelling state interest standard." 551 So.2d at 1192. *Accord N. Fla. Women's Health & Counseling Servs., Inc. v. State,* 866 So. 2d 612, 620-22 (Fla. 2003).

The communications between a woman and her obstetrician/gynecologist are undeniably personal matters that fall within the scope of the privacy clause of the Florida Constitution. Any attempt to confine or control a physician's professional discretion as to how to best inform his or her individual patient concerning a medical procedure and its consequences infringes on the privacy right that the Florida Constitution guarantees. *See Appellee Presidential's Answer Brief at p. 11-21*.

The Woman's Right to Know Act, *see* section 390.0111(3), Florida Statutes, as amended by chapter 97-151, Laws of Florida, (hereinafter referred to as "the Act"), is an unconstitutional intrusion upon the physician – patient relationship in that it requires the physician to provide information to the woman without regard to either

the woman's particular circumstances or the physician's professional judgment. Specifically, the Act requires that the physician performing the abortion or a referring physician inform the woman of "[t]he nature and risks of undergoing or not undergoing the proposed procedure that a reasonable patient would consider material to making a knowing and willful decision of whether to terminate a pregnancy" and provide, or at least offer, to her some state-prepared materials containing a "description of the fetus . . [a] list of agencies that offer alternatives to terminating the pregnancy . . . [and] detailed information on the availability of medical assistance benefits for prenatal care, childbirth, and neonatal care." §390.0111(3), Fla. Stat. This is in contrast to Florida's pre-existing and current Medical Consent Law, which requires that a physician provide the information that a "reasonable individual . . . under the circumstances" needs in order to understand the procedure, medically accepted alternatives, and the medically recognized substantial risks of the procedure. §766.103, Fla. Stat.

Thus, in contrast to the Act, Florida's existing informed consent law requires that the physician act in accordance with accepted standards of medical practice within the medical community and that the physician provide information that a reasonable person in that patient's circumstance would need in order to understand the treatment and risks. This standard respects the physician – patient relationship by recognizing the importance of the patient's role in decision-making and the

professional expertise of the physician. *See Gouveia v. Phillips*, 823 So.2d 215, 228 (Fla. 4th DCA 2002)(describing Florida Medical Consent Law); *see also* Appellee Presidential's Answer Brief at 30-34.

As the Fourth District Court of Appeal concluded in the case at bar, the new law infringes on the woman's ability to receive her physician's opinion as to what is best for her, considering her individual and personal circumstances. *State v. Presidential Women's Center*, 884 So.2d 526, 532 (Fla. 4th DCA 2004)(hereinafter referred to as "Presidential"). The Act also encumbers a physician in his or her ability to convey information to patients in a manner that is appropriate to that individual patient in light of her particular medical, social, and economic needs and her other unique circumstances. *Id.*

Rather than promoting true informed consent, the Act will interfere with constructive consultation between physicians and their patients and could undermine a patient's health. The Act's disclosure requirements limit the ability of physicians to tailor the informed consent process to the particular needs of their patients and mandate the disclosure of information that may be undesired, or even harmful, to the actual patient, in light of her individual circumstances. Thus, the requirements of the Act are contrary to widely-accepted medical-ethical principles of informed consent. The Act impermissibly interferes with the physician- patient relationship, and as such, it intrudes into the woman's protected privacy rights under the Florida Constitution.

As discussed in Appellee Presidential's Answer Brief, the Act must therefore survive strict scrutiny and it cannot do so.

The state suggests that the requirements of the Act are permissible because physicians are free to supply patients with any additional information they wish. This opportunity does not justify or authorize the intrusion into the physician-patient relationship and is not the least intrusive means available for the state to further its goals. To withstand constitutional scrutiny, the state must demonstrate that the foisting upon patients of state-mandated information is consistent with acceptable medical practices and is narrowly tailored to further a compelling state interest. Cf. Winfield v. Div. of Pari-Mutel Wagering, 477 So.2d 544, 548 (Fla. 1985)(where a law intrudes on the fundamental right to privacy guaranteed in Florida's Constitution, the State must demonstrate that the challenged regulation serves a compelling state interest and accomplishes its goal through the use of the least intrusive means); In re T.W., 551 So.2d at 1193-43. No such showing can be made with respect to this Act. The Fourth District ruled correctly that the Act is unconstitutional.

II. The Informed Consent Provisions of the Act Violate Fundamental Principles of Informed Consent

As discussed above, the requirements imposed by the Act violate the

fundamental right to privacy under Florida's Constitution by intruding into the physician- patient relationship. In addition, the Act violates fundamental principles of informed consent. The requirement that a physician obtain a patient's informed consent to a medical procedure is fundamental to the common law and medical ethics. The informed consent doctrine is rooted in respect for patient autonomy. *See, e.g., Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). It is also current Florida law and set forth in section 766.103, Florida Statutes (2005)("Florida Medical Consent Law"). That existing law requires that a physician provide information such that a reasonable individual in the patient's circumstances would have a general understanding of the procedure, the medically accepted alternatives, and the substantial risks inherent in the proposed procedure, which are recognized among other physicians in the same or similar community who perform similar procedures. *See* §766.103(1)(a)1. and 766.103(2), Fla. Stat. (2005).

Because the treatment decision must ultimately be based on the particular situation, wishes and options of that patient, it is not possible to devise and impose uniform, standardized language relevant to <u>every patient</u> for medical decisionmaking, whether by an individual physician or by the government. Similarly, it is impossible to devise a <u>universal list</u> of information for any treatment that will provide a "straw" patient with relevant information. It is also not appropriate to require every physician performing the abortion or every physician making the referral to provide all pregnant patients contemplating an abortion a standardized litany of information regardless of whether the patient sought the information or

whether the physician thought the information was necessary and relevant to the decision. Rust v. Sullivan, 500 U.S. 173, patient's See cf. 203 (1991)(unconstitutional to require all doctors to provide all pregnant patients the same list of information); Thornburgh v. American College of Obstetricians and Gynecologists, 476 U.S. 747 (1986)(unconstitutional to require a list of agencies offering alternatives to abortion and a description of fetal development to be provided to every woman considering abortion), overruled in part on other grounds, Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833 (1992)¹; City of Akron v. Akron Center for Reproductive Health, Inc., 462 U.S. 416, 423 (1983)(unconstitutional to require all physicians to make specific statements to all patients prior to performing an abortion), overruled in part on other grounds, Planned Parenthood of Southeastern Pa. v. Casev, 505 U.S. 833 (1992).

Good medical practice dictates that a patient and her physician should decide together on treatment based on the specific needs of <u>each</u> individual patient: "[E]thically valid consent is a process of shared decision making based upon mutual respect and participation, not a ritual to be equated with reciting . . . the risks of particular treatment." President's Commission for the Study of Ethical Problems in

¹ As discussed in Appellee Presidential's Answer Brief, federal cases decided prior to *Casey* applied a standard comparable to the standard applied by this Court in analyzing state restrictions on the fundamental right to privacy under Florida's Constitution. *See* Appellee Presidential's Answer Brief at p. 13 & 16.

Medicine and Bio-Medical and Behavioral Research, (1982) Making Health Care Decisions, at 2.

Legally mandated and standardized disclosure requirements run the risk that patients will be so overwhelmed with information that they will be unable to distinguish truly significant information from information that is of minor significance applicable to their own individual circumstances. *Id.* at 28. Mandatory disclosure requirements also fail to allow for situations in which certain information could result in anxiety, fear, emotional distress or even increased physical pain. In such cases, standard principles of informed consent permit physicians to decide, in the exercise of their professional judgment, what the patient should be told, considering the patient's personal circumstances. *See* F. Rozovsky, *Consent to Treatment: A Practical Guide*, Section 1.16.4 at pp. 86-87 (2d Ed. 1990).

In light of the individualized nature of the consultation process, the Act's attempt to structure the dialogue and impose a requirement for distribution of certain governmental pre-prepared and standardized documents strikes directly at the protected relationship between a woman and her physician. The state essentially seeks to dictate that certain information be covered in consultation with every patient, regardless of the physician's best judgment. It also forces the physician to act, at risk of the loss of his or her professional license, as an agent of the state to

distribute information which he or she had no role in preparing, regardless of his or her own personal viewpoint or beliefs on the accuracy and relevancy of the state's prepared information and the applicability and relevancy to the individual patient's circumstances.

Studies of medical decision-making have consistently demonstrated that patient's choices depend, at least in part, on the way information is presented to them. "Forcing the physician or counselor to present materials and the list [of state agencies] makes him or her in effect an agent of the State in treating the woman and places his or her imprimatur on both the materials and the lists." *Thornburgh*, 476 U.S. at 762-63. The Act interferes with the process of informed consent and compromises the integrity of the patient-physician relationship by requiring physicians to provide state-mandated information which may not be consistent with their own professional views based on their evaluation of a patient's needs.

Physicians are already required under existing ethical principles, established legal precedents and Florida law to disclose to their patients the information necessary for an "informed consent" to a medical procedure. Section 8.08 of the Code of Medical Ethics published by the Council on Ethical and Judicial Affairs of the American Medical Association provides that rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment. Therefore, physicians cannot be expected to obtain informed consent in a standardized, uniform fashion.

In sum, physicians already have a professional, and in Florida, statutory, obligation to obtain the informed consent of their patients before performing any medical procedure. The requirements of the Act, however, impermissibly intrude upon the informed consent process by dictating the content, nature and form of the physician-patient dialogue. The Act effectively makes physicians pawns in one of the most divisive social, ethical and moral issues of our times. As such, the informed consent provision of the Act violates the fundamental principles and ethics behind informed consent.

III. The Act Fails to Provide Physicians with Adequate Notice of Their Obligations and Fails to Provide Adequate Standards for Enforcement.

The Act requires that a physician performing an abortion must satisfy a unique

and confusing "reasonable patient" standard or risk disciplinary proceedings. Presidential, 884 So.2d at 533-34. Statutes that pose the risk of license sanctions must be strictly construed in determining whether they violate the due process clause of the Florida Constitution. Id. The due process clauses of the Florida Constitution and of the United States Constitution mandate that laws provide persons subject to regulation under them "a reasonable opportunity to know what [conduct] is prohibited, so [they] may act accordingly." Graynerd v. City of Rockford, 408 U.S. 104, 108 (1972); accord, e.g., D'Alemberte v. Anderson, 349 So.2d 164, 166-67 (Fla. 1977). A statute that is punitive in nature must be sufficiently defined "to give a person of ordinary intelligence fair notice that his contemplated conduct is forbidden by the statute." Coalutti v. Franklin, 439 U.S. 379, 390 (1979); accord, e.g., Aztec Motel, Inc. v. State, ex. Rel. Faircloth, 251 So.2d 849, 854 (Fla. 1971). Moreover, due process is violated if a statute provides no clear standard of conduct and so gives enforcement authorities unfettered freedom to act on nothing but their own preferences and beliefs. See Gravnerd; Kolender v. Lawson, 461 U.S. 352, 357 (1983); Aztec Motel, 251 So.2d at 854.

As discussed above, a physician's compliance with the Act is not measured against the existing standard in Florida under which the physician is able to consider the patient's circumstances and standards of the medical community in obtaining

informed consent. Instead, the physician is required to guess at what information a "reasonable" patient would expect to receive in making her decision. Given the clear changes in language from the Florida Medical Consent Law to the Act, neither the physicians nor this Court can read into the Act the words – "under the circumstances" -- that the Legislature removed. *See* Appellee Presidential's Answer Brief at p. 25-29.

Under the Act, the information to be provided by a physician is not limited to medical information, but, instead, includes any information regarding the "nature and risks of undergoing or not undergoing the proposed procedure" that a "reasonable patient" would consider material. Such information could be interpreted to include psychological, socioeconomic and perhaps religious issues which extend beyond the expertise of most referring physicians or physicians performing the abortion.

The Act is also unclear in that it states that the physician must provide materials "if [the patient] chooses to view [them]," but also requires a patient to acknowledge in writing that "the information required to be provided under this subsection has been provided." §390.0111(3)(a)3, Fla. Stat. This latter provision apparently applies even if the patient has made it clear to the physician that she does not wish to view the materials prepared by the state and the physician believes that providing such information would not be in the best interest of the patient. Thus, it

is unclear whether the physician can perform the abortion if the patient chooses not to view or receive the materials.

Under Section 390.0111(3)(b) of the Act, when a "medical emergency" exists and the physician cannot comply with the requirements for informed consent set forth in subsection (a), a physician may proceed "if he or she has obtained at least one corroborative medical opinion attesting to the medical necessity for emergency medical procedures and to the fact that to a reasonable degree of medical certainty the continuation of the pregnancy <u>would threaten the life</u> of the pregnant woman." (emphasis added). If "no second physician is available for a corroborating opinion, the physician may proceed but shall document reasons for the medical necessity in the patient's medical records." *Id*.

Thus, as written, the required consent procedure set forth in the Act must be followed even in an emergency situation where continuing the pregnancy would threaten the health, but not necessarily the life, of the patient. Even when the patient's life is threatened and it is not possible to obtain written informed consent from her, a physician must obtain at least one corroborative medical opinion or else the physician runs the risk of having to defend himself in a license disciplinary proceeding. This prospect increases the possibility of unnecessary delay while efforts are made to locate a corroborating physician. While the Act provides for a physician to document the circumstances that threaten the woman's life if a corroborating

physician cannot be found in an emergency situation, it is not clear that documenting the circumstances will provide a defense to disciplinary action under the Act. This lack of clarity may cause some physicians to act conservatively at a time when an emergency medical procedure may be necessary. At a minimum, some physicians will be put on the defensive to justify the actions they took in an emergency setting. In this regard, the Act unconstitutionally shifts the burden of proof in a license disciplinary action.

In addition, as noted above, under the Act a "medical emergency" apparently exists only when a pregnant woman's life is at risk, while Section 390.0111(3)(c) provides a defense to disciplinary action under the Act for a physician if there is "substantial compliance or reasonable belief that complying with the requirements of informed consent would threaten the life or health of the patient." Given the failure to include "health" considerations in subsection (3)(b), it is not clear that this general defense is available to an alleged failure to comply with the provisions of that subsection in a health-threatening emergency.

In any event, the defense in subsection (3)(c) impermissibly shifts the burden to the physician to affirmatively demonstrate that there was a reasonable belief that complying with the requirements of informed consent would threaten the life or health of the patient. License disciplinary proceedings are penal in nature and the

constitutional protections against self-incrimination are applicable. *See State ex rel. Vining v. Fla. Real Estate Comm.*, 281 So.2d 487, 491 (Fla. 1973); *Ferris v. Turlington*, 510 So.2d 292 (Fla. 1987). The Act unconstitutionally places a physician in a position of having to affirmatively defend his actions or lose his or her medical license.

The Act is vague and therefore unconstitutional. These deficiencies render it unacceptable, especially in an area where clarity in the law and the need for physician discretion are paramount. The duty and judgment of a physician, the needs and welfare of the patient, and the rights of both cannot be subjected to indefinite, uncertain, vague or unreasonable legislation. *State v. Barquet, 262 So.2d* 431 (Fla. 1972). The Act subjects physicians to potential disciplinary action without regard to fault. The lack of a *mens rea*, or a specific intent requirement in the statute exacerbates the uncertainty of the statute. *See Coalutti,* 439 U.S. at 395, 401.

CONCLUSION

Under the Florida constitutional right of privacy, the state cannot interfere with the physician-patient relationship by compelling the distribution of standardized information which may not be relevant to a particular patient and could, in some instances, be contrary to a physician's assessment of his or her patient's best interests. Moreover, the Act conflicts with traditional notions of informed consent and fails to provide adequate standards by which a physician can determine compliance with the Act's requirements.

Accordingly, amicus curiae ACOG-FS respectfully urges this Court to affirm the decision of the Fourth District Court of Appeal, which affirmed the trial court's Order granting summary judgment in favor of Appellees and finding unconstitutional Florida's abortion informed consent statute.

RESPECTFULLY SUBMITTED this 10th day of March, 2005.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. Mail to Louis F. Hubener, Chief Deputy Solicitor General, Office of the Attorney General, The Capitol, PL-01, Tallahassee, Florida 32399 (email address: Lou_Hubener@oag.st.fl.us); Marshall Osofsky, Moyle, Flanigan, et al, P. O. Box 3888, West Palm Beach, FL 33402; Bebe Anderson, Center for Reproductive Rights, 120 Wall Street, 14th Floor, New York, NY 10005; Barry M. Silver, Esq., 777 Glades Road, Suite 308, Boca Raton, FL 33434; Donna Lee, Planned Parenthood Federation of American, 434 W. 33rd Street, New York, NY 10001; Matthew Staver, Erik Stanley, and Anita Staver, Liberty Counsel, 210 East Palmetto Avenue, Longwood, FL 32750; Teresa Stanton Collett, St. Thomas School of Law, 1000 LaSalle Avenue, Suite 440, Minneapolis, MN 55403, by the 10th day of March, 2005.

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<u>Certificate of Compliance</u>

I hereby certify that this brief was prepared with Times New Roman 14 point, in compliance with Florida Rule of Appellate Procedure 9.210(a)(2).

Jo Ann Barone Kotzen, Esq.