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Good morning. Thank you Dr. Pellegrino and Council members for the opportunity to offer comment this morning on the impact of refusal clauses and institutional restrictions in the delivery of health care services.

I am Susan Berke Fogel, J.D. I am an attorney with the National Health Law Program, a national public interest law firm that seeks to improve health care for America's working and unemployed poor, minorities, the elderly and people with disabilities. NHeLP serves legal services programs, community-based organizations, policymakers, the private bar, providers and individuals who work to preserve a health care safety net for the millions of uninsured or underinsured low-income people.

We approach refusal clauses and denials of care from this quality and access perspective. We also understand that low-income women and other marginalized populations experience greater health disparities that are exacerbated by restrictions on care.

The basic principles of modern health care delivery are evidence-based practice, patient centeredness, and prevention, collectively ensuring quality care. Failure to adhere to prevailing "standards of care" harms the individual patient in real and concrete ways, undermines the medical system, and jeopardizes the health of the general public. These principles may be compromised by a range of structural factors such as lack of insurance, restricted geographic access, cost, language barriers, and immigration status. We are hoping that current political movements will be successful in promoting strategies to address these structural barriers to quality of care.

At the same time, health care refusals and denials of care are proliferating in the U.S. based on personal religious and moral beliefs that have nothing to do with scientific evidence, good medical practice or the needs of the patient. These restrictions and denials of care, which most often are related to reproductive health and disproportionately affect women, should be scrutinized to assess their impact on quality health care and redressed when they fall below the standard of care.

Analyses of health care denials traditionally construct the issue as a conflict of rights within the provider-patient relationship: the health care provider's right to exercise individual conscience

vs. the patient's right to exercise her autonomy. The question becomes how best to balance the rights and obligations within the relationship. This framework, while a common starting place, also needs to incorporate attention to the special context in which the debate is occurring: health care. The public discussion often fundamentally obscures the question of patient health by making it appear as if there is a moral contest between the patient and the provider.

Public discourse on refusals also relies on assumptions that we believe are subject to challenge:

1. That the services are optional, elective, not necessary to health and well-being, or based on the whims and desires of women;
2. That there are only limited or "acceptable" burdens on patients when providers refuse; and
3. That the patient can obtain the needed services elsewhere.

For low-income women in particular, these assumptions are often erroneous. While the health services impacted by refusals are most often related to reproductive and sexual health, they are implicated in a wide range of common health treatment and prevention strategies. The burdens on low-income women can be insurmountable when women and families are locked into managed care plans that do not meet their needs, or they cannot afford to pay out of pocket for services, or they cannot travel to another location. Last, in rural areas, or even in urban areas where insurance limits access, patients may simply be unable to obtain health and life preserving medical care.

These issues are not theoretical or philosophical for the real patients whose health is significantly impacted by refusals to provide information, referrals and care.

The sources of such restrictions arise in two intersecting spheres of health care delivery:

1. Refusal clauses or so-called "conscience clauses" where institutions and individuals are shielded from liability for failing to provide health services, counseling and/or referrals as expected under generally accepted medical guidelines because the individual or institution has an objection to the service.

Carla¹ who lives in eastern Oklahoma thought she had the flu. Her family doctor referred her to an Obstetrician/Gynecologist (OB/GYN) who discovered she was pregnant and that she had a large mass growing on her uterus. Carla's youngest child was already 16, and she decided to have an abortion, but when she went to the abortion clinic she was told that she needed to have the mass removed before she could have the abortion. Then her encounter with health care refusals began. The OB/GYN refused to remove the mass because it would endanger the pregnancy. The anesthesiologist in the practice group refused to give her any drugs that would harm the pregnancy. At this point the mass was shutting off her colon and bladder. Eventually Carla found a doctor an hour and a half away in another city, but due to the substantial delay, he had to remove her uterus, a procedure that would have been unnecessary if the abortion had been performed earlier in her pregnancy. Carla and her family were left with \$40,000 in medical bills.

2. Institutional restrictions, which often remain under the radar in public discussion, that prohibit the provision of certain services in their facilities, refuse to cover those services in their insurance products, or otherwise restrict services that meet evidence-based standards of care. In these situations, the individual provider may want to deliver the service to her patient, but is prohibited from doing so.

Dr. Smits² was a physician at St. Mary's hospital in a large Eastern city. The patient was 19 weeks pregnant and her membranes had ruptured. This is called pre-mature rupture of membranes or PROM. The fetus is not yet viable at that point. The patient was septic – a dangerous infection was in her system as a result of PROM. Dr. Smits and the patient wanted to end the pregnancy to save the woman's health, but the hospital ethics committee refused to approve the termination because the fetus still had a heartbeat. Dr. Smits was giving the woman medications to keep her blood pressure up and using a cooling blanket to keep her temperature down. As Dr. Smits said, "this woman was dying before our eyes." And still the ethics committee refused to approve the termination.

Outcome: Patient was in ICU for ten days, and nearly died. The fetus died in utero. The woman had substantial internal bleeding, developed pulmonary disease, and wound up being oxygen-dependent.

Critically assessing both of these situations is important because institutions that impose ideological restrictions on health care delivery have assumed increasing control of hospitals and managed care systems in the United States. According to Modern Healthcare, one in six Americans is treated in a Catholic hospital each year.

Using a Standards of Care framework to analyze refusal clauses and denial of care

Since refusal clauses are essentially permission to opt out of providing a service that would otherwise be required or expected, it is useful to analyze, "opt out from what?" Standards of care or professional practice guidelines are commonly understood to mean the practices that are medically necessary and the services that any practitioner under any circumstances should be expected to render. Standards of care statements are created to indicate the level of clinical practice endorsed by scientists and clinicians and grounded in evidence from investigations of a particular area of practice. Generally, standards are based on large quantities of evidence from studies (e.g. data generated from studies of practice or clinical trials), but clinicians' experience in practice may also form the basis for evolving standards when no evidence exists to guide care. Clinical guidelines are often used to indicate the consensus among an expert panel of clinicians and researchers, drawn from clinical practice experience, data from studies, and discussion/agreement among experts.

The provider-patient relationship is inherently unequal, and the denial of information or services directly impacts the patient's health and well-being. Health care is not like other fields. The delivery of health care is highly regulated, with good reason. Patients can only obtain certain care from professionals who are extended that privilege by the state through the laws of professional licensure. The standards of care also help to appropriately frame the boundaries of the provider-patient relationship, which our society views as one founded in trust, where the patient's interests are paramount. The basis for this relationship is recognition of the imbalance

of the provider's and patient's level of knowledge as well as respect for the patient's trust that the health professional's judgment is based on scientific principles.

Restrictions of information and services do not take place in an open marketplace. Placing decisions to allow health care refusals and restrictions only in a philosophical context fails to place the health of the patient as the highest priority. Instead of an evaluation of health care denials and restrictions as a balancing of rights, the consequences of denials of care are more fully understood in the context of quality and standards of care, and should be analyzed using the same yardsticks used to assess health care quality generally: evidence-based practice, patient-centeredness, and prevention. In this way health care denials may come to be understood as potential violations of the standard of care rather than as moral contests.

The traditional doctor-patient relationship based on a hierarchical arrangement is now viewed as insufficient and out-of-date. Evidence-based practice, patient-centeredness, and prevention are emerging as the new frameworks for delivering health care, transforming the provider-patient relationship to optimize health.

Evidence-based practice requires that health care decision-making is based on the best available scientific research, seeking to improve the quality and decrease the cost of health care by ensuring that patients receive treatments known to be effective and do not receive those treatments proven to be ineffective or harmful. Patient-centered care developed out of the institutionalization of informed consent as a means to achieve patient autonomy and address cultural variation. Evidence-based practice and patient-centered care work in tandem to ensure that patients receive care which is both scientifically sound as well as reflecting personal preference. In this way, care is individualized within a boundary of effectiveness and safety. Complementing these approaches is the burgeoning attention to prevention which focuses on optimizing health outcomes before the onset of disease.

Contrary to the trends in modern health care delivery, health care refusals and denials grounded in personal and religious beliefs rather than scientific evidence negate evidence-based practice, patient-centered care, and prevention. They take women's reproductive health backwards to the discredited model of paternalistic health care where treatment decisions are made by physicians and health systems regardless of patient needs and preferences, and they negate patients' capacity to make informed decisions.

Access to scientifically-grounded health care information and services related to contraception and pregnancy termination are critical to the health of women, as is care and information related to fertility attainment and healthy sexuality. Decisions to deny information and services based on personal and religious beliefs rather than scientific evidence ultimately result in poor health outcomes for women.

The standards of care help to establish parameters for fair access to health care. In a society concerned with fairness and equality of opportunity and the redemptive powers of science, health care is different from most other goods and services, and that equitable access to health care services is critical. The concept of justice, or equitable access to health care, encompasses not only the level of health care services that ought to be available to all, but also the extent to which

burdens can be imposed on those who seek access to services. If some health care providers fail to provide information regarding, and access to, specific types of health care based on factors other than patient need or scientific evidence as to the effectiveness of the health care service, affected patients will bear unreasonable burdens.

For example, an ectopic pregnancy is a pregnancy that develops outside the uterus, most commonly in the fallopian tube. If not removed, the ectopic pregnancy poses a serious risk to the woman's health and could result in death. The American College of Obstetricians and Gynecologists, Cochrane Review, and Royal College of Obstetricians and Gynecologists all recognize three medical approaches to terminate an ectopic pregnancy: drugs to dissolve the pregnancy, minimally invasive laparoscopy, or invasive surgery to remove a portion of the fallopian tube. All of these medical guidelines require that the decision of which procedure to use be based on the patient's medical condition and preference. Catholic hospital restrictions take that decision out of the hands of patients and physicians and impose their religious interpretation of what constitutes an abortion to limit the treatment options available to physician and patient, even though an ectopic pregnancy will never result in a viable pregnancy. This restriction may deny the patient the least invasive and best option to preserve her future fertility.

Refusals and restrictions on providing full and complete information

Informed consent is at the core of the individual's right to self-determination and to make his or her own decisions about medically appropriate health care. This right is conditional upon two factors: access to relevant and medically accurate information about treatment choices and alternatives; and provider guidance in helping patients make decisions about treatment options based on generally accepted standards of practice. Both factors make trust between patients and health care professionals a critical component of quality of care. According to the American Medical Association, "The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice."³

Informed consent is intended to help balance the relationship between health providers and patients, wherein patients authorize specific interventions. Disclosure of medical information is an essential component of the provider-patient relationship, and is embedded in medical and research codes. Informed consent also requires that physicians respect a patient's right to refuse treatment, but does not require that physicians provide treatments that a patient desires but that are outside acceptable practice or unnecessarily draw on limited resources.⁴

Informed consent is a core ethical as well as legal tenet for physicians according to the American Medical Association: "The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice."⁵

The American Nursing Association similarly requires that patient autonomy and self-determination are core ethical tenets of nursing. "Patients have the moral and legal right to determine what will be done with their own persons; to be given accurate, complete and

understandable information in a manner that facilitates an informed judgment; to be assisted with weighing the benefits, burdens and available options in their treatment.”⁶

The American Bar Association (ABA) has adopted policy in opposition to refusal clauses that restrict information that patients need to make sound medical decisions, stating “the ABA opposes governmental actions and policies that interfere with patients’ abilities to receive from their health care providers, including health care professionals and entities, in a timely manner: (a) all of the relevant and medically accurate information necessary for fully informed health care decision-making; and (b) information with respect to their access to medically accurate care, as defined by the applicable medical standard of care.”⁷

The Conflict between Professional Practice Guidelines and Refusals or Denials of Care

Listed below are just a few examples of professional practice guidelines in women’s health that require health care professionals to provide information, counseling, and access to contraception, sterilization and abortion. They illustrate how refusal clauses and institutional restrictions fail to meet the standards of acceptable medical practice.

Contraception

There are many medical conditions for which pregnancy prevention is an important component of disease management. For example, for women with chronic diseases such as diabetes, epilepsy, depression, lupus, some forms of cardiovascular disease, and other conditions, pregnancy may worsen a woman’s condition. Medical practice guidelines for the use of many pharmaceuticals require that women not become pregnant during their course of treatment.

According to a recent study, 11.7 million prescriptions for potentially teratogenic (causing impairments in the developing fetus) Class D or X medications are filled by women of reproductive age in the U.S. every year.⁸ Women taking these drugs who might be at risk for pregnancy are advised to use a reliable form of contraception to prevent pregnancy. In addition, the medical guidelines referenced below all require that health care providers inform their patients about the risks of pregnancy and the importance of contraception.

- **Isotretinoin**, sold under the brand name Accutane® or as a generic under the names Amnesteem, Claravis, and Sotret⁹ is a known human teratogen - an element that can cause multiple major fetal impairments, such as craniofacial, cardiac, thymic, and central nervous system malformations. Isotretinoin is associated with a pattern of fetal impairment in more than 35 percent of infants whose mothers take the drug during pregnancy. The concerns about Accutane® are so significant that the FDA instituted a risk management plan, called iPLEDGE, to ensure that female patients do not become pregnant while taking this drug.¹⁰ Female patients of childbearing potential¹¹ must have a series of pregnancy tests, be counseled on contraception, and use two forms of contraception. The FDA clarifies that “natural family planning (rhythm method), fertility awareness, and withdrawal” are not reliable forms of contraception.¹²
- **Iodine-131** used to treat thyroid disease, which is the second most common endocrine disease facing women of reproductive age. Hyperthyroidism occurs when the thyroid

produces excess thyroid hormone, producing symptoms ranging from mild nervousness, weight loss and insomnia to a dangerously fast heart beat which can be life-threatening.¹³ A radioactive form of iodine, Iodine-131, has been used for 40 years to treat hyperthyroidism and thyroid cancer, and in small doses, to test thyroid function.

The American College of Obstetricians and Gynecologists (ACOG) warns that women taking Iodine-131 should avoid pregnancy for a minimum of 4 months after completing the treatment because Iodine-131 may destroy the developing fetus' thyroid. ACOG recommends that women taking Iodine-131 who are at risk for pregnancy should also be prescribed contraceptives. Moreover, if a woman becomes pregnant during Iodine-131 treatment, and her exposure is at 10 weeks gestational age or less, the physician should advise the woman of the risks to the fetus so that the patient can decide whether to continue the pregnancy.¹⁴

- **Chronic Disease** Millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to maternal risk or even death during pregnancy. The CDC recently released its *Recommendations to Improve Preconception Health and Health Care*¹⁵ to identify specific interventions to improve birth outcomes and maternal health. The CDC notes a range of conditions that should be addressed before pregnancy in order to improve pregnancy outcomes. The goal of these interventions is to reduce health conditions that are amenable to preconception care while preventing pregnancy until the conditions are controlled to support healthy pregnancies and optimal outcomes under the circumstances.¹⁶

During “Preconception care” and “interconception care” women are advised to use effective contraceptive methods to prevent pregnancy until chronic conditions that could lead to adverse birth outcomes or threaten maternal health are brought under control.¹⁷

Pregnancy Prevention: Sterilization

Sterilization is the most common method of contraception in the United States.¹⁸ According to ACOG, sterilization accounts for 39 percent of contraceptive method use: 28 percent of women have had tubal sterilization and 11 percent have male partners who have had vasectomy. Tubal sterilization is more effective than short-term contraceptive methods and equal in effectiveness to Interuterine Contraception (IUC). ACOG recommends that women who have completed their families should be informed about the option of sterilization.¹⁹ The American Society of Anesthesiologists Task Force on Obstetrical Anesthesia found that post-partum tubal ligation can be safely performed within eight hours of delivery.²⁰ In addition, sterilization may be recommended for women with certain chronic diseases such as some forms of diabetes and cardiovascular disease for which pregnancy can be medically very risky. In all cases of sterilization, there is a heightened need for fully informed consent to ensure that fully informed consent is given voluntarily.

ACOG also suggests that women with certain complications associated with pregestational diabetes (i.e. serious vasculopathy) or who have completed their families consider sterilization.²¹

Emergency Contraception for Victims of Sexual Assault

In 2005, 189,000 sexual assaults and rapes were reported. It is estimated that 12,500 resulting pregnancies could have been prevented with timely access to emergency contraception.²² These numbers do not account for the numerous sexual assaults and rapes that go unreported. The professional guidelines that require health providers to offer and provide emergency contraceptives in all cases of unprotected sex often make specific references to the standard of care to offer and provide emergency contraception to victims of sexual assault. According to the American College of Obstetricians and Gynecologists, “Emergency contraception should be offered to all victims of sexual assault if they are at risk of pregnancy.”²³ Practice guidelines from the American College of Emergency Physicians state, “Victim[s] of sexual assault should be offered prophylaxis for pregnancy and for sexually transmitted diseases, subject to informed consent and consistent with current treatment guidelines.”²⁴

The American Medical Association policy states, “it is the policy of our AMA: . . . (3) to recognize that information about emergency contraception is part of the comprehensive information to be provided as part of the emergency treatment of sexual assault victims.”²⁵

Pregnancy Termination

In 1995, the Institute of Medicine urged a new national norm establishing every pregnancy as a wanted pregnancy.²⁶ Key to achieving that norm is access to contraception and access to abortion. Abortion is a common health care service in the United States and the one of the most common surgical procedures for women. In 2000 over 1.3 million pregnancies ended in abortion.²⁷ In 2002, 20.8 out of every 1,000 American women aged 15–44 had an abortion; in 2003, 23.8 percent of pregnancies (excluding fetal losses) were terminated by abortion.²⁸

Women who obtain abortions reflect the diversity of the American population across age, race, ethnicity, religious affiliation, and geographic location. Over sixty percent of abortions are among women who have had one or more children. Reflecting a significant disparity in health, the abortion rate among women living below the federal poverty level is more than four times that of women about 300 percent of poverty.²⁹

While most often associated with factors related to an unintended pregnancy, abortion care is also needed for women with medical or fetal complications associated with a wanted or intended pregnancy. Eight percent of the pregnancies ending in abortion that women reported in the face-to-face interviews for the National Center of Health Statistics 2002 National Survey of Family Growth were described as intended.³⁰ However, because abortions are substantially underreported in the National Survey of Family Growth, analyses based on these reports are likely to be unreliable.³¹ Thus while it is unknown the exact percentage of women who undergo abortions for medical or fetal indications it is important to explore the extent to which denials of care specifically affect these populations.

Once a woman has decided to carry her pregnancy to term, there are still a number of medical developments that may put her or her fetus at significant risk. Medical standards developed by American College of Obstetricians and Gynecologists, Royal College of Obstetricians and

Gynecologists, and Cochrane Collaboration all recognize that in these situations, the patient must make a serious decision about balancing her health and life - with a full understanding of the medical consequences of her decision - with the prospects for fetal survival. Universally, these practice guidelines place that decision in the hands of the patient. They also charge the physician with giving the patient full and complete medical information about her treatment options.

- **Premature Rupture of Membranes (PROM)** Premature rupture of membranes occurs when the amniotic membranes surrounding a pregnancy rupture before the pregnancy has reached term (at 37 weeks). Complications due to premature rupture include severe bleeding (hemorrhage) and infection. Risk of chorioamnionitis, a serious infection of the placental lining and fluid, increases dramatically when patients with PROM do not receive prompt care. Intraamniotic infection occurs in 13-60 percent of women with preterm PROM.³² Maternal sepsis is a rare, but very serious complication of untreated PROM. Sepsis is an infection of the body which involves all major organ systems. If left untreated or diagnosed too late, this condition can be fatal. Risk to the fetus is infection, compression of the umbilical cord reducing nutrients and oxygen, and neurological impairment.³³

The incidence of infection increases for women whose pregnancies are at lesser gestational ages. The American College of Obstetricians (ACOG) and the American Academy of Pediatrics (AAP) recommend that women whose fetuses are pre-viable (<24 weeks) should be counseled regarding the health impact of immediate delivery (pregnancy termination) and the potential risks and benefits of “expectant management.”³⁴ ACOG practice guidelines require that the pregnant woman should participate fully in the decision regarding her pregnancy.³⁵

- **Pre-eclampsia and Eclampsia** Pre-eclampsia and eclampsia are serious and related pregnancy complications, generally experienced after 20 weeks gestation, although they may manifest earlier in a pregnancy. Each of these conditions can pose serious risks to maternal and fetal health. Pre-eclampsia is a hypertensive condition which affects about 8 percent of pregnant women in the U.S. and is a major cause of maternal and fetal death.³⁶ The American College of Obstetricians and Gynecologists and the American Academy of Pediatrics (ACOG/APA) note that the risks to the woman from persistent severe pre-eclampsia are such that delivery (pregnancy termination) is usually suggested regardless of fetal age or potential for survival.³⁷

ACOG and the Cochrane Review analysis state clearly that the only known cure for pre-eclampsia or eclampsia is delivery.³⁸ The ACOG/AAP guidelines further recommend that the decision to terminate a pregnancy take into consideration factors such as severity of pre-eclampsia, gestational age, maternal condition, fetal condition and prospect for fetal survival. ACOG recommends management only if the pre-eclampsia is mild.³⁹

- **Anencephaly – Fetus incompatible with life** Anencephaly is a neural tube defect of the developing fetus, where the head end of the neural tube fails to close. As a result, the forebrain and cerebrum of the brain fail to develop, and the fetus is missing major portions of the skull and scalp.⁴⁰ An infant born with this disorder is usually blind, deaf, unconscious, unable to feel pain, and likely to die within hours or days of birth. Anencephaly can be diagnosed as early as the 10th – 12th week of pregnancy, but is more often diagnosed through

prenatal ultrasound between 15 – 18 weeks. There is no treatment for anencephaly. Many professional organizations recommend abortion to reduce the potential of complications for the woman carrying the pregnancy and to alleviate maternal distress and anxiety.⁴¹

Conclusion

Refusal clauses and denials of care undermine standards of care by shielding providers from delivering health care services and information that would otherwise be required by generally accepted practice guidelines. The consequences of public policies that allow health care denials or restrictions that do not meet the relevant standards of care are that patients do not have the information they need to make informed treatment decisions and the care they do receive may result in poorer health outcomes.

The current public discourse about refusal clauses and restrictions is poised as a moral contest between the providers' "rights of conscience" vs. the autonomy and self-determination of patients. This discourse takes place in a theoretical and ideological framework without a full understanding of the impact on women's health, and without due regard for medical quality and patient well-being. The authors of this report hope to start to change how policymakers, providers, and the public view ideologically or religiously based care denials and restrictions as violating the medical standards of care and jeopardizing patient and public health.

As state and national policymakers consider health reform proposals, it is important that refusal clauses and denials of care, as well as prospective hospital mergers, be evaluated using the same measurements used to evaluate quality generally:

- Evidence-based
- Patient-centered
- Prevention

Only with full information on the table can the medical community and policymakers make decisions about where to draw these lines.

¹ This is a fictitious name to protect the family's privacy; cited in Freedman, L., Willing and Unable: Doctors' Constraints in Abortion Care, PhD Dissertation, University of California at Davis, Department of Sociology (June 2008).

² Names and location have been changed to protect the privacy of those involved; cited in Freedman Willing and Unable.

³ American Medical Association, Medical Ethics E-8.08 Informed Consent (Issued March 1981, updated October 4, 2005).

⁴ Abram, M. B., Ballantine, H. T., et al. Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-practitioner Relationship, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982).

⁵ American Medical Association, Medical Ethics E-8.08 Informed Consent (Issued March 1981; updated Oct. 4, 2005).

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- ⁶ American Nurses Association, Code of Ethics for Nurses, Provision 1.4, http://nursingworld.org/ethics/code/protected_nwcoe813.htm.
- ⁷ American Bar Association, Policy # 05M104 (2005).
- ⁸ Schwarz, E. B. MD, MS; Postlethwaite, D.A. RNP, MPH; Hung, Y. Y. PhD; and Armstrong, M. A. MA, Documentation of Contraception and Pregnancy When Prescribing Potentially Teratogenic Medications for Reproductive-Age Women, *Ann Intern Med.* 2007;147:370-376 (Sept. 18, 2007).
- ⁹ U.S. Food and Drug Administration, iPLEDGE Update (March 23, 2006).
- ¹⁰ iPLEDGE replaces the System to Manage Accutane Related Teratogenicity (S.M.A.R.T.) pursuant to an FDA assessment in 2004 and recommendations of an FDA Drug Safety and Risk Management and Dermatologic and Ophthalmic Drugs joint advisory committee which determined the need to include mandatory registration of all participants and to link negative pregnancy testing to prescription dispensing for female patients who can become pregnant. U.S. Food & Drug Admin., Accutane (isotretinoin) Questions and Answers (Oct. 28, 2005).
- ¹¹ A prescriber must determine if a female patient is of childbearing potential before she can be enrolled in the iPLEDGE program. A female patient with “childbearing potential” is defined as someone who is nonmenopausal who has not had a hysterectomy, bilateral oophorectomy, or medically documented ovarian failure. This includes a young woman who has not yet started menstruating. A woman who has had a tubal sterilization is still considered to be of childbearing potential under this program. iPLEDGE, Guide to Best Practices for Isotretinoin. (2005) at 16.
- ¹² iPLEDGE, Frequently Asked Questions at 12
- ¹³ New York Thyroid Center, Hyperthyroidism, <http://cpmcnet.columbia.edu/dept/thyroid/index.html>
- ¹⁴ American College of Obstetricians and Gynecologists, Practice Bulletin No. 37 (Aug. 2002).
- ¹⁵ *Centers for Disease Control and Prevention "Recommendations to Improve Preconception Health and Health Care." MMWR 55(RR06);1-23 (Apr. 21, 2006).*
- ¹⁶ *Centers for Disease Control and Prevention "Recommendations to Improve Preconception Health and Health Care." MMWR 55(RR06);1-23 (Apr. 21, 2006).*
- ¹⁷ *Centers for Disease Control and Prevention "Recommendations to Improve Preconception Health and Health Care." MMWR 55(RR06);1-23 (Apr. 21, 2006).*
- ¹⁸ American College of Obstetricians and Gynecologists Practice Bulletin, Benefits and Risks of Sterilization, No. 46 (Sept. 2003).
- ¹⁹ American College of Obstetricians and Gynecologists, Guidelines for Women’s Health Care, second edition (2002), at 153.
- ²⁰ Practice Guidelines for Obstetrical Anesthesia: A Report by the American Society of Anesthesiologists Task Force on Obstetrical Anesthesia, *Anesthesiology*:Vol. 90(2) (Feb. 1999) at 600-611.
- ²¹ American College of Obstetricians and Gynecologists. Pregestational Diabetes Mellitus. ACOG Practice Bulletin. (March. 2005).
- ²² Stewart, F. and Trussell, J., Preventing Pregnancy Resulting from Rape: a Neglected Healthcare Measure, *19 Am. J. of Preventive Medicine* 4:228 (Nov. 2000).
- ²³ American College of Obstetricians and Gynecologists Practice Bulletin, Emergency Contraception, No. 69 (2005).
- ²⁴ American College of Emergency Physicians, Management of the Patient with the Complaint of Sexual Assault, Revised and approved by the ACEP Board of Directors October 2002. This statement replaces one with the same title originally approved by the ACEP Board of Directors January 1992 and reaffirmed June 1999 (Policy #400130, Revised October 2002).
- ²⁵ American Medical Association, H-75.985 Access to Emergency Contraception, CMS Rep.1, 1-00; Appended: Res. 408, A-02; Modified Res. 443, A-04.
- ²⁶ Institute of Medicine, *The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families*, National Academy Press (1995) at 252.

²⁷ Finer, L. B. and E. K. Henshaw "Disparities in Rates of Unintended Pregnancy in the United States, 1994 and 2001." *Perspectives on Sexual and Reproductive Health* **38**(2): 90-96.

²⁸ Finer and Henshaw.

²⁹ Jones, R. K., Darroch, J. E., & Henshaw, S. K. (2002). Patterns in the socioeconomic characteristics of women obtaining abortions in 2000-2001. *Perspectives on Sexual and Reproductive Health*, *34*(5), 226-235.

³⁰ A Survey of Men and Women, 2002: Cycle 6 of the National Survey of Family Growth (NSFG).

³¹ Finer and Henshaw.

³² American College of Obstetricians and Gynecologists Practice Bulletin, Premature Rupture of Membranes, No. 1 (June 1998).

³³ American College of Obstetricians and Gynecologists Practice Bulletin, Premature Rupture of Membranes, No. 1 (June 1998).

³⁴ American College of Obstetricians and Gynecologists /American Academy of Pediatrics, Guidelines for Perinatal Care, 4th Ed. (1997).

³⁵ American College of Obstetricians and Gynecologists Practice Bulletin, Premature Rupture of Membranes, No. 1 (June 1998).

³⁶ American College of Obstetricians and Gynecologists /American Academy of Pediatrics, Guidelines for Perinatal Care, 4th Ed. (1997) at 135.

³⁷ American College of Obstetricians and Gynecologists/American Academy of Pediatrics at 136.

³⁸ Churchill D, Duley L, "Interventionist versus expectant care for severe pre-eclampsia before term, The Cochrane Database of Systematic Reviews 2006 Issue 2, The Cochrane Collaboration, <http://www.cochrane.org/reviews/en/ab003106.html> last visited 7/12/06; American College of Obstetricians and Gynecologists, Practice Bulletin No. 33 Diagnosis and Management of Preeclampsia and Eclampsia (Jan. 2002).

³⁹ American College of Obstetricians and Gynecologists Practice Bulletin No. 33 at 8.

⁴⁰ NINDS Anencephaly Information Page, National Institute of Neurological Disorders and Stroke, National Institutes of Health, <http://www.ninds.nih.gov/disorders/anencephaly/anencephaly.htm>.

⁴¹ Association for Spina Bifida Hydrocephalus; Anencephaly: Information for Parents After Diagnosis (rev. June 2, 2008); <http://www.asbah.org/Spina+Bifida/information sheets/anencephaly.htm>.