RAISING THE STANDARD OF ABORTION INFORMED CONSENT: LESSONS TO BE LEARNED FROM THE ETHICAL AND LEGAL REQUIREMENTS FOR CONSENT TO MEDICAL EXPERIMENTATION

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INTRODUCTION

In the aftermath of *Planned Parenthood of Southeastern Pennsylvania v. Casey*,[1] state legislatures have restricted access to abortions by regulating the informed consent process. Taking as an invitation the Court's holding that a state is permitted "to further its legitimate goal of protecting the life of the unborn by enacting legislation aimed at ensuring a decision that is mature and informed, even when in so doing the State expresses a preference for childbirth over abortion,"[2] states began to legally mandate specific required disclosures, language, or procedures for obtaining informed consent to abortions. While all states require informed consent before medical procedures either by statute or by case law, the details of the process have traditionally been self-regulated by the medical profession through medical ethics.[3] Currently, thirty-four states have

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[1] Planned Parenthood of Southeast Pennsylvania v. Casey, 505 U.S. 833 (1992).

[2] *Id.* at 883.

[3] Rachel Benson Gold & Elizabeth Nash, *State Abortion Counseling Policies and the Fundamental Principles of Informed Consent*, 10 GUTTMACHER POL'Y REV. 6, 7 (2007), *available at* http://www.guttmacher.org/pubs/gpr/10/4/gpr100406.pdf.

abortion-specific informed consent statutes.[4] However, these statutes mandate disclosures of information that not only go beyond what is required for other medical procedures, but also include information that is inaccurate, incomplete, or irrelevant to the particular abortion procedure to be performed. Thus, states, under the shield of the *Casey* decision, have used abortion informed consent statutes to express their preference for childbirth over abortion in a way that serves to unduly influence a woman's choice, in violation of the ethical boundaries of medical informed consent.

Under general informed consent principles, abortion providers must disclose information typically required for other medical procedures: the nature and type of the abortion procedure, the risks and consequences of the abortion procedure, alternatives to abortion, and the risks and consequences of not having the procedure, i.e. continuing the pregnancy.[5] The rationale behind these disclosures is to "protect autonomous choice," that is, to ensure the patient's self-determination of whether to undergo a particular medical procedure.[6] However, despite the growing number of state-required disclosures on the risks of the abortion procedure, only twenty-eight states explicitly require physicians to disclose the risks of continuing the pregnancy.[7] This suggests that states are stating their preference for childbirth over abortion but not ensuring that women make a fully informed decision.

Indeed, twenty-four of the thirty-four states with abortion-specific informed consent requirements mandate disclosures of information that go beyond what would be required by medical ethics and general medical informed consent laws and thus do

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[4] GUTTMACHER INST., STATE POLICIES IN BRIEF: COUNSELING AND WAITING PERIODS FOR ABORTION 1 (2010), *available at* http://www.guttmacher.org/statecenter/spibs/spib_MWPA.pdf [hereinafter GUTTMACHER COUNSELING].

[5] Gold & Nash, *supra* note 3, at 7.

[6] TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 118 (6th ed. 2009).

[7] GUTTMACHER COUNSELING, *supra* note 4, at 3.

not aid the informed consent process.[8] Despite these additional requirements for abortion informed consent, equal protection challenges brought by providers on the grounds that the abortion procedure is being treated unequally, as compared with other medical procedures, have generally been unsuccessful.[9] Further, under *Casey,* a state's regulation of the abortion informed consent procedure by requiring disclosures of certain information is permissible if the information is "truthful and not misleading."[10] However, these more detailed abortion informed consent statutes require providers to disclose information about risks of abortion that is inaccurate, incomplete, or irrelevant to the particular abortion procedure that the patient will undergo—for example, mandated disclosures that abortion will increase the woman's risk of depression and suicide, or disclosures about fetal anatomy and pain beyond the gestational stage of the woman's own pregnancy.[11]

These disclosures violate patient autonomy through what bioethicists Tom Beauchamp and James Childress call "informational manipulation."[12] Informational manipulation is a "deliberate act of managing information that nonpersuasively alters a person's understanding of a situation and motivates him

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[8] *See* Jeffrey A. Van Detta, *Constitutionalizing* Roe, Casey, *and* Carhart: *A Legislative Due-Process Anti-Discrimination Principle that Gives Constitutional Content to the "Undue Burden" Standard of Review Applied to Abortion Control Legislation*, 10 S. CAL. REV. L. & WOMEN'S STUD. 211, 257–61 (2001) (describing how the informed consent requirements for abortions go beyond that which is required for other medical procedures and essentially "morally Mirandize" the woman).

[9] Christine L. Raffaele, Annotation, *Validity of State "Informed Consent" Statutes by Which Providers of Abortions Are Required to Provide Patient Seeking Abortion with Certain Information*, 119 A.L.R. 5th 315, § 2 (2004). *But see* Freiman v. Ashcroft, 584 F.2d 247, 251–52 (8th Cir. 1978) (holding that a Missouri statute requiring physicians to disclose that infants born alive will become wards of the state is a "violation of the equal protection clause of the Fourteenth Amendment inasmuch as it singles out the abortion operation for the imposition of this 'straitjacket' requirement").

[10] *Casey*, 505 U.S. at 882 (1992).

[11] GUTTMACHER COUNSELING, *supra* note 4, at 2–3.

[12] BEAUCHAMP & CHILDRESS, *supra* note 6, at 134.

or her to do what the agent of influence intends."[13] Beauchamp and Childress assert that "many forms of informational manipulation are incompatible with autonomous decision-making," listing as examples, "withholding information and misleading exaggeration with the intent to lead persons to believe what is false."[14] Thus, while supposedly required in order to ensure informed consent, many of the abortion disclosure requirements in fact block informed consent by preventing autonomous decision-making.

Perhaps the broadest development of codified guidelines and regulations to prevent such information manipulation of informed consent has occurred in the area of medical experimentation. The informed consent requirements for medical experimentation arose as a reaction to the abuses of the Nazi doctors who conducted medical experiments on concentration camp victims, as well as to abuses by public health officials and investigators in this country during the Tuskegee syphilis study, in which treatment was withheld from African American men with syphilis who were misled into believing they were in fact receiving treatment.[15] As Berg et al. characterize the development, "informed consent was seen as a protection from abuse by untrustworthy professionals."[16]

From the inception of medical ethics with the post-Nazi trial Nuremberg Code, the principles of informed consent have been reiterated in numerous federal statutes and regulations, as well as in international professional codes and human rights instruments. Broadly, they require an autonomous decision

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[13] *Id.*

[14] *Id.*

[15] *See* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION (George J. Annas & Michael A. Grodin eds., 1992); FRANK D. GRAY, THE TUSKEGEE SYPHILIS STUDY: THE REAL STORY AND BEYOND (1998).

[16] JESSICA W. BERG ET AL., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE 20 (2d ed. 2001).

without coercion or manipulation.[17] To that end, they require disclosures of possible risks of the experiment. Indeed, consent in research was originally premised on the "very notion that makes research distinct, namely the risk of the unknown."[18] These uncertainties include, for example, whether a particular treatment will be proven efficacious, whether the experiment will actually benefit science and society, and whether there may be unforeseen risks to the subject. Furthermore, the requirements seek to protect the individual's interests from the competing interests of the state, science, and society.[19]

The circumstances surrounding abortion are similar to those of medical experimentation. Abortion also includes uncertainties that go beyond the philosophical question of whether the fetus is a human being. Due to the challenge of finding proper control groups against which to compare abortion patients, there is a dearth of methodologically sound studies that confirm the actual risks of abortion. In addition, and equally important, is that both medical experimentation and abortion involve interests that compete against the patient's interests in autonomy, the self-determination of her well-being, and bodily integrity. In medical experimentation, there exist the interests of investigators in contributing to scientific knowledge, as well as the interests of the state and society in gaining not only new

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[17] *See* Nuremberg Code ¶ 1 (1947) [hereinafter Nuremberg], *available at* http://ohsr.od.nih.gov/guidelines/nuremberg.html; World Med. Ass'n Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects ¶ 22 (2008) [hereinafter Helsinki], *available at* http://www.wma.net/en/30publications/10policies/b3/index.html; COUNCIL FOR INT'L ORGS. OF MED. SCI., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 32 (2002) [hereinafter CIOMS GUIDELINES], *available at* http://www.cioms.ch/publications/layout_guide2002.pdf; Oviedo Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine art 5., E.T.S. No. 164 (entered into force Jan. 12, 1999) [hereinafter Oviedo Convention], *available at* http://www.univie.ac.at/ierm/php/Dokumente/Oviedo-%DCb-E.pdf; Universal Declaration on Bioethics and Human Rights, UNESCO 33 C/Res. 24, arts. 5–6 (October 19, 2005) [hereinafter Declaration on Bioethics].

[18] Karine Morin, *The Standard of Disclosure in Human Subject Experimentation*, 19 J. LEGAL MED. 157, 189 (1998).

[19] *See, e.g.*, Declaration on Bioethics, *supra* note 17, at art. 3.2.

knowledge, but also new medical treatments. In abortion, as noted in *Casey*, the state has a competing interest in "protecting the life of the unborn."[20] Given abortion's similarities to medical experimentation, including the danger of informational manipulation, it follows that, as with medical experimentation, heightened protection of the abortion patient from the state's competing interests through and during the informed consent process is necessary.

Based on that premise, this Article argues that when viewed under the ethical and legal requirements for medical experimentation informed consent, the current abortion informed consent case law fails to adequately protect the patient seeking an abortion. Part I will provide an overview of the ethical and legal requirements for medical experimentation informed consent. Part II will discuss the development of the legal requirements for abortion informed consent in the United States and show how current abortion informed consent case law fails to meet the ethical standards of informed consent, based on the ethical requirements for medical experimentation informed consent. Finally, Part III will discuss how current state requirements for abortion informed consent violate ethical informed consent requirements due to the case law's failure to adequately protect the abortion patient from undue state interference.

I. Ethical and Legal Requirements for Informed Consent to Medical Experimentation

A. Professional Ethical Codes

1. The Nuremberg Code

The Nuremberg Code (Nuremberg) is often considered the founding document of the development of international and

[20] *Casey*, 505 U.S. 833, 883 (1992).

national codes on the ethics of human experimentation.[21] Enumerated as part of the judgment against the Nazi doctors in 1947,[22] it was the first international code to establish ethical standards for human experimentation.[23] Nuremberg laid out ten principles, including that subjects give voluntary consent, that the experiment "yield fruitful results for the good of society, unprocurable by other methods," that the experiment "be so conducted as to avoid all unnecessary physical and mental suffering and injury," and that the "degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment."[24] These requirements were based on the ethical principle of the subject's autonomy and self-determination.[25]

It is of little surprise, then, that the first and most detailed principle enumerated in Nuremberg is that of voluntary consent. Nuremberg defines "voluntary consent" as such:

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[21] Sharon Perley et al., *The Nuremberg Code: An International Overview*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 15 at 149, 149 ("The Nuremberg Code has often been cited as one of the leading influences on the subsequent development of international and national codes governing the ethical aspects of research involving human subjects."). *See also id.* at 152 ("A series of international documents were thereafter created whose genesis can be traced to the Nuremberg Code.").

[22] *Id.* at 151 (discussing that the Nuremberg Code was part of the judgment against Nazi doctor Karl Brandt and his co-defendants and that it was based on the testimony of two U.S. doctors).

[23] *Id.* at 150. Perley et al. note that while the Nuremberg Code "raised the consciousness of the global community," there were many national documents establishing ethical standards in human experimentation that preceded Nuremberg. *Id.* at 150, 152.

[24] Nuremberg, *supra* note 17, ¶¶ 1, 2, 4, 6.

[25] *See* Morin, *supra* note18, at 180 ("[T]he theory of self-determination . . . begins with an analysis of the Nuremberg Code"); Jay Katz, *The Consent Principle of the Nuremberg Code: Its Significance Then and Now*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 15 at 227 ("Never before in the history of human experimentation, and never since, has any code or any regulation of research declared in such relentless and uncompromising a fashion that the psychological integrity of research subjects must be protected absolutely.").

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.[26]

Nuremberg then further defines the requirement that the subject have "sufficient knowledge and comprehension" as meaning that the following information should be disclosed to the subject: (1) the "nature, duration, and purpose of the experiment"; (2) the "method and means by which it is to be conducted"; (3) "all inconveniences and hazards reasonably to be expected"; and (4) the "effects upon his health or person which may possibly come from his participation in the experiment.[27] Thus, under Nuremberg, the disclosure of this information is necessary to ensure the subject's self-determination.

Nuremberg also gives guidance on the amount of information that must be disclosed to satisfy the requirement of voluntary consent. It first states that "all inconveniences and hazards *reasonably* to be expected" should be disclosed to the subject.[28] This seems to indicate a standard of less than absolute full disclosure of all risks. However, Nuremberg then includes the required disclosure of "effects upon his health or person which *may possibly come* from his participation in the experiment" without saying more about the degree of probability at which this requirement attaches.[29] In contrast to the previous disclosure of reasonably expected hazards, this required

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[26] Nuremberg, *supra* note 17, ¶ 1.

[27] *Id.*

[28] *Id.* (emphasis added).

[29] *Id.* (emphasis added).

disclosure of health effects seems potentially to require absolute full disclosure of all known risks, regardless of the probability of the risk actually occurring. While commentators have acknowledged Nuremberg's strict standard of requiring absolute voluntary consent in all circumstances,[30] they have not commented on this seeming conflict between requiring disclosure of all reasonably expected risks versus all known risks. Rather, they note that the amount of disclosure required by Nuremberg in the setting of medical experimentation is likely more than that generally required for medical treatment.[31]

In addition to requiring that the investigator ensure the subject holds "sufficient knowledge" by making these enumerated disclosures, Nuremberg also requires that the subject have sufficient "comprehension."[32] Barber points out that this requirement of "sufficient information and comprehension" then leads to the question of what "sufficient" means, and in particular, how courts define it.[33] While Nuremberg's broad mandates leave such questions open, it lays the foundation for informed consent beyond simply requiring the investigator to make known certain information: it also places a duty on the investigator to ensure that the subject understands the implications of the information that is being disclosed to her before making a decision on whether to participate in the experiment Nuremberg's informed consent requirements are thus based on the principle of self-determination.

2. The Declaration of Helsinki

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[30] *See, e.g.*, Perley et al., *supra* note 21, at 155; BERG ET AL., *supra* note 16, at 251(discussing how Nuremberg fails to allow for research with subjects who lack legal capacity).

[31] *See* Morin, *supra* note 18, at 205 (discussing a North Carolina case that acknowledged that the Nuremberg's required disclosure was more than that statutorily required in the state for treatment—"only the usual and most frequent risks").

[32] Nuremberg, *supra* note 17, ¶ 1.

[33] BERNARD BARBER, INFORMED CONSENT IN MEDICAL THERAPY AND RESEARCH 36 (1980).

The next major international professional code on the ethics of human experimentation was the World Medical Association's (WMA) Declaration of Helsinki (Helsinki), which was adopted by the WMA general assembly in 1964 and most recently amended in 2008.[34] What has been considered the most important difference between Nuremberg and Helsinki is that while Nuremberg deals with experimentation only on healthy subjects for the sole purpose of scientific advancement,[35] Helsinki makes a distinction between research on healthy subjects and research on sick subjects who may derive therapeutic benefits from the research, which is often referred to as "therapeutic experimentation."[36] In addition, Helsinki's introduction refers to the WMA's Declaration of Geneva's physician's oath—"The health of my patient will be my first consideration"—as well as the declaration in the WMA's International Code of Medical Ethics—"A physician shall act in the patient's best interest when providing medical care."[37] Hence, Helsinki requires experimenting physicians to uphold another principle in addition to that of the subject's self-determination: the subject's well-being.

Regardless of whether a subject is only a subject or also a patient, Helsinki requires that "[i]n medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests."[38] This implies that no matter how great the potential benefit to the community, a study would never be justified if it infringed on the subject's

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[34] Helsinki, *supra* note 17. The WMA is an international organization that provides ethical guidance to physicians. The WMA's membership consists of national medical associations. The United States is a member through the American Medical Association.

[35] Perley et al., *supra* note 21, at 156.

[36] Helsinki, *supra* note 17, ¶ ¶ 31–35.

[37] *Id.* ¶ 4 (citing Declaration of Geneva and International Code of Medical Ethics, *available at* http://www.wma.net/en/30publications/10policies/c8/index.html). The Declaration of Geneva is considered a "modern restatement of the Hippocratic oath." Perley et al., *supra* note 21, at 154.

[38] Helsinki, *supra* note 17, ¶ 6.

well-being.[39] However, while making the subject's well-being the top priority, Helsinki also acknowledges that "[i]n medical practice and in medical research, most interventions involve risks and burdens."[40] Thus, Helsinki allows for subjects to participate in an experiment even though it may not solely enhance their well-being and may even cause some harm.

Helsinki resolves the tension between the subject's well-being and the inherent risks of all medical treatment and research by prohibiting research on human subjects unless the physician is "confident that the risks involved have been adequately assessed and *can be satisfactorily managed*."[41] As a result, the investigator must not only disclose a potential risk and ensure that the subject has comprehended the implications of the risk, but she must also ensure that she can "satisfactorily" manage the adverse event should it occur. This may also be interpreted to mean that the investigator must take steps to prevent the risk from occurring and have a plan of treatment should the risk in fact occur. Thus, Helsinki handles the uncertainty of the occurrence of certain risks in medical experimentation by requiring confidence in the ability to manage those risks.

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[39] The principle of protecting the well-being of the subject may come in direct conflict with the principle of self-determination in cases where the subject may wish to participate in research despite the harm that she may suffer. *See* Morin, *supra* note 18, at 184–85 (discussing how the principle of self-determination was "compromised severely by the introduction of a second and supposedly equal value in the model, that of well-being" by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research). *See also* BEAUCHAMP & CHILDRESS, *supra* note 6, at 105 ("Respect for autonomy has only prima facie standing, and competing moral considerations sometimes can override this principle . . . . The principle of respect for autonomy does not by itself determine what a person ought to be free to know or do or what counts as a valid justification for constraining autonomy."). *But see* CIOMS GUIDELINES, *supra* note 17, at 48 ("Paragraphs 5 and 18 of the Declaration of Helsinki do not preclude well-informed volunteers, capable of fully appreciating risks and benefits of an investigation, from participating in research for altruistic reasons or for modest remuneration.").

[40] Helsinki, *supra* note 17, ¶ 8.

[41] *Id.* ¶ 20 (emphasis added).

Helsinki also expands the required sources from which investigators must derive knowledge of the risks and benefits of their experiments. Nuremberg states that the "experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment."[42] Helsinki, perhaps in line with the current state of research and the easy access to medical experiment results, not only requires "adequate laboratory and, as appropriate, animal experimentation," it also requires the investigator to possess a "thorough knowledge of the scientific literature."[43] As with the requirement of confidence in managing risks, Helsinki's requirement that the investigator possess thorough knowledge of topics relevant to her study mitigates the inherent uncertainty of risks surrounding medical experimentation.

Finally, in addition to prioritizing the well-being of the subject, Helsinki explicitly states that physicians have a duty to protect a subject's "right to self-determination," consistent with the foundational principle of Nuremberg.[44] To ensure a subject's self-determination, Helsinki requires the disclosure of "potential risks" without further explaining what would be considered such a risk.[45] However, it does state that "[s]pecial attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information."[46] This seems to suggest that the investigator may have some discretion as to what information needs to be disclosed according to individual subjects' needs. While at first glance it may appear that this requirement is less stringent than Nuremberg's requirement of disclosing all "effects upon his

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[42] Nuremberg, *supra* note 17, ¶ 3.

[43] Helsinki, *supra* note 17, ¶ 12.

[44] *Id.* ¶ 11.

[45] *Id.* ¶ 24.

[46] *Id.*

health or person which may possibly come,"[47] it is a standard that requires more attention and effort from the investigator. The goal is to ensure that the "potential subject has understood the information."[48] Thus, Helsinki builds on Nuremberg's requirements of disclosure of information and assurance of subject comprehension by requiring the investigator to tailor the disclosure and content of the disclosure according to the particular subject's needs.

Helsinki expands the requirements of Nuremberg. Under Helsinki, in addition to upholding the principle of subject autonomy and self-determination, the investigator is to ensure the well-being of the subject. Furthermore, the investigator is expected not only to disclose potential risks but also to be confident in her ability to manage the risks satisfactorily. The investigator must also have thorough knowledge of the scientific literature relevant to her study. And finally, the informed consent process and the information disclosed must be individually tailored to each subject's needs. Through adequate scientific knowledge, the ability to manage risks, and holding central the subject's well-being and self-determination, Helsinki manages the uncertainty of outcome in medical experimentation.

3. The CIOMS Guidelines

The third major professional code for ethical human experimentation is the International Ethical Guidelines for Biomedical Research Involving Human Subjects ("CIOMS Guidelines"), issued in 1982 by the Council for International Organizations of Medical Sciences ("CIOMS"), in collaboration with the World Health Organization ("WHO") and currently in

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[47] Nuremberg, *supra* note 17, ¶ 1. *See infra* Part III for further discussion on tailoring informed consent disclosures to individual subjects' needs, a framework that has been called the "subjective standard" of informed consent.

[48] Helsinki, *supra* note 17, ¶ 24.

its third edition.[49] The CIOMS Guidelines are based on three ethical principles: respect for persons, beneficence, and justice.[50] They define "respect for persons" as a "respect for autonomy."[51] Beneficence, in turn, "refers to the ethical obligation to maximize benefits and minimize harms."[52] Finally, justice "refers to the ethical obligation to treat each person in accordance with what is morally right and proper, to give each person what is due to him or her" and, with respect to human experimentation, refers primarily to distributive justice—that is, "equitable distribution of both the burdens and the benefits of participation in research" among various populations.[53] Built upon these three basic ethical principles, there are twenty-one CIOMS guidelines for human experimentation.

The CIOMS Guidelines build on the ethical foundations laid by Nuremberg and Helsinki. With respect to informed consent, they state, "Informed consent is a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision *without having been subjected to coercion, undue influence or inducement, or intimidation*."[54] As with Nuremberg and Helsinki, the CIOMS Guidelines are based on the principle of self-determination, as evidenced by the statement, "Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research. Informed consent protects the

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[49] CIOMS GUIDELINES, *supra* note 17. CIOMS is an international, non-governmental, non-profit organization, established jointly by the World Health Organization (WHO) and the U.N. Educational, Scientific and Cultural Organization (UNESCO) in 1949, that aims to facilitate international biomedical scientific activities. CIOMS, *What is CIOMS?*, *available at* http://www.medauthor.com/docs/CIOMS.pdf (last visited July 12, 2011).

[50] CIOMS GUIDELINES, *supra* note 17, at 17.

[51] *Id.*

[52] *Id.*

[53] *Id.*

[54] *Id.* at 32 (emphasis added).

individual's freedom of choice and respects the individual's autonomy."[55]

With regard to what risks must be disclosed, Guideline 5 calls for the disclosure of "any foreseeable risks."[56] While Nuremberg and Helsinki do not fully address what risks should be disclosed—that is, all possible risks versus only those risks that are reasonably anticipated—the CIOMS Guidelines more explicitly explain what disclosures are required. They state that the investigator must discuss "known risks and possible hazards," seeming to suggest at first glance, as with Helsinki, that not only reasonably expected risks may be required to be disclosed but also any other possible, though uncertain, risks.[57] However, the CIOMS Guidelines then state, "In complex research projects it may be neither feasible nor desirable to inform prospective participants fully about every possible risk. They must, however, be informed of all risks that a '*reasonable person*' would consider *material* to making a decision about whether to participate . . . ."[58] Thus, not only must any foreseeable risk be disclosed under Guideline 5, in determining what other risks among all possible risks must be disclosed, the CIOMS Guidelines adopt a "reasonable person's materiality" standard.

In addition, the CIOMS Guidelines, as with Nuremberg and Helsinki, require that the research be based on adequate scientific knowledge. Guideline 1 states, "Moreover, because scientifically invalid research is unethical in that it exposes research subjects to risks without possible benefit, investigators and sponsors must ensure that proposed studies involving human subjects conform to generally accepted scientific principles and are based on adequate knowledge of the pertinent scientific literature."[59] Presumably this would mean that not only must the

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[55] *Id.* at 33.

[56] CIOMS GUIDELINES, at 38.

[57] *Id.* at 43.

[58] *Id.* (emphasis added).

[59] *Id.* at 23.

design of the study itself be scientifically sound, but also the determination of risks, which is an equally important part of a study, must be based on those "generally accepted scientific principles," as well as knowledge of the scientific literature. Thus, a determination of what would be a risk for a study depends not merely on the existence of a suggestion of a risk in the literature but also on a scientifically sound evaluation of the applicability to the study at hand.

Furthermore, the CIOMS Guidelines shed light on not only which risks must be disclosed but also what information about the risks must be provided. The Preamble states that investigators are required to disclose to an ethics committee prior to conducting a study both the "nature and *degree* of any known risks."[60] It seems likely that if such a disclosure is required to be given to a committee who will be deciding whether the study is safe enough to be conducted in the first place, a similar disclosure would be required to be made to the actual individual who will be taking on the potential risk. Thus, the CIOMS recognizes that in disclosing a possible risk, the magnitude of the harm and the likelihood of occurrence of that harm must also be disclosed.[61]

In line with Helsinki, the CIOMS Guidelines also emphasize the form of communication as being essential to the subject's comprehension.[62] The commentary to Guideline 4—the requirement for voluntary informed consent—states:

> Informing the individual subject must not be simply a ritual recitation of the contents of a written document. Rather, the investigator must convey the information, whether orally or in writing, in language that suits the individual's level of understanding. The investigator must bear in mind that the

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[60] *Id.* at 21 (emphasis added).

[61] *See* Morin, *supra* note 18, at 13; BARBER, *supra* note 33, at 3 ("When we speak of the risk-benefit ratios . . . we are referring to the two dimensions of *amount* and *probability* of injury . . . ").

[62] CIOMS GUIDELINES, *supra* note 17, at 23.

> prospective subject's ability to understand the information necessary to give informed consent depends on that individual's maturity, intelligence, education and belief system. It depends also on the investigator's ability and willingness to communicate with patience and sensitivity.[63]

The CIOMS Guidelines also explicitly recognize that the ability to give adequate informed consent may be limited in those who are "unfamiliar with medical concepts and technology."[64] The remedy for this, however, is not the provision of more information and explanations to the subject but rather the independent review of the risks and benefits by an ethical review committee.[65]

The CIOMS Guidelines enumerate the obligations of investigators in much greater detail than Nuremberg and Helsinki. In particular, CIOMS Guideline 6 imposes a duty to "refrain from unjustified deception, undue influence, or intimidation" and to "seek consent only after ascertaining that the prospective adequate understanding of the relevant facts and of the consequences of participation . . . ."[66] With respect to the prohibition on undue influence, the CIOMS Guidelines state that the investigator must give "no unjustifiable assurances about the benefits, risks, or inconveniences of the research."[67] They also caution, "The borderline between justifiable persuasion and undue influence is imprecise, however."[68] Thus, the information

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[63] *Id.*

[64] *Id.* at 35.

[65] *Id.* at 24. The ethical review committee is to be comprised of scientific experts, both physicians and non-physician scientists, as well as other professionals—nurses, lawyers, ethicists, clergy—and lay persons "qualified to represent the cultural and moral values of the community and to ensure that the rights of the research subjects will be respected." *Id.* at 24–30.

[66] *Id.* at 40.

[67] CIOMS GUIDELINES, *supra* note 17, at 42.

[68] *Id.*

that the investigator discloses to the subject and the manner in which she does so must not only be truthful but also must not mislead and must not serve to unduly influence the subject's decision.

Thus, the CIOMS Guidelines build on the requirements of Nuremberg and Helsinki. They reiterate the principles of protecting a subject's well-being and autonomy. In addition, the CIOMS Guidelines add new considerations. First, while any foreseeable risks must be disclosed, in determining which among the universe of possible, but not foreseeable risks must also be disclosed, the investigator should apply a "reasonable person's materiality" standard. Second, the study design, including the determination of risks, must be based not only on a thorough knowledge of the scientific literature, but also on generally accepted scientific principles. Third, both the nature and the degree of the risk must be disclosed. Finally, a subject must not be deceived, misled, or unduly influenced by the information presented by the investigator.

B. International Human Rights Instruments on Bioethics

The Nuremberg Code, the Declaration of Helsinki, and the CIOMS Guidelines are professional codes that have been adopted by international professional organizations. This limits the impact of these codes in that they are not in themselves enforceable in courts of law.[69] Furthermore, as professional codes, they target the investigators and physicians themselves,

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[69] *See* Perley et al., *supra* note 21, at 160 (discussing how neither the Nuremberg Code nor the Declaration of Helsinki are binding legal authority and that the principles stated in the codes therefore need to be included in national legislation or international documents with binding authority to be enforceable in courts of law). But George J. Annas et al., in INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA 8 (1977), states:

> While disputed as international law by some, [the Nuremberg Code's] adoption by the United Nations General Assembly on December 11, 1946, and its use as a basis for other international documents, such as the Declaration of Helsinki . . . lead to the almost inescapable conclusion that the decision is properly viewed as part of international customary or common law.

not states. However, recently international human rights instruments on bioethics have begun to be developed, pushing these principles, which are already widely accepted in the scientific and medical arenas, more visibly into the international legal arena.

As yet, there are no universal treaties on the bioethics of human experimentation. The United Nations Educational, Scientific and Cultural Organization has, however, promulgated a non-binding Universal Declaration on Bioethics and Human Rights (Declaration on Bioethics).[70] The influence of the professional codes is apparent. First, the declaration establishes the principle of autonomy, stating, "The autonomy of persons to make decisions, while taking responsibility for those decisions and respecting the autonomy of others, is to be respected."[71] Furthermore, the "interests and welfare of the individual should have priority over the sole interest of science or society."[72] Thus, as with the professional codes, the protection of the individual's autonomy and well-being are core principles of the Declaration on Bioethics.

In addition, the Declaration on Bioethics calls for the promotion of transparency and sound scientific basis in ethical decision-making and "in particular declarations of all conflicts of interest and appropriate sharing of knowledge. Every endeavour should be made to use the best available scientific knowledge and methodology in addressing and periodically reviewing bioethical issues."[73] And in regard to informed consent, it requires that for scientific research, the information should be "adequate" and "provided in comprehensible form."[74] Interestingly, however, other than the requirement of providing the subject with adequate information, the Declaration on Bioethics does not explicitly address the disclosure of risks.

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[70] Declaration on Bioethics, *supra* note 17.

[71] *Id.* at art. 5.

[72] *Id.* at art. 3.2.

[73] *Id.* at art. 18.1.

[74] *Id.* at art. 6.2.

While the Declaration on Bioethics is non-binding, the Council of Europe has promulgated a binding human rights treaty on bioethics: the Convention on Human Rights and Biomedicine ("Oviedo Convention").[75] While this instrument does not hold legal force in the United States, it does show which points of the Declaration on Bioethics and the professional codes were deemed of sufficient importance to warrant being mandated by law. The principle of autonomy found in the professional codes is present in the Oviedo Convention's requirement that parties to the convention "guarantee everyone, without discrimination, respect for their integrity . . . ."[76] As with the Declaration on Bioethics, the Oviedo Convention also prioritizes the subject's well-being, stating, "The interests and welfare of the human being shall prevail over the sole interest of society or science."[77] Furthermore, informed consent is required before human experimentation,[78] and the "person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks."[79] Other than requiring that the risk disclosure be "appropriate," the Oviedo Convention does not specify whether disclosure of all risks is required.

Thus, the Declaration on Bioethics and the Oviedo Convention reiterate the professional codes' core principles of protecting the subject's autonomy and well-being. Importantly, they require that the individual's well-being take precedence over the interests of science and society. However, both of these human rights instruments are general in their requirements for informed consent. In particular, while Nuremberg, Helsinki, and especially the CIOMS Guidelines explicitly address what kinds

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[75] Oviedo Convention, *supra* note 17.

[76] *Id.* at art. 1.

[77] *Id.* at art. 2.

[78] *Id.* at art. 16 ("Research on a person may only be undertaken if . . . the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented.").

[79] *Id.* at art. 5.

of risk disclosures must be made, both the Declaration on Bioethics and the Oviedo Convention Convention merely require that "adequate" or "appropriate" information be given to the subject, with the Declaration on Bioethics not even mentioning risk disclosures. While the Declaration on Bioethics and the Oviedo Convention are steps forward in the advancing bioethical principles in the international law, they fall short in providing guidelines to the extent that the professional codes do.

C. Federal Statutes and Regulations Governing Consent to Medical Experimentation

Despite the influences the Nuremberg Code had on the development of the informed consent doctrine in international human rights, Nuremberg was criticized for being largely ignored.[80] The most famous breach of Nuremberg in the United States was perhaps the Tuskegee syphilis study .[81] Tuskegee involved a study of low-income African-American men with syphilis in which some patients were not treated so that the investigators could study the disease's natural progression.[82] Consent for experimentation had not been obtained and in fact those not receiving treatment were misled into believing they were receiving treatment.[83] This created a public outcry that

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[80] Perley et al., *supra* note 21, at 157 ("[T]he Code has been criticized merely because it has been ignored. Even after its promulgation, blatant breaches of the principles enumerated in the Code still occurred.").

[81] *Id.* While the Tuskegee syphilis study was initiated in the 1920s, prior to the promulgation of the Nuremberg Code, it did not end until the 1970s, well after Nuremberg had been generally established and even after the adoption of Helsinki.

[82] GRAY, *supra* note 15.

[83] *Id.*

resulted in the promulgation of the National Research Act.[84] Pursuant to the National Research Act, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created, and Department of Health, Education and Welfare regulations on human experimentation were issued.[85]

One of the main functions of the regulations was to codify a requirement for an ethical review committee, such as that required by Helsinki and the CIOMS Guidelines,[86] which the regulations call the "institutional review board."[87] The regulations also codify a requirement for informed consent prior to human experimentation.[88] However, they provide for an exception to requiring consent if the "research involves no more than minimal risk" and if, among other requirements, the "research could not practicably be carried out without the waiver or alteration," subject to institutional review board approval.[89]

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[84] Jay M. Zitter, Annotation, *Recovery for Nonconsensual Human Medical Experimentation*, 42 A.L.R. 6th 301 § 2 (2009); National Research Act of 1974, Pub. L. No. 93-348, 88 Stat. 1974,. For a discussion on the development of informed consent legislation for the Federal Drug Administration, see Morin, *supra* note 18, at 170–73. Other breaches of the Nuremberg Code included the Willowbrook Studies, in which mentally ill children were intentionally infected with hepatitis; the Jewish Chronic Disease Hospital case, in which cancer cells were injected into elderly patients with uncertain mental capacity; and the case of an unsuccessful transplant of a chimpanzee kidney into a human being. *Id.* at 173, 175.

[85] The Commission was created pursuant to § 201(a) of the National Research Act of 1974, and the regulations were promulgated pursuant to § 474(c). The promulgated regulations are 45 C.F.R. §§ 46.101–124. *See also* Leonard H. Glantz, *The Influence of the Nuremberg Code on U.S. Statutes and Regulations*, *in* THE NAZI DOCTORS AND THE NUREMBERG CODE, *supra* note 15, at 183, 187.

[86] Helsinki, *supra* note 17, ¶ 15; CIOMS GUIDELINES, *supra* note 17 at 24.

[87] Irb-Membership, 45 C.F.R. §§ 46.107–09.

[88] General Requirements for Informed Consent, 45 C.F.R. § 46.116 ("Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject . . . .").

[89] 45 C.F.R. § 46.116(d).

The regulations consider research to hold "minimal risk" if "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."[90] The regulations thus make a distinction between those risks that will be considered legally significant—that is, falling within the purview of the informed consent requirements—and those that are exempt.

In addition, the federal regulations explicitly limit the risk disclosures to those risks which are known to be created or increased by the study itself. The regulations also do not require full disclosure of all possible risks, but only those risks that are "reasonably foreseeable."[91] However, in line with the principle of prioritizing the subject's well-being, the regulations require that "[r]isks to subjects are minimized" and that "[r]isks to subjects are reasonable to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result."[92] Hence, the federal regulations acknowledge that the receipt of health benefits does not mean that an experiment must be risk-free, but rather that there may exist some reasonable, and therefore acceptable, risks.

A commentator has observed that, generally, the "federal regulations express much more enthusiasm for human research than the [Nuremberg] Code does."[93] Indeed, the regulations are more permissive than the professional codes in that they allow for a waiver of informed consent if the risks, based on probability and magnitude, are minimal. In addition, they acknowledge that a beneficial effect can carry with it reasonable risks that are acceptable, which seems to expand on Helsinki Principle 8's acknowledgement that any medical treatment or

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[90] 45 C.F.R. § 46.102.

[91] 45 C.F.R. § 46.116(a)(2).

[92] Criteria for Irb Approval of Research, 45 C.F.R. § 46.111(1)-(2).

[93] Glantz, *supra* note 85, at 198. It should be noted that these regulations only apply to federally-funded research.

research has risks and burdens.[94] Thus, the federal regulations impose a legal standard that may be more permissive than what ethics may require and reflect the state's competing interests vis-à-vis the individual's. However, it should be kept in mind that the investigator is not required to adopt these more lax components and, if she chooses, may impose upon her study the more rigorous requirements of the professional codes.

In addition to the general principles of disclosing risks of the study to the subject and ensuring the subject's comprehension of those risks, the professional ethics codes, international human rights instruments on bioethics, and the United States federal regulations governing federally-funded research provide additional guidance on which interests take priority, which risks should be disclosed, how the determination of risks must be made, and what information about the risks must be disclosed for informed consent to satisfy ethical and legal standards. First, the subject's well-being must be prioritized over all other interests;[95] specifically, the individual's interests must take precedence over the interests of science or society.[96] Second, only material risks must be disclosed, either as determined by a "reasonable person's materiality" standard as described in the CIOMS Guidelines,[97] or, inferring from the federal regulations' definition of a minimal risk study, defined as a risk that is not encountered in daily life or encountered in routine medical examinations.[98] Third, an investigator must have a sound scientific basis in their determination of the risks to be disclosed by using thorough knowledge of the scientific literature and generally accepted scientific principles.[99]

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[94] Helsinki, *supra* note 17, at ¶ 8.

[95] Helsinki, *supra* note 17, at ¶ 16.

[96] Declaration on Bioethics, *supra* note 17, at art. 3.2; Oviedo Convention, *supra* note 17, at art. 2.

[97] CIOMS GUIDELINES, *supra* note 17, at guideline 6 cmt.

[98] 45 C.F.R. § 46.116(d).

[99] Declaration on Bioethics, *supra* note 17, at art. 18.1; Helsinki, *supra* note 17.

Furthermore, the investigator must tailor the mode and content of the information disclosed to the individual's needs.[100] Generally, however, both the nature and the degree of a risk must be disclosed.[101] And importantly, the disclosed information should not deceive, mislead, or influence the subject.[102] Finally, while the study need not be risk-free, the risks must be reasonable for the anticipated benefits,[103] and the investigator must be able to manage those risks, either by preventing them or by mitigating them should they arise.[104]

These ethical, and in some cases legal, requirements for informed consent to medical experimentation serve to ensure both the autonomous decision-making of individuals on whether to participate in a study and the protection of the primacy of the individual's interests against the competing interests of science and society. The following section will describe the development of the informed consent requirements for abortion in the United States through federal case law and will discuss how the current legal informed consent requirements for abortion compare to the requirements for medical experimentation.

II. The Legal Requirements for Abortion Informed Consent

A. Development Through Federal Case Law

In the aftermath of *Roe v. Wade*, states began to use that seminal case's language—"protecting maternal health," "maintaining medical standards," "protecting potential life"—to enact statutes requiring certain disclosures, beyond that required by the common law duty of informed consent, to be made by the

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[100] Declaration on Bioethics, *supra* note 17, at guideline 4 cmt.; Helsinki, *supra* note 17, ¶ 24.

[101] CIOMS GUIDELINES, *supra* note 17, at pmbl.

[102] *Id.*, at guideline 6 cmt.

[103] 45 C.F.R. § 46.111(1)–(2).

[104] Helsinki, *supra* note 17, ¶ 20.

physician performing an abortion.[105] Shortly after *Roe v. Wade*, the Supreme Court in *Planned Parenthood of Central Missouri v. Danforth* upheld the constitutionality of a Missouri abortion statute that required the woman's written certification of consent.[106] The Court justified this requirement as valid because the decision to undergo an abortion was an "important, and often stressful one."[107] Thus began state enumeration of specific required acts within the informed consent process, an arena that had typically been left to the physician and the patient with the courts announcing only broad standards for disclosure.[108]

The courts, however, were not always so willing to give full deference to state legislatures' informed consent requirements. For example, the District Court for the District of North Dakota, in *Leigh v. Olson*, struck down a North Dakota statute that required the physician to disclose the "probable anatomical and physiological characteristics" of the fetus and the "immediate and long-term physical dangers of abortion, psychological trauma resulting from abortion, sterility and increases in the incidence of premature births, tubal pregnancies and stillbirths in subsequent pregnancies, as compared to the dangers in carrying the pregnancy to term."[109] This pre-*Casey* court found that these disclosures were of uncertain validity and held that the statute imposed an unconstitutional burden on a woman's ability to obtain an abortion.[110]

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[105] Roe v. Wade, 410 U.S. 113, 152–53 (1973). *See also* Allyson M. Rucinski, *Finding the Middle Ground:* Acuna v. Turkish *and the New Jersey Supreme Court's Reaffirmation of a Doctor's Role Under the Doctrine of Informed Consent in the Digital Age*, 29 PACE L. REV. 797, 805 (2009).

[106] Planned Parenthood of Central Moussori v. Danforth, 428 U.S. 52 (1976).

[107] *Id.* at 66–67.

[108] *See* Van Detta, *supra* note 8, at 222 (describing how the regulation of abortions is unlike that of any other medical procedure).

[109] Leigh v. Olson, 497 F. Supp. 1340, 1344 (D.N.D. 1980) (citing N.D. CENT. CODE §14-02.1-02(4) (1979)).

[110] *Id.* at 1345–46.

Similarly, in *Charles v. Carey*, the Seventh Circuit struck down an Illinois statute that required the physician to disclose that a fetus is capable of feeling pain.[111] The court criticized the disclosure as being "medically meaningless, confusing, medically unjustified, and contraindicated."[112] Thus, the statute, which hindered the patient's autonomous decision-making, was an unconstitutional burden on a woman's ability to obtain an abortion.

City of Akron v. Akron Center for Reproductive Health continued the line of cases restricting compelled disclosures.[113] There, the Supreme Court struck down an Ohio provision requiring the disclosure that the "unborn child is a human life from the moment of conception."[114] The Court explained that it was "inconsistent with the Court's holding in *Roe v. Wade* that a State may not adopt one theory of when life begins to justify its regulation of abortions."[115] It therefore affirmed the lower court's decision, which had been based on the reasoning that while the state could require abortion counseling, it could not "specify what each patient must be told. That determination must be left to the individual counselor based upon the needs of the particular patient."[116] *City of Akron* thus established a patient-centric, individualized model for informed consent disclosures.

Consistent with *City of Akron*, the Supreme Court in *Thornburg v. American College of Obstetricians and Gynecologists* invalidated a Pennsylvania informed consent statute that required the physician to disclose "all 'particular

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[111] Charles v. Carey, 627 F.2d 772, 782 (7th Cir. 1980).

[112] *Id.* at 784.

[113] City of Akron v. Akron Ctr. for Reprod. Health, 462 U.S. 416 (1983), *overruled by Casey*, 505 U.S. 833 (1992).

[114] *Id.* at 423–24 (quoting Akron Codified Ordinances 160-1978 § 1870.06 (1983)).

[115] *Id.* at 444 (citing *Roe*, 410 U.S. at 159–162 (1973)).

[116] Akron Ctr. for Reprod. Health, Inc. v. City of Akron 479 F. Supp. 1172, 1203 (N.D. Ohio 1979).

medical risks'."[117] It recognized, "This type of compelled information is the anti-thesis of informed consent. That the Commonwealth does not, and surely would not, compel similar disclosure of every possible peril of necessary surgery or of simple vaccination, reveals the anti-abortion character of the statute and its real purpose."[118] The Court also acknowledged that this would not only infringe on the physician's professional judgment, it might also increase patient anxiety.[119] It concluded that these required disclosures were attempts by the state to discourage women from having an abortion and were therefore unconstitutional.[120]

However, *City of Akron* and *Thornburg*'s requirements of patient-centric, individualized, and focused informed consent disclosures were overruled by *Planned Parenthood of Southeastern Pennsylvania v. Casey*, which set the current standard for abortion informed consent disclosures.[121] There, the Supreme Court upheld a provision of a Pennsylvania statute that required the physician to inform the woman of the availability of state-published materials that described the fetus and provided information on medical assistance for childbirth, child support from the father, and agencies that provide alternatives to abortion.[122] The *Casey* Court held that these disclosures were permissible as long as the information was "truthful and not misleading."[123] Thus, the Court gave the states a broad standard within which to impose abortion informed consent requirements.

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[117] Thornburg v. Am. Coll. of Obstetricians and Gynecologists, 476 U.S. 747, 764 (1986), *overruled by Casey*, 505 U.S. 833 (1992).

[118] *Thornburg*, 476 U.S. at 76

[119] *Id.*

[120] *Id.* at 765.

[121] *Casey*, 505 U.S. at 882.

[122] *Id.* at 620.

[123] *Id.* at 882.

In addition, *Gonzales v. Carhart* gave the states further fuel with which to regulate the abortion informed-consent process.[124] The Supreme Court upheld the federal Partial-Birth Abortion Ban Act of 2003, 18 U.S.C. § 1531, on the grounds that in the setting of medical uncertainty, Congress had determined that an intact dilation and evacuation procedure is never necessary to preserve the health of a woman.[125] The Court concluded that it "has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty" and that "[c]onsiderations of marginal safety, including the balance of risks, are within the legislative competence when the regulation is rational and in pursuit of legitimate ends."[126] As a result, the Court gave room to legislatures to determine which uncertain risks are to be deemed significant in all abortion cases, and to usurp what was typically a decision made between the doctor and the patient.[127]

The boundaries of *Casey*'s "truthful and not misleading" standard and *Gonzales*'s legislative deference in the face of medical uncertainty was demonstrated in *Planned Parenthood Minnesota, North Dakota, South Dakota v. Rounds*.[128] There, the South Dakota legislature had passed a statute requiring the

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[124] Gonzales v. Carhart, 550 U.S. 124 (2007).

[125] *Id.* at 163–67. An intact dilation and evacuation, often referred to as simply an intact D & E, is a variation of the dilation and evacuation procedure in which the "fetus remains intact as it is removed from the woman's uterus" and, according to the American College of Obstetricians and Gynecologists, "offers significant safety advantages over the non-intact method." Press Release, Am. College of Obstetricians and Gynecologists, ACOG Files Amicus Brief in *Gonzales v. Carhart* and *Gonzales v. PPFA* (Sept. 22, 2006), *available at* http://www.acog.org/from_home/publications/press_releases/nr09-22-06.cfm.

[126] *Id.* at 163, 166.

[127] It should be noted, however, that *Gonzales* differs from a typical abortion informed consent case in that the decision to be made was not whether to undergo an abortion or not, rather which of two standard procedures to choose. In addition, the cases that *Gonzales* cites as precedent for giving deference to legislatures in light of medical uncertainty all dealt with cases where there was a risk of public harm, not simply risks to the patient herself.

[128] Planned Parenthood Minnesota v. Rounds, 650 F. Supp. 2d 972 (D.S.D. 2009).

physician to disclose to the patient, among other things, that the "abortion will terminate the life of a whole, separate, unique, living human being," and that abortions increase the risk of suicide.[129] The District Court for the District of South Dakota, following a previous Eighth Circuit en banc opinion,[130] held that the required disclosure that the life of a human being will be terminated was not untruthful or misleading because it was based on a statutory definition of "human being" as an "individual living member of the species of Homo sapiens," a definition which the Eighth Circuit had stated was biological, not ideological, in nature.[131]The district court, quoting the Eighth Circuit, explained:

> Once one accepts that the required disclosure must take into account the limiting definition [of human being], the evidence submitted by the parties regarding the truthfulness and relevance of the [biological disclosure] generates little dispute. The disclosure actually mandated by [the biological disclosure], in concert with the definition [of human being], is that the abortion will terminate the life of a whole, separate, unique, living human being, [biological disclosure], and that human being in this case means an individual living member of the species of Homo sapiens . . . during [its] embryonic [or] fetal age.[132]

Hence, the laxity of the *Casey* "truthful and not misleading" standard can be seen in *Rounds*, under which otherwise ideological phrases such as "human being" are considered truthful and not misleading so long as the legislature defines

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[129] S.D. CODIFIED LAWS § 34-23A-10.1 (2005).

[130] *Rounds*, 530 F.3d 724, 735 (8th Cir. 2008).

[131] *Rounds*, 650 F.Supp.2d at 976 (D.S.D. 2009).

[132] *Id* (emphasis omitted). While the statute itself did not require disclosure of the legislature's definition of "human being," the district court interpreted this statement by the Eighth Circuit as requiring disclosure of the legislative definition of "human being." *Id.*

them using biological language. *Casey* has given state legislatures wide room to maneuver semantically within their legislation in order to meet the "truthful and not misleading" standard.

On the other hand, the South Dakota District Court struck down, as untruthful and misleading, the required disclosure of increased risk of suicide.[133] It based this decision on the fact that the South Dakota legislature had changed the statutory language from requiring disclosure of "particular medical risks *associated* with the particular abortion procedure" to disclosure of "all known medical risks of the procedure," including an "[i]ncreased risk of suicide ideation and suicide."[134] The court concluded that this changed language indicated a required finding of more than mere association, requiring now a finding of causation—that is, that abortion in itself directly causes suicide.[135] However, because the evidence did not show that it is "generally recognized that having an abortion causes an increased risk of suicide ideation and suicide," the court held that the required disclosure was untruthful and misleading.[136]

Importantly, the South Dakota District Court defined "known risk" as "one that is generally recognized."[137] The court noted that the American College of Obstetricians and Gynecologists and the American Psychological Association had rejected the claim that suicide is a risk of abortion.[138] In addition, the FDA had approved the abortion-inducing drug mifepristone without listing suicide as a risk.[139] Thus, South Dakota could not use their experts' opinions and five limited

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[133] *Rounds*, 650 F. Supp.2d at 983.

[134] *Id.* at 982 (emphasis added).

[135] *Id.*

[136] *Id.* at 983.

[137] *Id.*

[138] *Id.*

[139] *Rounds*, 650 F. Supp. 2d.. at 983.

studies to show that suicide was a "known risk" of abortion.[140] While *Gonzales* may have opened the door for more deference to legislatures' risk determinations in cases of medical uncertainty, *Rounds* shows that a state cannot simply choose one side of a medical debate on a potential risk and require physicians to disclose that risk as a "known risk" during the informed consent process. However, the *Rounds* decision is limited to prohibiting required disclosures explicitly or impliedly stating that abortion causes a particular adverse event without evidence of a general consensus that it does so; the decision does not give further guidance on what type of risk disclosures a state may require—that is, only generally recognized risks or any risk ever identified—and in either case, what other information regarding the weight of evidence or the likelihood of the risk should also be disclosed.

Planned Parenthood of the Heartland v. Heineman shows why further guidance on the content of the risk disclosures is needed.[141] There, the District Court for the District of Nebraska enjoined Nebraska from enforcing a bill signed by the governor in April 2010 that imposed extensive abortion risk disclosures based on the legislature's finding that "the existing standard of care for preabortion screening and counseling is not always adequate to protect the health needs of women" and that "clarifying the minimum standard of care for preabortion screening and counseling in statute is a practical means of protecting the well-being of women . . . ."[142] Nebraska, within the context of *Gonzales*'s greater deference to legislative decisions in determining medical risk, had made this finding based not on a general consensus of the scientific community, but on a few anecdoctal stories about women who had had adverse psychological effects after an abortion and despite

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[140] *Id.*

[141] Planned Parenthood of Heartland v. Heineman, 724 F. Supp. 2d 1025 (D. Neb. 2010).

[142] B. 594, 101st Leg., 2d Sess., at § 2 (Neb. 2010).

testimony in opposition by the Nebraska Psychological Association, researchers, and health care providers.[143]

The Nebraska bill required the physician to provide the patient a written checklist indicating whether she had or did not have certain risk factors associated with abortion.[144] The bill defined "risk factor" as follows:

> Risk factor associated with abortion means any factor, including any physical, psychological, emotional, demographic, or situational factor, for which there is a statistical association with one or more complications associated with abortion such that there is less than a five percent probability ($P < .05$) that such statistical association is due to chance. Such information on risk factors shall have been published in any peer-reviewed journals indexed by the United States National Library of Medicine's search services (PubMed or MEDLINE) or in any journal included in the Thomson Reuters Scientific Master Journal List not less than twelve months prior to the day preabortion screening was provided[.][145]

In addition, if the woman was found to have a particular risk factor for a complication, the physician was required to disclose "[a]ny quantifiable risk rates whenever such relevant data exists."[146] South Dakota had impermissibly required physicians to disclose suicide as a known risk of abortion, without more,

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[143] *Hearing on LB675, LB676, LB594, and LR26 Before the Nebraska Committee on Judiciary*, 100th Leg., 1st Sess., 61–81 (Neb. 2009).

[144] B. 594, 101st Leg., 2d Sess., at § 4 (Neb. 2010).

[145] B. 594, 101st Leg., 2d Sess., at § 3 (Neb. 2010). A complication was similarly defined as "any adverse physical, psychological, or emotional reaction associated with abortion that is reported in a peer-reviewed journal to be statistically associated with abortion such that there is less than a five percent probability ($P < .05$) that the result is due to chance." *Id.*

[146] *Id.*

implying that abortion may cause suicide; in contrast, Nebraska had gone to the other extreme, requiring disclosures of any risks ever found to have a significant statistical association with abortion in any peer-reviewed journal in major journal databases.[147]

While the court found that the risk evaluation and disclosure requirements "appear[ed] to be extraordinarily difficult, if not impossible, given the breadth and depth of the research required," it did not hold this provision unconstitutional on the basis of its creating a barrier to informed consent.[148] Rather, the court held this provision invalid due to an additional provision that would find a physician who did not comply with this requirement civilly liable for the wrongful death of the fetus.[149] Because such civil liability could potentially take an abortion provider out of practice, the court concluded that the bill created an unconstitutional barrier to a woman's access to abortion.[150] As a result, it remains unclear whether such an extensive risk disclosure, absent potential civil liability for the physician, would be deemed a barrier to the woman's ability to give informed consent and therefore an unconstitutional obstacle to abortion.

Casey's broad "truthful and not misleading" standard for abortion informed consent remains the law. Moreover, *Gonzales*'s deference to legislatures' risk determinations in the face of medical uncertainty has opened the door for states to use greater authority in determining which risks are significant and must therefore be disclosed. The South Dakota and Nebraska cases show that states will indeed work at the boundaries of the broad *Casey* standard. While both *Rounds* and *Heineman* found certain required disclosures unconstitutional, their holdings are limited. *Heineman* held the extensive Nebraska risk disclosures an unconstitutional obstacle to abortion but only because the

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[147] Again, it should be noted that a statistical association does not in itself show causation.

[148] *Heineman*, 724 F. Supp. 2d at 1033.

[149] B. 594, 101st Leg., 2d Sess., at § § 6, 10 (Neb. 2010).

[150] *Heineman*, 724 F. Supp. 2d at 1039-40.

physician civil liability provision could remove the availability of abortion providers. *Rounds* held that the portrayal of a disputed risk as one that is generally recognized is untruthful and misleading; however, it did not categorically prohibit disclosures of such disputed risks. Furthermore, *Rounds*, in allowing the state to mandate a statement about the fetus being a human being by defining "human being" elsewhere in the statute using biological terms, has opened the door to states using semantic devices in their legislative drafting to include what would otherwise be considered unconstitutional information on when life begins. The abortion informed consent case law, as it stands, provides only minimal protection for the woman seeking an abortion from state intrusion into her decisionmaking. The next section will discuss how the legal standard for abortion informed consent permits ethical violations of informed consent.

B. Assessment of the Current Abortion Informed Consent Law Through the Lens of the Medical Experimentation Consent Requirements

Casey's "truthful and not misleading" standard has allowed states to mandate informed consent requirements for abortion that fall short of the medical experimentation consent requirements in three predominant ways. First, because *Casey* did not further describe what counts as truthful information about a risk, state legislatures, especially under *Gonzales*, may be legally permitted to violate the principle of basing risk disclosure decisions on a thorough knowledge of the scientific literature (as mandated by Helsinki and the CIOMS Guidelines) and on generally accepted scientific principles (as mandated by the CIOMS Guidelines). While *Rounds*, in line with this bioethical principle, struck down South Dakota's mandate that a physician disclose that suicide is a known risk of abortion based only on limited and flawed studies, it is unclear what other jurisdictions might find. In addition, it is unclear whether courts would strike down a requirement that physicians disclose all stastically significant risks found in the scientific literature, versus only those generally accepted risks or risks relevant to the patient. The continued existence of a significant number of state-mandated inaccurate disclosures, as will be discussed in Part III, shows that states have indeed interpreted "truthful" liberally, and

have not hesitated to stretch their authority under *Casey*'s broad standard.

Second, the current abortion informed consent law underemphasizes the ethical requirement of not unduly influencing or manipulating the woman's decision. *Casey*, in espousing its "truthful and not misleading" standard, stopped one step short of explicitly prohibiting a state from unduly influencing a woman to choose to continue her pregnancy. While the *Casey* court held that the "means chosen by the State to further the interest in potential life must be calculated to inform the woman's free choice, not hinder it,"[151] it also affirmatively held that states may "express . . . a preference for childbirth over abortion."[152] However, as the CIOMS Guidelines caution, there is a fine line between "justifiable persuasion and undue influence."[153]

The requirements for informed consent in medical experimentation demand the disclosure of only non-deceptive and non-misleading information based on sound, generally accepted principles of science, not ideology. Indeed, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research stated that "individuals are 'entitled to accept or reject health care interventions on the basis of their own personal values and in furtherance of their own personal goals'."[154] The state's interest in potential life, however, is one based on ideology, not on science,[155] and because *Casey* does not prohibit this interest, the woman is left vulnerable to a violation of her autonomy from the

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[151] *Casey*, 505 U.S. at 877.

[152] *Id.* at 883.

[153] CIOMS GUIDELINES, *supra* note 17, at guideline 6 cmt.

[154] Gold and Nash, *supra* note 3, at 2.

[155] *See, e.g., Rounds*, 530 F.3d 724, 742 (8th Cir. 2008) (dissenting opinion) ("[T]here is no consensus in the medical community or society supporting [the] position that a six-to eight-week-old embryo is, as a matter of biological fact—as opposed to a moral, theological, or philosophical judgment —'a complete, separate, unique and irreplaceable human being'." (quoting *Acuna v. Turkish*, 192 N.J. 399, 930 (N.J. 2007)).

undue and unethical state influence. This was demonstrated in *Rounds* when the court upheld South Dakota's mandated disclosure that an abortion "terminates the life of a whole, separate unique living human being" as being truthful because "human being" was defined by the statute in biological language as a "member of the species of Homo sapiens."[156] But as the dissent in the Eighth Circuit decision stated:

> Although a legislature may choose to give words its own unique definition, it cannot establish by fiat that the term 'human being' has only biological connotations, for the constitutional analysis of whether the mandated statements convey factual truths of contestable ideology is not controlled by the wording of the Act.[157]

Nevertheless, because stating that a fetus is of the species Homo sapiens is not untruthful, South Dakota has been allowed to mandate that physicians disclose that an abortion terminates the life of a human being, despite the ideological overtones carried by that term.

However, while the human-being disclosure may meet legal muster by being truthful, and assuming arguendo that it is also not misleading, it fails to meet the ethical informed consent requirement of not unduly influencing or manipulating the patient. Such a disclosure aims to have the patient make a choice that is consistent with the state's interest in a continued pregnancy, and not necessarily her own. Hence, the disclosure violates the medical experimentation professional codes' and human rights instruments' requirement of holding the individual's autonomy and well-being over the interests of science and society, and thereby also over the interests of the state. Such biased disclosures are particularly dangerous when it is the healthcare provider—whom most patients trust as a credible communicator of medical truths—who is relaying the

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[156] *Rounds*, 650 F. Supp. at 976–77.

[157] *Rounds*, 530 F.3d 724, 744 (8th Cir. 2008) (dissenting opinion).

state-mandated information.[158] Therefore, without a stricter standard that includes a prohibition of mandated disclosures of biased, albeit truthful, information, women are left vulnerable to undue influence from the state, through the physician, urging them to choose to continue their pregnancies.

As a result, in giving such broad allowance to the states with its "untruthful and not misleading" standard and permission to "express" their interest in childbirth, *Casey* has over-prioritized the states' ideological interests over the woman's, starting a trend where subsequent cases have focused more on a state's expression of this interest vis-à-vis case law and the Constitution rather than on the tangible interests of and effects on the woman. The *Rounds* court upheld South Dakota's mandated human being disclosure based on an intricate statutory and semantic analysis. The *Heineman* court may have enjoined Nebraska's risk factor disclosure requirements, but it did so based on the professional burden and civil liability of physicians, rather than focusing on the woman's interests in receiving truthful, not misleading, and non-manipulative information. Thus, abortion informed consent law unethically prioritizes the state's interest in the fetus in both the substantive outcomes of the case law as well as in the analytical approaches to those outcomes.

While the South Dakota and Nebraska cases are the only recent informed consent disclosure statutes brought to court, unethical informed consent disclosure requirements abound in state legislation. The following section will discuss examples of how the current state of abortion informed consent law has led to the provision of untruthful, misleading, and unduly influential information to women seeking abortions.

III. Application of Medical Experimentation Consent Principles to Current State Abortion Informed Consent Requirements

Under *Casey*, a state may further its "legitimate goal of protecting the life of the unborn" by regulating the informed

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[158] *See* Jeremy A. Blumenthal, *Abortion, Persuasion, and Emotion: Implications of Social Science Research on Emotion for Reading* Casey, 83 WASH. L. REV. 1, 22 (2008).

consent process, even if the legislation "expresses a preference for childbirth over abortion," as long as information to be given to the woman is "truthful and not misleading."[159] States have interpreted "truthful" broadly, mandating disclosures of risks that may be supported by a medical study, but a study whose scientific soundness is questioned after examination and in comparison with other studies in the scientific literature. These mandated disclosures thus violate the principle of basing risk disclosures on thorough knowledge of the scientific literature, as required by both Helsinki and the CIOMS Guidelines, and on generally accepted scientific principles, as required by the CIOMS Guidelines. Furthermore, because an otherwise uninformed woman will likely understand that information to be the complete truth, she will also be misled, resulting in a violation of not only the ethical principle to not deceive or mislead, but also the legal disclosure standard of *Casey*.

For example, despite refutation of the theory by the medical community, Texas requires the inaccurate disclosure of an increased risk of breast cancer following abortion.[160] Under the Texas' Woman's Right to Know Act, a physician must inform a woman of 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."[161] This statute exists despite the National Cancer Institute's concluding, "Induced abortion is not associated with an increase in breast cancer risk."[162] While the statute states that a physician must disclose a possibility of increased breast cancer risk only when it is "medically accurate,"[163] the Texas Department of Health's booklet, which the physician must provide on request by the patient and which is also available on the Department of

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[159] *Casey*, 505 U.S. at 882–83.

[160] TEX. HEALTH & SAFETY CODE ANN. § 171.012(a)(1)(B)(iii).

[161] *Id.*

[162] NAT'L CANCER INST., SUMMARY REPORT: EARLY REPRODUCTIVE EVENTS AND BREAST CANCER WORKSHOP (2003), http://www.cancer.gov/cancertopics/crc-workshop-report.

[163] TEX. HEALTH & SAFETY CODE ANN. § 171.012(a)(1)(B)(iii) (West 2009).

Health's website, nevertheless states that abortion may increase the risk of breast cancer.[164] Alaska, Mississippi, Oklahoma, and West Virginia include similar breast cancer risk disclosures in their state-written materials despite the fact that such disclosures are not mandated by statute.[165] These states are therefore violating the ethical requirement of basing risk disclosures on generally accepted scientific principles.

In addition, both Texas and South Dakota require incomplete disclosures about an increased risk of infertility following an abortion without providing the necessary context of the risk. For example, the South Dakota statute requires that the physician provide the patient with a written statement that describes "all known medical risks of the procedure . . . including the risk of . . . danger to subsequent pregnancies, and infertility."[166] This is required regardless of what kind of abortion procedure the patient is receiving, medical or surgical. The Texas statute also requires a disclosure that abortion may create a "potential danger to a subsequent pregnancy and of infertility."[167] As with the breast cancer risk disclosure, although the risk of infertility is only required to be disclosed by the physician if it is "medically accurate,"[168] the Texas Department of Health's booklet, which must be offered to all women who request it, describes a cut or torn cervix, which "may make it difficult or impossible to become pregnant in the future or to carry a pregnancy to term," as being a general risk associated with abortions without specifying that such a risk only applies to

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[164] TEX. HEALTH & SAFETY CODE ANN. § 171.012(a)(2)(D), 171.013; TEX. DEP'T OF HEALTH, A WOMAN'S RIGHT TO KNOW 17 (2003), *available at* http://www.dshs.state.tx.us/wrtk/default.shtm. The breast cancer risk disclosure in the Woman's Right to Know booklet has never been challenged in court.

[165] GUTTMACHER COUNSELING, *supra* note 4, at 3.

[166] S.D. CODIFIED LAWS § 34-23A-10.1(1)(c).

[167] TEX. HEALTH & SAFETY CODE ANN. § 171.012(a)(1)(B)(ii).

[168] TEX. HEALTH & SAFETY CODE ANN. § 171.012(a)(1)(B).

surgical abortions, not medication abortions.[169] Hence, these required infertility disclosures violate the CIOMS Guidelines' requirement of not disclosing all possible risks but only those relevant to the individual, and in particular, only those risks that an individual would find material to her decision. It seems unlikely that a woman would consider material information on risks of a procedure she is not actually undergoing.

In addition, the South Dakota and Texas disclosures do not mention that the overwhelming medical consensus is that vacuum aspiration, the most common type of first-trimester abortion, poses virtually no long-term risk of infertility.[170] Furthermore, they do not inform the woman that medical advances have reduced the likelihood of infertility due to a second trimester dilatation and evacuation procedure.[171] Thus, they violate the CIOMS Guidelines' requirement of also disclosing the degree of the risk.

While *Rounds* may have struck down the suicide risk disclosure in South Dakota, seven states, continue to require, either through an explicit statutory requirement of disclosure during the informed consent counseling process or by inclusion in written materials that the physician must provide on request, both inaccurate and incomplete disclosures about a risk of psychological harm, including depression and suicide, after an abortion.[172] However, comprehensive reviews of the scientific literature on the mental health effects of abortion, conducted by both the American Psychological Association and Johns Hopkins University, have concluded that the highest quality studies show no difference in risk of mental health sequelae between women who had abortions and their respective comparison groups.[173]

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[169] TEX. DEP'T OF HEALTH, *supra* note 165, at 17. As with the breast cancer risk disclosure, the infertility risk disclosure found in the WOMAN'S RIGHT TO KNOW booklet has never been challenged in court.

[170] Gold & Nash, *supra* note 3, at 11.

[171] *Id.*

[172] GUTTMACHER COUNSELING, *supra* note 4, at 3.

[173] GUTTMACHER INST., GUTTMACHER ADVISORY: ABORTION AND MENTAL HEALTH 1 (2010) [hereinafter GUTTMACHER MENTAL HEALTH].

Further, an American Psychological Association report states, "Across studies, prior mental health emerged as the strongest predictor of postabortion mental health."[174] According to the Guttmacher Institute, women report feeling a range of emotions after having an abortion, ranging from relief to sadness or guilt.[175] Thus, disclosing to a woman only the possible negative mental health effects of an abortion is incomplete and misleading information, serving unethically to influence a woman to not choose abortion.

These disclosures are not only problematic in that they deceive and mislead, but also because most of the disclosures are made in written materials that must either be given to all woman seeking an abortion or offered to those who request the materials. However, there is no concomitant mandate that the health care provider also go through every piece of information within the written materials with the woman. Therefore there is no guarantee that the woman will have fully comprehended the information, and the possibility that the woman will consent to the procedure without being truly informed remains. Hence, the ethical principle of tailoring the mode of communication to the particular individual's needs, as required by Helsinki and the CIOMS Guidelines, is violated.

Furthermore, in addition to inaccurate, incomplete, or irrelevant risk disclosures, many states also require disclosures about the nature of the abortion procedure that are irrelevant to the particular patient, again violating the principle of tailoring information to the individual's needs. For example, seventeen states require that women be given descriptions of all common abortion procedures, not just the specific procedure she will be having.[176] Two states, Texas and South Dakota, provide these disclosures despite a lack of a legal mandate. As with the

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[174] Brenda Major et al., Report of the Am. Psychological Ass'n Task Force on Mental Health and Abortion 4, (2008), *available at* http://www.apa.org/pi/women/programs/abortion/mental-health.pdf.

[175] GUTTMACHER MENTAL HEALTH, *supra* note 170, at 2.

[176] *Id.* This requirement results in a woman undergoing a medication abortion to have to listen to all of the details of the invasive surgical abortion procedures.

infertility risk disclosures, it is difficult to see, for example, how for a woman seeking a medication abortion, information on the more invasive surgical procedure will be material to or help inform her decision to have an abortion. Thus, these states violate the ethical requirement of individually tailoring informed consent to ensure the patient understands her specific situation.

In addition to the required disclosures about the risks and nature of abortion, many states also require disclosures about the fetus. Nineteen states require disclosure of fetal development to the end of pregnancy, regardless of the point at which the woman is in her pregnancy.[177] While some states have tried to ensure that their fetal development disclosure requirements pass muster under the *Casey* "truthful and not misleading" standard by including requirements of scientific accuracy, the relevance of giving information on the anatomy of a viable fetus to a woman at the beginning of a pregnancy remains questionable.[178]

Moreover, seven states require disclosures of the ability of the fetus to feel pain, with three states providing such disclosures in their written materials despite a lack of a legal mandate to do so.[179] Arkansas, Minnesota, and Oklahoma require this disclosure only for women at 20 weeks gestation or later.[180] Missouri requires it for women at 22 weeks gestation or later. The others provide this disclosure regardless of their point of gestation.[181] However, a Journal of the American Medical Association review of the medical literature found that the fetus does not develop the necessary physical structures to perceive pain until 23 weeks or later, with limited data showing that the fetus is unlikely to have the ability to transmit or perceive

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[177] GUTTMACHER COUNSELING, *supra* note 4, at 2.

[178] *See, e.g.*, K.Y. REV. STAT. ANN. § 311.725(2)(b) ("The materials . . . shall include *only accurate scientific information* about the zygote, blastocyte, embryo, or fetus . . . .") (emphasis added).

[179] GUTTMACHER COUNSELING, *supra* note 4 at 2.

[180] *Id.*

[181] *Id.*

sensory information until it is at 29 weeks.[182] The fetal pain disclosure is not only irrelevant to most women undergoing abortions, but to those for whom the disclosure is relevant, the broad statement that her fetus may feel pain is still likely inaccurate and therefore misleading.

What is perhaps most problematic about these irrelevant disclosures about the fetus, in concert with the irrelevant disclosures about the nature and risks of abortion, is that their irrelevance makes them no longer a simple expression of the state's interest in the protection of the fetus but rather an active mechanism for influencing the woman to choose childbirth over abortion. The state cannot argue that these disclosures are necessary to protect the woman's health or her fully informed decision since they do not apply to this particular woman. Thus, they violate the core principle behind informed consent: autonomous decision-making. Unfortunately, because these requirements largely remain unchallenged in court, they remain on the books and in practice, standing as an obstacle to women seeking abortions in states that have implemented such requirements.

CONCLUSION

While all medical interventions require informed consent, state legislatures, under *Casey*, have interfered in the abortion informed consent process by enacting requirements for disclosing inaccurate, incomplete, or irrelevant information on the risks and nature of abortion and the fetus. They have thus introduced into the abortion informed consent process questions of informed consent content and method, as well as of the management of competing individual and state interests—questions that are similarly raised in the medical experimentation context. The current state of abortion law falls short of requiring the ethical principles of basing risk determination and disclosure on sound scientific knowledge and principles; tailoring information and the mode of communicating that information to the individual's needs; not deceiving, misleading, or unduly influencing the individual's decision; and prioritizing the individual's interests over those of the state or

[182] Gold and Nash, *supra* note 3, at 12.

society. Abortion informed consent law thus fails to protect the patient's autonomy from being violated by the state.

Because the ethical codes and federal statutes and regulations on consent to medical experimentation arose as a response to past abuses by the state and the scientific community, and because the potential for similarly abusive state interference in a woman's decision to have an abortion is high, the principles enumerated in the medical experimentation professional codes and human rights instruments should be a starting point from which to determine what disclosures may be required for abortion informed consent. It should be kept in mind, however, abortions and medical experimentations differ, in that the primary goal of the former is the treatment of the patient.[183] Hence, while the principle of self-determination should be a primary guiding principle, the fact that the abortion informed consent process is taking place in a therapeutic setting should heavily favor the principle of the patient's well-being as a primary interest. Furthermore, the benefits of the abortion procedure should be included in the competing-interests analysis: while the efficacy of the treatment is uncertain in the context of medical experimentation, for abortions the efficacy is certain.

The CIOMS Guidelines, which are the most developed professional ethical guidelines for medical experimentation, indicate that those risks that a reasonable patient would find material should be disclosed to a woman seeking an abortion.[184] The reasonable patient materiality standard is the same standard used in most jurisdictions for other medical procedures.[185] In terms of disclosure, what is ethically required in the abortion context, even with its attendant uncertainties, is the same as for other medical procedures. In addition, in light of the fact that most patients have already made their decisions on whether to receive treatment prior to the informed consent conversation, the additional disclosures imposed by states for abortions are likely

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[183] *See Whitlock*, 637 F. Supp. 1468, 1471 (M.D.N.C. 1986).

[184] CIOMS GUIDELINES, *supra* note 17, at guideline 8 cmt.

[185] *See* Zeller v. Greater Baltimore Medical Center, 506 A.2d 646, 651 (Md. Ct. Spec. App. 1986).

irrelevant to the medical decision-making process.[186] Furthermore, it has been argued that the required abortion risk disclosures dissuade by frightening potential patients.[187] Indeed, it has been shown that over-disclosure of risks can lead to increased anxiety and in fact decreased comprehension of said risks.[188]

As a result, because the abortion informed consent case law is less protective of individual autonomy than what is ethically required, states have been allowed to enact informed consent disclosure requirements that not only permit physicians to violate ethical principles of informed consent, but in fact require them to do so. It therefore seems that in addition to overturning these unethical disclosure laws, new ethical and legal protections for abortion patients also need to be codified. Evidence has shown that states will overstep ethical boundaries if the law is too permissive. Will history show that in the end, we as a country have not learned from the Nuremberg Trials or our own mistakes during the Tuskegee syphilis study?

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[186] Berg et al., *supra* note 16 at 17.

[187] Blumenthal, *supra* note 151, at 20–23.

[188] Morin, *supra* note 18, at 194. *See also* Berg et al., *supra* note 16, at 28.

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NOTE FROM THE EDITORS OF THE *JOURNAL OF GENDER AND LAW* 2011–2012

It is with great pride that we present our readers with Issue 21.2 which commemorates the Symposium co-hosted by Columbia Law School's Center for Gender and Sexuality Law and the *Columbia Journal of Gender and Law* honoring Judith Butler's contributions to gender and sexuality law.

Hosted March 5, 2010, Issue 21.2 has been a long time coming, with preparations for the symposium, initial editing, initial production, and final production spanning three years. Without a doubt, this issue would not have come to print without the efforts of *JGL* staff and editors serving *JGL* 2009–2010, 2010–2011, and 2011–2012.

JGL is reprinting Issue 21.2 in order to include Prof. Morris B. Kaplan's piece "Absent Friends: Scenes of Address and an Ethic of Self-Making." Through our error, the piece was left out of the initial printing of the issue. The issue is being reprinted in full so that Prof. Kaplan's piece can be presented in the company and context of the other contributions to the symposium. The *Columbia Journal of Gender and Law* regrets the error.

In addition, *JGL* is indebted to the efforts of **Vina Tran**, **Michelle Greenberg-Kobrin**, **Ilene Strauss**, and **Mary Welsh** who ensured this issue was ultimately brought to print.

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