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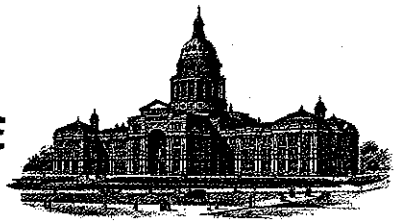

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January 28, 2010

FRANK J. CORTE JR.

The Honorable Greg Abbott
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P.O. Box 12548
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RQ-0858-GA

FILE # ML-46326-10
I.D. # 46326

Re: Proper Interpretation of TEX. HEALTH & SAFETY CODE § 171.012

Dear General Abbott:

This letter requests an opinion from your office regarding whether the Texas Department of State Health Services has properly interpreted a key provision of the Texas Woman's Right to Know Act, TEX. HEALTH & SAFETY CODE § 171.001 *et seq.* (Supp. 2009), regarding the means by which informed consent is obtained prior to the performance of an abortion. As Chairman of the House Committee on Defense and Veterans' Affairs, I am requesting an opinion from your office on the following question: May an abortion facility use either a pre-recorded telephonic message or a one-way "conference call" to provide the information mandated by Health & Safety Code §§ 171.012(a)(1)(A)-(D) and 171.012(a)(2)(A)-(D)?

The Statute

Section 171.012 of the Woman's Right to Know Act provides in relevant part:

> Voluntary and Informed Consent. (a) Except in the case of a medical emergency, consent to an abortion is voluntary and informed only if:
>
> (1) the physician who is to perform the abortion or the referring physician informs the woman on whom the abortion is to be performed of:
>
> (A) the name of the physician who will perform the abortion;
>
> (B) the particular medical risks associated with the particular abortion procedure to be employed, including, when medically accurate:

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(i) the risks of infection and hemorrhage;

(ii) the potential danger to a subsequent pregnancy and of infertility; and

(iii) the possibility of increased risk of breast cancer following an induced abortion and the natural protective effect of a completed pregnancy in avoiding breast cancer;

(C) the probable gestational age of the unborn child at the time the abortion is to be performed; and

(D) the medical risks associated with carrying the child to term;

(2) the physician who is to perform the abortion or the physician's agent informs the women that:

(A) medical assistance benefits may be available for prenatal care, childbirth, and neonatal care;

(B) the father is liable for assistance in the support of the child without regard to whether the father has offered to pay for the abortion;

(C) public and private agencies provide pregnancy prevention counseling and medical referrals for obtaining pregnancy prevention medications or devices, including emergency contraception for victims of rape or incest; and

(D) the woman has the right to review the printed materials described by Section 171.014, that those materials have been provided by the Texas Department of Health and are accessible on the Internet website sponsored by the department, and that the materials describe the unborn child and list agencies that offer alternatives to abortion;

(3) the woman certifies in writing before the abortion is performed that the information described by subdivisions (1) and (2) has been provided to her and that she has been informed of her opportunity to review the information described by Section 171.014; and

(4) before the abortion is performed, the physician who is to perform the abortion receives a copy of the written certification required by Subdivision (3).

(b) The information required to be provided under Subsections (a)(1) and (2) must be provided:

(1) orally by telephone or in person; and

(2) at least 24 hours before the abortion is to be performed.

HEALTH & SAFETY CODE § 171.012(a), (b) (emphasis added).

The Department's Interpretation

On their website, the Texas Department of State Health Services (DSHS) has listed a series of questions and answers regarding the legal obligations of facilities that perform abortions. Two of those questions and answers are the subject of this letter request:

> [Question] ***4. May a referral physician or the physician who is to perform the abortion, use a pre-recorded tape to "orally by telephone" inform the woman on whom an abortion is to be performed of the information required by Section 171.012(1)(A)-(D). Two categories a) taped by the facility medical director who is not the doctor who is to perform the procedure and b) taped by the doctor who will perform the procedure.***[1]
>
> ANSWER. HSC Chapter 171.012(b) states "the information provided to the woman under Subsection (a)(1) & (2) must be provided: (1) orally by telephone or in person; and (2) at least 24 hours before the abortion is to be performed." The facility must have mechanisms in place to ensure (1) that the information is provided to the woman by the *referring physician* or *the physician who is to perform the procedure* for Sec. 171.012(a)(1)(A)-(D); (2) that the physician who is to perform the abortion or the physician's agent provides the woman with the information required in Sec. 171.012(a)(2)(A)-(D); *and* (3) that this is done at least 24 hours before the abortion is to be performed. So, yes, taping is acceptable, **however** the referring physician or the physician who will perform the abortion must be the person on the tape and the information must be specific to the gestational age.

(http://www.dshs.state.tx.us/HFP/AbortionFAQ.shtm) (emphases and bold in original).

> [Question] ***9. May this information be provided via a live "conference call" during which the physician talks to whomever is on the call? The callers will not be able to participate, only listen. Verification that a woman listened to a call at a specific date and time is through a password and is documented in the woman's clinical record.***

[1] The Department miscited the statutory reference. It is § 171.012(a)(1)(A)-(D), not § 171.012(1)(A)-(D). Also, although the question posed by the Department was intended to refer only to subsection (a)(1), its answer deals with both subsections (a)(1) and (a)(2).

ANSWER: Yes, as long as mechanisms are in place to ensure that all the provisions in Sec. 171.012(a)-(d) have been met.

(http://www.dshs.state.tx.us/HFP/AbortionFAQ.shtm) (emphases and bold in original).

Statutory Analysis

The Department's interpretation of the statute is clearly at odds with its plain language. The information mandated by § 171.012(a)(1) and (2) must be provided "orally by telephone or in person," "at least 24 hours before the abortion is to be performed." § 171.012(b)(1), (2). Section 171.012(b)(1) does not, by its express terms or by reasonable implication, permit that information to be presented via a pre-recorded telephone message or a live, one-way "conference call" in which the callers are "not able to participate, only listen." Nor can the Department's interpretation be reconciled with standard rules of statutory construction.

The Code Construction Act specifies that "[w]ords and phrases shall be read in context." TEX. GOV'T CODE § 311.011(a) (2005). In context, "orally by telephone or in person" means either an interactive conversation over the telephone or an interactive conversation in person. It is axiomatic that a patient who is provided with information legally required to obtain her consent to a medical or surgical procedure must *understand* what she has been told in order for her consent to be truly "informed." If she does not understand what she has been told, or has questions or concerns that need to be answered or addressed, she must be able to speak with her physician *at the time the information is conveyed* which, for purposes of the Woman's Right to Know Act, must be "at least 24 hours before the abortion is to be performed." § 171.012(b)(2).[2] Under the Department's interpretation of § 171.012(b)(1), however, a patient who does not understand what she has been told in a pre-recorded telephone message or in a one-way "conference call," or has questions or concerns regarding what she has heard, has no opportunity, *at that time*, to speak with *her* physician.[3] If it had been the Legislature's intent to permit a pre-recorded telephone message (or a one-way "conference call"), without any interaction between the patient and her physician, there would have been no reason for specifying that only the referring physician or the attending physician provide the information. The required information could just as well be provided by *any* physician. The illogical consequences of this interpretation militates against its acceptance. *See* GOV'T CODE § 311.023(5) ("in construing a statute . . . , a court may consider among other matters the . . . consequences of a particular construction").

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[2] It is irrelevant, therefore, whether the patient is able to ask questions or clarify matters immediately before the abortion is performed. Understanding comes too late.

[3] The implausibility of the Department's interpretation is obvious when one realizes that, unless an abortion facility has only one physician who performs abortions, there is no way of ensuring that the physician who records the informed consent message (or conducts the live, one-way "conference call") is also the referring or attending physician for a particular patient, as the statute clearly requires and as DSHS itself acknowledges.

There is another rule of construction which cuts against the Department's interpretation. The adverb "orally" in HEALTH & SAFETY CODE § 171.012(b)(1) applies to *both* methods–by telephone or in person. *See* GOV'T CODE § 311.011(a) ("[w]ords and phrases shall be read in context and construed according to the rules of grammar and common usage"). Under the Department's view, an employee of an abortion clinic could play a pre-recorded message regarding informed consent (dictated by a physician) for a patient in her physical presence (at least twenty-fours hours before the abortion was to be performed), and that would comply with the law. That cannot be the case.

Common Law

Common law informed consent principles do not control the construction of statutory informed consent requirements to the extent that such principles are modified, amplified or qualified by statute. *See, e.g.*, CIV. PRAC. & REM. § 74.101 *et seq.* (informed consent). But those principles may be helpful guides in interpreting informed consent requirements imposed by statute. *See* GOV'T CODE § 311.023(4) ("[i]n construing a statute . . . , a court may consider among other matters the . . . common law . . . ." Under Texas law, "it is the duty of the treating physician . . . to secure the informed consent of the patient." *Ritter v. Delaney*, 790 S.W.2d 29, 31 (Tex. App.–San Antonio 1990, *writ denied*). *See also Espalin v. Children's Medical Center of Dallas*, 27 S.W.3d 675, 686 (Tex. App.–Dallas 2000, *no writ*) (duty is nondelegable). In order to discharge that duty, the physician is required "to *discuss* with a patient risks and benefits of a procedure." *Gibson v. Methodist Hospital*, 822 S.W.2d 95, 101 (Tex. App.–Houston [1st Dist.] 1991, *writ denied*) (emphasis added). What emerges from a review of the decided cases is that informed consent envisions a *dialogue* between physician and patient–not a physician's *monologue*–and a *discussion* of the relative risks and benefits of treatment vs. nontreatment. *Tajchman v. Giller*, 938 S.W.2d 95, 99 (Tex. App.–Dallas 1996, *writ denied*) (citing *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir. 1972).[4] "True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each." *Karp v. Cooley*, 493 F.2d 408, 419 (5th Cir. 1974) (applying Texas law). A pregnant woman considering an abortion cannot be expected to "evaluate knowledgeably" her available options and "the risks attendant upon each" without having the opportunity to speak directly to her physician, ask him or her questions and gain understanding from the answers. This is confirmed when we turn from Texas common law to the standards for obtaining informed consent that have been adopted by professional medical associations, recommended by presidential commissions and advocated by experts in medical ethics. Those standards uniformly envision informed consent as an ongoing process of communication in which the patient is afforded the opportunity to have her questions answered and her concerns addressed. In short, they envision a *dialogue* between physician and patient, not a *monologue* by the physician in which the patient is unable to participate.

[4] For an example of how the dialogue between patient and physician ensures that informed consent has been obtained, *see Ocomen v. Rubio*, 24 S.W.3d 461, 468-69 (Tex. App. – Houston [1st Dist.] 2000, *no writ*).

Texas Medical Association

The Texas Medical Association (TMA), with more than 43,000 physician and medical student members, is the largest professional medical association in Texas. In an analysis of informed consent, TMA recognizes that informed consent "is more than a form; it is a *process* that includes," among other things, "*discussion.*" *Informed Consent: A Process of Communication* at 1 (http://www.texmed.org/Template.aspx?id=1745) (emphasis added). Under the heading of "Discussion," TMA states that "[f]rank and open dialogue with patients is the most important step in the informed consent process, providing an opportunity for physicians to establish rapport and engage patients in making decisions about their own care." *Id.*

The discussion, which should emphasize "the physician-patient team in the decision-making process" includes the following information:

- Differential diagnosis,
- Description and purpose of proposed treatment,
- Benefits and expected outcome of proposed treatment,
- Risks associated with treatment,
- Alternatives to treatment (including risks and benefits), and
- Consequences of no treatment.

Informed Consent: A Process of Communication at 1.

As part of the process of obtaining informed consent, TMA recommends the following:

- The physician who sits down during discussions with patients displays a caring and concerned attitude and appears to be willing to spend adequate time to ensure that all patient questions and concerns will be addressed.
- Choose a quiet setting for the discussion where patients aren't likely to be distracted.
- Use descriptive, simply stated terminology to ensure patients understand complicated medical procedures. Use key repetitive phrases and then ask patients to repeat what you have said. Draw diagrams if necessary.

Informed Consent: A Process of Communication at 2.

It is (or should be) obvious that the use of a pre-recorded telephone message to provide informed consent does not permit any "discussion" between the physician and his or her patient, nor does it allow for a "frank and open dialogue" between provider and patient or any opportunity for the patient to have her questions answered and her concerns addressed. The same is true, of course, for a so-called "conference call" during which the physician conducts a one-way "conversation" with multiple callers who are "not able to participate, only listen."

American Medical Association

The American Medical Association (AMA) is the largest association of physicians in the United States. The AMA has posted on its website a succinct statement of the requirements of informed consent (AMA *Informed Consent*, Jan. 14, 2010, http://www.ama-assn.org/ama/pub/physician-resources/legal-topics/patient-physician-relationship-topics/informed-consent.shtml). "Informed consent," the statement reads, "is more than simply getting a patient to sign a written consent form. It is *a process of communication* between a patient and a physician that results in the patient's authorization or agreement to undergo a specific medical intervention." *Id.* (emphasis added). In this process, "the physician providing or performing the treatment and/or procedure (not a delegated representative)" has the responsibility to "disclose and discuss" with the patient the following:

- The patient's diagnosis, if known;
- The nature and purpose of a proposed treatment or procedure;
- The risks and benefits of a proposed treatment or procedure;
- Alternatives (regardless of their cost or the extent to which the treatment options are covered by health insurance);
- The risks and benefits of the alternative treatment or procedure; and
- The risks and benefits of not receiving or undergoing a treatment or procedure.

Id.

The AMA's statement emphasizes that the patient "should have an opportunity to ask questions to elicit a better understanding of the treatment or procedure, so that he or she can make an informed decision to proceed or to refuse a particular course of medical intervention." *Id.* The AMA stresses that "[t]his communication process, or a variation thereof, is both an ethical obligation and a legal requirement spelled out in statutes and case law in all 50 states." *Id.* Neither the use of a pre-recorded informed consent message nor a one-way "conference call" accords with these ethical and legal imperatives because, in each case, the patient is deprived of *any* opportunity to ask questions and the physician is denied the opportunity to answer those questions and otherwise evaluate the patient's understanding of what she has been told.

American College of Obstetricians and Gynecologists

The American College of Obstetricians and Gynecologists (ACOG), the principal professional association of women's health care physicians in the United States, has addressed the issue of informed consent, and its requirements, in many of its publications. ACOG's Code of Professional Ethics provides:

> The obstetrician-gynecologist has an obligation to obtain the informed consent of each patient. In obtaining informed consent for any course of medical or surgical treatment, the obstetrician-gynecologist must present to the patient . . . pertinent medical facts and recommendations consistent with good medical practice. Such information should be presented in reasonably understandable terms and include alternative modes of treatment and the objectives, risks, benefits, possible complications, and anticipated results of such treatment.

Code of Professional Ethics of The American College of Obstetricians and Gynecologists, reprinted as Appendix A in ACOG's GUIDELINES FOR WOMEN'S HEALTH CARE[:] A RESOURCE MANUAL 455 (3d ed. 2007). Of course, a physician (or other health care provider) has no way of determining whether a patient understands the information that has been conveyed to her without talking with her, either in person or in a live, inter-active conversation over the telephone.

ACOG notes that it is the responsibility of the health care practitioner to secure the patient's informed consent. GUIDELINES FOR WOMEN'S HEALTH CARE at 125. That responsibility entails, among other things, that the "risks and benefits of and alternative to the proposed procedure, test, or treatment . . . be *discussed* with the patient," which "discussions" should be "documented appropriately in the patient's medical record." *Id.* (emphasis added). This is a matter of basic medical ethics. "Informed consent," ACOG explains, "is the willing and uncoerced acceptance of a medical intervention by a patient after appropriate disclosure by the clinician of the nature of the intervention and its risks and benefits as well as the risks and benefits of alternatives." *Id.* at 80. "The primary purpose of the consent process is the exercise of patient autonomy," which includes not only the right to make a decision to accept treatment, but also to refuse treatment. *Id.* "[T]he health care professional enables the patient to exercise personal choice" by "encouraging *ongoing and open communication* about relevant information . . . ." *Id.* at 80-81 (emphasis added). "This sort of communication," ACOG stresses, "is central to the patient-clinician relationship." *Id.* at 81. One-way "communication," however, is not the kind of communication envisioned by ACOG. For example, "[a]t times, a patient's capacity to comprehend and process the medical information presented to her may be in doubt." *Id.* In such cases, "the health care professional, through consultation and further discussion with the patient, should attempt to clarify and improve the patient's ability to provide consent." *Id.* Needless to say, a patient's capacity "to comprehend and process the medical information presented to her" cannot be determined by either a pre-recorded telephone message or a one-way "conference call." ACOG emphasizes that "informed consent is a *process*," which is not synonymous "with the informed consent forms used to document that the informed consent process has taken place." *Id.* (emphasis added).

In August 2009, ACOG's Committee on Ethics issued its most recent opinion on informed consent. The abstract of the opinion states that, "[a]s an ethical doctrine, informed consent is a *process of communication* whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care." ACOG Committee Opinion, No. 439 (August 2009), *Informed Consent* (Committee on Ethics) (emphasis added). The Committee on Ethics affirms eight statements regarding informed consent, two of which are particularly relevant to the issue at hand. First, "[*c*]*ommunication is necessary* if informed consent is to be realized, and physicians can and should help to find ways *to facilitate communication* . . . in individual relations with patients . . . ." *Informed Consent* at 1 (emphasis added). Second, "[i]nformed consent should be looked on *as a process* rather than a signature on a form. *This process includes a mutual sharing of information over time between the clinician and the patient to facilitate the patient's autonomy in the process of making ongoing choices.*" *Id.* (emphasis added).[5] "The ethical concept of 'informed consent,' contains two major elements: 1) comprehension (or understanding) and 2) free consent." *Id.* at 2. To ensure that the element of comprehension (understanding) is satisfied, a proper view of informed consent "posits *a dialogue between patient and health care provider* in support of respect for patient autonomy." *Id.* at 4 (emphasis added). To ensure that the element of free consent is satisfied, which includes "freedom from ignorance," there must be a "disclosure of information and *a sharing of interpretations of its meaning by a medical professional.*" *Id.* at 5 (emphasis added).

The Committee on Ethics emphasizes that "communication between physician and patient" is "central" to obtaining informed consent. *Informed Consent* at 6. The focus on communication "underline[s] the fact that informed consent involves *a process*," "a process of communication that leads to initial consent (or refusal to consent) and that can make possible appropriate ongoing decision making." *Id.* (emphasis added). "[T]he ethical requirement to obtain informed consent, no less than a requirement for good medical care, extends to a requirement for reasonable communication." *Id.*[6]

In an earlier opinion, ACOG's Committee on Ethics stated that the "primary purpose" of the consent process "is to protect patient autonomy. By encouraging *an ongoing and open communication of relevant information* (adequate disclosure), the physician enables the patient to

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[5] "A signed consent document . . . does not ensure that the process of informed consent has taken place in a meaningful way or that the ethical requirements have been met." *Id.* at 2.

[6] In an earlier opinion, the Committee on Ethics recognized "[p]atient autonomy and the concept of informed consent or refusal" as "central" to issues regarding the patient's choice to have or not to have a surgical procedure." ACOG Committee Opinion, No. 395 (January 2008), *Surgery and Patient Choice* (Committee on Ethics) at 1-2. It is the obstetrician-gynecologist's responsibility "to fully inform the patient regarding treatment options and the potential risks and benefits of those options," and to "*discuss*[] these options" with her. *Id.* at 2 (emphasis added). Although the Committee was focusing on issues related to surgery, it noted that "the ethical principles are the same as for other health care decisions" including "medical therapy." *Id.* at 1. Accordingly, the same requirements of full disclosure and a thorough discussion of the treatment options and their potential risks and benefits apply to medical, as well as surgical, abortions.

exercise personal choice. This sort of communication is central to a satisfactory physician-patient relationship." ACOG Committee Opinion, No. 390 (December 2007), *Ethical Decision Making in Obstetrics and Gynecology* (Committee on Ethics) at 5 (emphasis added). There is no "ongoing and open communication of relevant information" when a provider relies upon a pre-recorded telephone message (or a one-way "conference call") to provide informed consent. The Committee emphasized that "[o]ne of the most important elements of informed consent is the patient's capacity to understand the nature of her condition and the benefits and risks of the treatment that is recommended as well as those of the alternative treatments." *Id.* at 6. "A patient's capacity to understand," however, "depends on her maturity, state of consciousness, mental acuity, education, cultural background, native language, the opportunity and willingness to ask questions, and the way in which the information is presented." *Id.* It goes without saying that a provider cannot assess a patient's "capacity to understand," much less answer questions the patient may have, when he or she relies upon a pre-recorded telephone message or a one-way "conference call" in which the caller cannot participate.

National Abortion Federation

The National Abortion Federation (NAF) describes itself as "the professional association of abortion providers in the United States and Canada," whose "mission" is "to ensure safe, legal, and accessible abortion care to promote health and justice for women." NAF *2009 Clinical Policy Guidelines* (title page). In their *2009 Clinical Policy Guidelines*, NAF states that the "goal" of informed consent "is to assure that the woman's decision is voluntary and informed, and to obtain legal permission for an abortion." *Guidelines* at 3. To that end, NAF requires its members to adhere to two standards: First, "[t]he clinician must ensure that accurate information is provided regarding the risks, benefits, and possible complications of abortion." Second, "[t]here must be documentation that the patient affirms that she understands the procedure and its alternatives; the potential risks, benefits, and possible complications; that her decision is uncoerced; and that she is prepared to have an abortion." *Id.* Needless to say, neither a pre-recorded presentation of "the risks, benefits, and possible complications of abortion" nor a one-way "conference call" in which such information is presented can "assure that the woman's decision is voluntary," that "she understands the procedure and its alternatives," its "potential risks, benefits, and possible complications," that "her decision is uncoerced," or that "she is prepared to have an abortion." Although NAF's policy guidelines propose, as an option, that the informed consent information "may be provided either on an individual basis or in group sessions," *id.*, they do not authorize or even mention providing informed consent via a pre-recorded telephone message or a one-way "conference call."

In addition to its policy guidelines, which are updated from time to time, NAF has recently published a text authored by Maureen Paul, M.D., and five other abortion providers, entitled MANAGEMENT OF UNINTENDED AND ABNORMAL PREGNANCY[:] COMPREHENSIVE ABORTION CARE (Wiley-Blackwell 2009). In the chapter dealing with informed consent, patient education and counseling (Ch. 5), the authors stress that "[p]roviding proficient patient education and informed consent protects both the provider and the patient," that "[e]ffective communication between provider and patient helps to optimize the outcome of the procedure," and that "[t]he patient's history, circumstances, and feelings may need exploration and counseling intervention for adequate decision-making, acceptance, and management of the

procedure, as well as coping afterwards." COMPREHENSIVE ABORTION CARE at 48. With a pre-recorded telephone message or a one-way "conference call," there is no opportunity for the "communication" that is essential to obtaining a patient's informed consent, much less of "explor[ing]" the patient's "history, circumstances, and feelings . . . ." In the first paragraph of the introduction to the chapter, the authors note that some women considering an abortion "may wish to explore their options more fully and obtain help in making a decision." *Id.* Once again, there is no possibility of "explor[ing]" options with a pre-recorded telephone message or in a one-way "conference call."

NAF stipulates that abortion providers "may designate trained staff members to obtain informed consent from patients, except where law mandates *clinicians only* may conduct the informed consent process." COMPREHENSIVE ABORTION CARE at 49 (emphasis in original). What is important to emphasize here is that obtaining informed consent is a *process*, which includes "providing the patient with the information she needs in order to make a voluntary, informed decision about her pregnancy options and, if she chooses abortion, about the methods of abortion available to her,"[7] and "*answering the patient's questions*, such as those pertaining to how the procedure is performed, the length of time required, and issues of pain and safety." *Id.* Emphasis added.[8] Neither a pre-recorded telephone message nor a one-way "conference call" can "answer[] the patient's questions." NAF recognizes that informed consent information may be communicated in various ways ("written material, verbal instructions, or audiovisual media"), but, significantly, it does not propose or suggest that such information may be communicated via a pre-recorded message or a one-way "conference call." *Id.* In itemizing the "elements of informed consent," NAF listed, among other things, the "voluntary nature of the patient's decision," and "her understanding of the [informed consent] forms," *id.* at 50 (Table 5.1, fourth and twelfth points), neither of which can be confirmed via a pre-recorded message or a one-way "conference call." "Obtaining informed consent, addressing the contraceptive needs of women, and attending to any emotional needs that may arise are essential to providing high-quality abortion care," and require "[t]he use of effective communication skills and needs assessment to discern patients' concerns . . . " *Id.* at 61. Without a two-way conversation, however, there is no "effective communication" and no opportunity to "discern patients' concerns."

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[7] According to NAF, "the patient must acknowledge" "the options of parenting or making an adoption plan." COMPREHENSIVE ABORTION CARE at 49.

[8] The need to be able to answer a woman's questions exists regardless of the method of abortion that is chosen–surgical or medical. "Giving women an informed choice in the method of abortion" requires staff to provide "written and verbal instructions about the process," and "adequate time to present the realities of the process, *answer questions*, and address emotional concerns." *Id.* at 60 (emphasis added). In a chapter addressing medical abortion (Ch. 9), NAF stated that it was important to "[*d*]*iscuss* the decision to have an abortion and confirm that it is certain and voluntary," and "[*d*]*iscuss* the treatment alternatives (medical abortion or aspiration) and the benefits and risks of each method." *Id.* at 124 (Table 9.4, points 1, 2) (emphasis added). It is impossible to have a "discussion" with a recording or a one-way "conference call."

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

In October 1982, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued a report on the ethical and legal implications of informed consent in the patient-practitioner relationship, entitled *Making Health Care Decisions*. The Commission concluded that "ethically valid consent" is "a process of shared decisionmaking based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risk of particular treatments." *Making Health Care Decisions* at 2 (University of Michigan reprint of report). Such decisionmaking envisions "appropriate discussion" between physician and patient, and contemplates a "dialogue," *not* a "monologue." *Id.* at 5, 30, 38, 69, 70, 71, 74, 76. "The professional's goal," the report states, "should be a tactful discussion, sensitive to the needs, intellectual capabilities, and emotional state of the particular patient at the time, in terms that the patient can understand, assimilate, and work with as part of the ongoing decisionmaking process." *Id.* at 71. A health care professional has an obligation "to provide each patient with a basis for effective participation in decision-making about his or her own health care." *Id.* at 113. "This obligation," the report explained, "entails providing information, answering questions, talking over options and doubts, and helping patients to clarify the values and goals relevant to the decision. Such discussion serves to enhance patients' competence and hence the likelihood that the course of action selected represents the patient's voluntary choice." *Id.* Needless to say, a physician is not able to "answer[] questions," "talk[] over options and doubts" or "help[] patients to clarify the values and goals relevant to the decision" when he relies upon a pre-recorded informed consent message or a one-way "conference call" in which the callers (the prospective patients) are not able to "participate, only listen."

Medical Ethics Texts

A leading text on medical ethics notes that "[l]egal, regulatory, philosophical, medical, and psychological literatures tend to favor the following elements as the components of informed consent: (1) competence, (2) disclosure, (3) understanding, (4) voluntariness, and (5) consent." Tom L. Beauchamp and James F. Childress, PRINCIPLES OF BIOMEDICAL ETHICS 120 (6th ed. 2009) (Oxford University Press). Because of the "wide variation" patients exhibit "in their understanding of information about diagnoses, procedures, risks, probable benefits, and prognoses." and the need to ensure that a patient's decision represents her free, uncoerced and informed choice, it is essential that physicians "probe for and ensure understanding and voluntariness." *Id.* at 104, 120. Of course, it is impossible to "probe for and ensure understanding and voluntariness" through the use of a pre-recorded informed consent message or a one-way "conference call" in which the callers are unable to participate.

An earlier, well known text on medical ethics explained why "effective communication" between physician and patient is crucial in determining whether consent is truly informed:

> First, insofar as professionals are frequently the primary source of information available to patients . . . , it is critical that the latter be able to understand *what* the professional is saying, both in the core disclosure and in the professional's response to questions. Second, even if the . . . patient's general understanding of the situation does not depend heavily on the professional's disclosure, unless the professional is understood, there is no guarantee that the parties have the same intervention in mind–the "shared understanding" just described. Finally, unless the professional understands messages from the patient . . . , the professional cannot provide satisfactory responses to questions, and thus the patient . . . is unlikely to obtain the information needed to make a substantially autonomous choice. Unless the professional understands the patient . . . , it would also be difficult to identify and help modify false beliefs and confusions.

Ruth R. Faden and Tom L. Beauchamp, A HISTORY AND THEORY OF INFORMED CONSENT 314 (1986) (Oxford University Press) (emphasis in original). Thus, "the adequacy of a . . . patient's understanding may ultimately depend both on the adequacy of the person's understanding of disclosed information and on the adequacy of the professional's grasp of the person's questions and responses." *Id* at 316. With the use of a pre-recorded informed consent message (or a one-way "conference call") there is no opportunity for physician and patient to come to a "shared understanding," much less for the physician to answer the patient's questions or evaluate her level of understanding of the information that has been conveyed.

Conclusion

In light of the foregoing authorities, it is apparent that, properly understood, informed consent is *a process of communication* that requires a physician not only to impart information to a patient, but also to ensure that the patient *understands* what has been communicated and that she has been afforded an opportunity to have her *questions answered* and her *concerns addressed*. The process, in other words, calls for a *dialogue*, not a *monologue*. Given the legal and ethical consensus as to what informed consent is (and, equally important, what it is not), DSHS's interpretation of Texas law, allowing informed consent to be provided via a pre-recorded telephone message (or a "live" conference call in which the callers are "not able to participate, only listen") is unreasonable and indefensible. It is, therefore, not surprising that in the only reported case to date to discuss the issue, a federal district court held unequivocally that the use of a pre-recorded informed consent message does *not* comply with the ethics of the medical profession.

In *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 744 F. Supp. 1323 (E.D. Pa. 1990), *aff'd in part, rev'd in part*, 947 F.2d 682 (3d Cir. 1991), *aff'd*, 505 U.S. 833 (1992), the federal district court determined that, "[a]s a general rule, informed consent requires communications between the doctor or counselor and the patient to assure that the patient has made a treatment choice based upon knowledge of his or her condition, the benefits and risks of a particular treatment and its alternatives. In order to be informed, consent must be made voluntarily and competently." 744 F. Supp. at 1351.

> Although the informed consent dialogue may be brief . . . , personal contact between the patient and the person rendering the informed consent is essential. The physician's or counselor's observation of the person's demeanor and reactions to medical information provided is essential to permit the physician or counselor to determine whether the patient is competent to give informed consent and whether the patient fully understood the information imparted during the dialogue. Further, personal contact is necessary to determine whether the patient is under duress from extrinsic sources while providing informed consent. Even defendants' expert witness testified that telephone informed consent could only be justified, if subsequent face-to-face contact occurs.

Id. (citations to trial testimony omitted).

Apropos of the issue, which is the subject of this opinion request, the district court in *Casey* found that "[a] patient's informed consent cannot be obtained *through the use of a tape recorded message* or printed materials." *Id.* (citing trial testimony) (emphasis added). Nor, for that matter, may it be obtained through a one-way "conference call" with multiple patients.[9]

The Department's interpretation of TEX. HEALTH & SAFETY CODE § 171.012(b)(1) is not supported by the language of the statute itself, is inconsistent with common law informed consent principles and violates all recognized standards of medical ethics. There is a presumption that, in enacting a statute, "a just and reasonable result is intended." GOV'T CODE § 311.021(3). The Department's interpretation of HEALTH & SAFETY CODE § 171.012(b)(1) is neither "just" nor "reasonable." Accordingly, it should be repudiated.

Sincerely,

[9] There is a sequel to the *Casey* litigation that should be mentioned. It is my understanding that, following the Supreme Court decision in *Casey* in June 1992, several abortion providers in the Commonwealth began using pre-recorded informed consent messages. The State Board of Health notified these providers that the use of pre-recorded messages did *not* comply with the requirements of the informed consent statute that had been upheld by the Supreme Court. It is my further understanding that the Pennsylvania Medical Society issued a statement that the use of pre-recorded informed consent messages did not comport with the ethics of the medical profession.