



# **Health Care Refusals:**

Undermining Quality Care for Women

***The National Health Law Program is 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, 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.***

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**National Health Law Program  
Standards of Care Project**

## Standards of Care Project

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## Table of Contents

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<b>Chapter One: Standards of Care</b>	<b>6</b>
Introduction	6
Standards of Care	8
Quality of Care	9
Consequences of Health Care Restrictions and Refusals	11
Applying the Standards of Care Framework	13
Ideological Restrictions in Health Care	14
Refusal Clauses (also known as “conscience clauses”)	15
Institutional Restrictions	17
Political Restrictions	19
Informed Consent	20
Restrictions on Patients’ Ability to Give Informed Consent	21
Research Methodology	24
<b>Chapter Two: Pregnancy Prevention</b>	<b>26</b>
Overview	26
Women’s Decisions to Prevent Pregnancy	26
Drugs that Significantly Impair the Developing Fetus	28
Preconception Management of Chronic Conditions	31
Ideological Restrictions on Practice Guidelines on Pregnancy Prevention	36
Contraception	36
Sterilization	38
Emergency Contraception	40
<b>Chapter Three: Abortion</b>	<b>46</b>
The Decision to Terminate a Pregnancy	46
Terminating a Pregnancy when the Health of a Woman or her Fetus is at Serious Risk	47
Abortion: Emergent conditions	47
Ideological Restrictions on Pregnancy Termination	51
Ectopic Pregnancy	56
<b>Chapter Four: Pregnancy Attainment</b>	<b>60</b>
Overview	60
Cancer	61
Ideological Restrictions on Treatment for Pregnancy Attainment	62
<b>Chapter Five: Healthy Sexuality</b>	<b>64</b>
Condoms and Preventing Sexually Transmitted Diseases and Infections, and HIV/AIDS	64
Ideological Restrictions on the Use of Condoms	64
<b>Chapter Six: Conclusion</b>	<b>66</b>
<b>Appendix</b>	<b>67</b>
<b>References</b>	<b>70</b>

Our vision is for a health care system that draws on the best evidence to provide the care most appropriate to each patient, emphasizes prevention and health promotion, delivers the most value, adds to learning throughout the delivery of care, and leads to improvements in the nation's health.

*Institute of Medicine Roundtable on Evidence-Based Medicine, 2008*

## Chapter One

# Standards of Care

### Introduction

People in the United States expect the health care they receive to reflect medical practice grounded in evidence and endorsed by scientists and clinicians. For physicians, nurses, pharmacists and other health care providers, the primary commitment and duty is to provide the best care possible to the patient. Failure to adhere to prevailing “standards of care,” defined as medically necessary services, harms the individual patient, undermines the health care system, and jeopardizes the health of the general public. It is the responsibility of health care providers and policy makers to ensure that medical guidelines are enforced and that patients receive quality health care services that meet the standard of care.

***In a Self Magazine survey, 1 in 20 women reported that a doctor or other health care provider refused them care or a service based on the provider's personal, moral, or religious objection.<sup>2</sup>***

The basic principles of modern health care delivery are evidence-based practice, patient centeredness, and prevention. Collectively they ensure quality care. 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. Current political movements are 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 ideological and political justifications that have nothing to do with scientific evidence, good medical practice, or patient needs. These refusals and denials of care should be scrutinized to assess their impact on quality health care and redressed when they fall below the standard of care. Unlike structural defects in the health care system, ideological restrictions are not being addressed in the current health care debate; they will not be resolved by current reform proposals; and, in fact, there is a serious risk that these restrictions will be institutionalized without careful evaluation of their public health impact.<sup>1</sup>

This report specifically addresses those health care refusals and denials of care rooted in political ideology or institutional or personal religious objections and evaluates their potential impact on access to care.

The products and services most often restricted based on ideology and personal belief are those related to reproductive health and sexual activity. In recent years, there has been a broad expansion of these restrictions linked to a growing and more vocal contingent of physicians and other health providers who refuse to provide services to which they have personal and religious objections. Restrictions have also expanded due to the

growth of large religiously-controlled non-profit health care corporations, and political trends that have favored ideology over science. Despite the threats to patient health, the leading quality monitoring and enforcement agencies have failed to incorporate any quality measures related to these restrictions.

Institutions that impose ideological restrictions on health care delivery have assumed increasing control of hospitals, clinics and managed care systems in the United States. These organizations often impose limitations on the health care the clinicians in their systems can offer, essentially preventing health care professionals from delivering the care they were trained to provide. At the same time, broad statutory refusal clauses allowing health care personnel to refuse to provide critical information and services based on their personal beliefs also are proliferating. When ideological restrictions are imposed, patients may be denied access to quality health care and may not even receive appropriate information or referrals for the care they need.

To date there has been no rigorous analysis examining the extent to which denials of care affect the overall health of women, particularly low-income women whose choice of health providers is often limited. *Health Care Refusals: Undermining Quality Care for Women* investigates and documents whether and to what extent these denials conflict with professionally-developed, accepted medical standards of care, and analyzes the potential health consequences for patients. This analysis provides a new framework for evaluating refusal clauses and denials of care, hospital mergers, and other transactions when they conflict with accepted and expected medical practice.

This report provides background and analysis of the ethical and legal concepts of standards of care and informed consent, and then analyzes religious, ideological and political restrictions and denials of care that conflict with and undermine established medical standards. Second, it provides detailed descriptions and analysis of the standards of care that govern medical practice for a range of common health conditions and illustrates how refusals and denials of care violate those standards and put women's health at risk.

*Carla,<sup>3</sup> 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.<sup>4</sup>*

## Standards of Care

Standards of care are defined as the practices that are medically necessary and the services that any practitioner under any circumstances should be expected to render.<sup>5</sup> 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. Unlike “best practices” that focus on the highest level of care a patient can receive, standards of care establish a baseline of professionally agreed-upon practices. Generally, standards are based on large quantities of evidence from empirical 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 systematic evidence exists to guide care. The quality or level of the evidence is rated to indicate the strongest evidence for a practice, ranging from a randomly allocated, controlled, clinical trial to observational studies or meta-analyses. Rating systems differ slightly across disciplines and countries, but rating systems share a hierarchy of evidence approach, with controlled trials preferred over either historical precedent or clinical experience.

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 and agreement among experts.

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The term “standard of care” is also used in the medical liability context. In that context, evidence is reduced to legal liability and the prevailing community practice. Standards of care in this report are discussed in the context of enhancing the quality of health outcomes rather than that of assessing liability.

Some professional medical associations are beginning to address refusals and provide guidance to medical providers. The American College of Obstetricians and Gynecologists has recognized that a patient’s health should always come first, and that access to health services should be based on the patient’s medical needs, not the provider’s personal or religious beliefs. In a recent Committee on Ethics Opinion, ACOG states that the patient’s autonomy, and physical and mental health, limit the physician’s ability to refuse. ACOG recommends that a provider’s personal beliefs can be accommodated only when the primary duty to the patient can be fulfilled; providers must give patients full, accurate and unbiased information; providers have a duty to refer; and in an emergency, providers have an obligation to provide needed care regardless of the provider’s personal objections.<sup>6</sup>

The American Medical Association has also addressed provider refusals in the context of hospital mergers. Despite the AMA core principle of medical ethics that states, “A physician, while caring for a patient, must regard responsibility to the patients as paramount,”<sup>7</sup> the AMA bowed to pressure from the Catholic Church hierarchy to pass a watered-down resolution that both reaffirmed the importance of access to reproductive health services, but also stated that medical professionals and hospitals should not be required to violate personally held moral principles.<sup>8</sup>

The American Nurses Association Code of Ethics for Nurses allows nurses to refuse to engage in practices which they find morally objectionable but obligates the nurse “to provide for the patient’s safety, to avoid patient abandonment, and to withdraw only when assured that alternative sources of nursing care are available to the patient.”<sup>9</sup>

In responding to a published editorial on pharmacists’ refusals to fill prescriptions for contraception, the executive directors of the Academy of Managed Care Pharmacy, the American College of Clinical Pharmacy, the American Pharmacists Association, and the American Society of Health-System Pharmacists issued a press release reaffirming that their organizations’ policies “support the ability of the pharmacist to opt-out of dispensing those prescriptions where the pharmacist has an objection to the intended use of the medication while concurrently supporting the establishment of systems to assure patient access to legally prescribed, clinically safe therapy.” They conclude that their “organizations support the pharmacist ‘stepping away’ from participating in that activity, but oppose the pharmacist ‘stepping in the way’ of the patient accessing that therapy.”<sup>10</sup>

## Quality of Care

Cases involving denials of care are receiving increasing scrutiny in the public media and professional press,<sup>11,12</sup> particularly those involving pharmacists refusing to fill emergency contraception prescriptions<sup>13-16</sup> and physicians unwilling to perform elective abortions. However, the ramifications of refusal clauses and religious restrictions on health care are much broader than pharmacists and elective abortion – they impact a wide range of common health conditions. Denials of care based on religious and ideological objections have expanded to include the right not to provide care, not to provide referrals, and not to offer information about a range of legally available care, and in doing so, fundamentally challenge the core values of modern health care and affect the well-being of all women.

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.<sup>17,18</sup> The question becomes how best to balance the rights and obligations within the relationship.<sup>19</sup> This framework, while a common starting place, fails to attend to the special context in which the debate is occurring: health care. The moral contest framework fundamentally obscures the impact on patients’ health.

Health care is not like other fields. The delivery of health care is highly regulated, with good reason. The purpose of health care regulation is to protect patients from untrained or inadequate providers who would do them harm. Practicing medicine, providing nursing care, or distributing drugs without a license is forbidden by law. Patients can only obtain certain kinds of care from professionals who are extended that privilege by the state through the laws of professional licensure. Restrictions of information and services do not take place in an open marketplace. The provider-patient relationship is inherently unequal, and the denial of information or services directly impacts the patient’s health and well-

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being. Contemporary debates over refusals and denials of care have disproportionately focused on philosophical issues of balancing patients' rights and providers' beliefs. This framing fails to address the real life consequences refusals and denials of care have for patient health. Refocusing on medical quality and standards of care prioritizes a patient's health over the provider's personal beliefs and raises the visibility of institutional policies that prohibit health professionals from providing certain care, even when they themselves do not object to such care. This report analyzes health care refusals and denials of care using the same measures used to assess health care quality in general: evidence-based practice, patient-centeredness, and prevention. In this framework, health care denials can be understood as violations of the standard of care rather than as moral contests.

Professional policies and standards of care are designed to ensure consistent care even as professionals exercise discretion about specific treatments for specific patients. Refusals and denials of care threaten the consistency of health care by allowing professionals to base their treatment decisions on religious and moral beliefs that fall outside the purview of professional discretion. As a result, patient access to care is constrained by the specific professional or institution from whom she seeks care.

Professional ethics are also patient-centered. Ethical principles such as autonomy and informed consent are designed to ensure that the patient receives the best care possible. Medical, nursing, and pharmacy codes of ethics focus on how health care professionals should inform patients about treatment options, while recognizing that selection among professionally-determined options, and even the choice to receive care, belongs to the patient.

Delivering quality care requires that health care professionals provide information and care consistent with the highest standards of scientific evidence, based on individual patient need, and with the goal of maximizing wellness. Within this paradigm, the failure of health care professionals to provide information regarding or access to specific types of health care is not solely an exercise of individual conscience but rather the provision of substandard care.

## Consequences of Health Care Restrictions and Refusals

Major changes in the delivery of health care are underway in the United States. The traditional doctor-patient relationship based on a hierarchical arrangement is now viewed as insufficient and out-of-date.<sup>20</sup> Evidence-based practice, patient-centeredness, and prevention have emerged as the new frameworks for delivering health care, transforming the provider-patient relationship to optimize health. Denials of health care information and services directly reverse traditional trends towards evidence-based practice, patient-centered care, and prevention.

The framework of the World Health Organization's (WHO) definition of health as a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity,<sup>21</sup> includes specific attention to reproductive health which addresses the reproductive processes, functions and systems at all stages of life. Reproductive health includes the right of men and women to be informed of and to have access to safe, effective, affordable, and acceptable methods of fertility regulation of their choice. It also includes the right to access appropriate health care services that will enable women to go safely through pregnancy and childbirth and to provide potential parents with the best chance of having a healthy infant.<sup>22</sup>

The Institute of Medicine's influential *Crossing the Quality Chasm* report (2001)<sup>20</sup> identifies the new paradigms of evidence-based medicine and patient-centered care as explicit means for achieving better health outcomes among individual patients and the U.S. population. Complementing these approaches is the commitment to prevention that has moved from public health to mainstream medicine.<sup>23</sup>

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.<sup>24</sup> 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 high quality health care.<sup>20</sup> 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.<sup>25</sup>

Through specialized training, health care professionals learn the principles of evidence-based practice and patient-centered care while internalizing a shared set of ethical principles designed to create consistency of care. Professionals practicing with a shared set of ethical beliefs will provide patients with similar types of health care options while supporting the patient's right to choose among them. Professionals who draw on personal religious beliefs to guide practice will present patients with different sets of options, leaving out evidence-based options to which the professional objects. Similarly, institutional

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prohibitions limit what providers can offer or discuss with their patients. These practices compromise ethical principles of autonomy and informed consent by constraining patient information and treatment alternatives.

Contrary to the trends in modern health care delivery, health care denials and prohibitions 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. The information flow between practitioners and patients affects the quality of care patients receive. Paternalistic models of health care saw the patient as an object to be acted upon by the health care system. Decisions about medical care rested squarely with the provider, and the patient accepted provider recommendations due to the provider's extensive knowledge and training. Inequality between provider and patient limited quality of care by restricting the information the patient received. Contemporary models of care treat the patient as a partner, or at least as an informed participant, working with the provider to assess the problem and work towards a solution. By involving the patient in the assessment and treatment process, providers increase quality of care and receive information they may not have otherwise accessed. Refusals, or fear of refusals, can again limit the information the provider receives because fear of judgment may prevent patients from fully participating in the treatment process. The physician-patient relationship is further undermined because the patient's trust may be eroded when she doesn't know if she is getting complete and evidence-based information about her treatment options.

Institutional restrictions determine what care and information health care professionals may offer to their patients. The professional's medical judgment and ability to provide quality care is replaced by the institution's policies. In these cases, medical decision-making is taken away from both professional and patient and replaced by the beliefs of a third party.

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.

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## Applying the Standards of Care Framework

Ethical arguments justifying providers' choices to reject standardized treatment primarily rest on the provider's autonomy, and the right to maintain personal religious and ideological beliefs and to use these beliefs to guide their practices. Likewise imbuing health care institutions with religious ideology allows those beliefs to supersede those of the health care professional and/or patient. However, the importance and nature of health care, and the nature of the relationship between a health care provider and his/her patient, render that justification inadequate.

Refusal clauses and denials of care undermine standards of care by allowing or requiring health care professional to abrogate their responsibility to deliver services and information that would otherwise be required by generally accepted practice guidelines. Informed consent, a key tenet of professional ethics, means providing patients with the information they need to select among health care options. By allowing or requiring health care providers to offer patients incomplete information about treatment alternatives, public policies deny informed consent, undermine standards of care, and contribute to poor health outcomes. These denials disproportionately impact women's health care.

Attention to health care is critical because health status affects many other aspects of life. As noted by the *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research*, health care is unlike other commodities because good health is, by definition, important to well-being – relieving pain and suffering, restoring functioning, preventing death, and improving an individual's opportunity to pursue a life plan.<sup>26</sup> While there is some ability, through lifestyle and preventative measures, to influence individual health status, many health problems are inherent in life. In a society concerned with fairness and equality of opportunity and the redemptive powers of science, these considerations support the notion that health care is different from most other goods and services, and that equitable access to health care services is critical.

The standards of care help to establish parameters for fair access to health care. 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. Here, access means not only literal access to care, but access to consistent, quality care. If some health care professionals fail to provide information regarding and access to, specific types of health care based on factors other than patient need or scientific evidence regarding 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, The Cochrane Collaboration, and Royal College of Obstetricians and Gynaecologists 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.<sup>27-29</sup> All of these medical guidelines require that procedure selection is based on the patient's medical condition and preference.

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Catholic health care restrictions, however, take that decision out of the hands of patients and physicians and may prohibit some treatment options such as the use of medications to dissolve the pregnancy. This limit is based on the religious view that the use of such medications constitutes an abortion, even though an ectopic pregnancy will never result in a viable pregnancy. This restriction may deny the patient the least invasive and potentially best option to preserve her future fertility.

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. A physician whose clinical judgment about indicated tests, treatments, or referrals is determined by personal ideology eschews the provider's responsibilities in this relationship. And when physicians are prohibited from providing care in accordance with their clinical judgment, because of the ideology of the institution in which they are employed, patient care is also negatively affected. Just as physicians have faced pressures by managed care to limit patient care,<sup>30</sup> when a physician's conflict arises from personal ideology, his/her adherence to standards of care should assure protection of the fiduciary relationship between provider and patient.

### **Ideological Restrictions in Health Care**

Ideological restrictions are denials of care based on the provider's or providing institution's ideological, personal, or religious beliefs. Ideological restrictions are not governed by patient need, evidence, or medical conditions, and, in fact, they often directly contradict medical practice guidelines and the standard of care. These restrictions manifest in three ways:

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 objects on moral or religious grounds.
2. Institutional restrictions 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.
3. Political restrictions which are laws and regulations that are enacted based on political ideology or electoral politics to impose restrictions on what care can be delivered and how it must be delivered.

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## Refusal Clauses (also known as “conscience clauses”)

Refusal clauses or conscience clauses are statutory or regulatory “opt out” provisions that give health professionals and personnel permission to refuse to provide services that would otherwise be required under law or medical guidelines, and that shield them from liability for the consequences of their refusals. The first major refusal clauses were adopted in the 1970’s at the time of the Supreme Court decision *Roe v. Wade*.<sup>31</sup> The Church Amendment, named for its author, Senator Frank Church, allows individuals and institutions who receive federal funding to opt out of providing abortions or sterilizations, or refuse to allow them to be performed in their facilities.<sup>a</sup> Almost all states have similar refusal clauses pertaining to abortion and/or sterilizations. The Church Amendment also allows individuals to refuse to “perform or assist in the performance” of a health care service program or research activity to which they have a religious or personal moral objection.

Recently, however, much broader refusal clauses have been proposed and enacted that allow more personnel in health care settings to opt out of participating in almost any service to which they have a personal objection. For example, Mississippi has enacted one of the broadest refusal clauses in the nation.<sup>32</sup> The Mississippi statute allows a wide range of medical personnel, facilities, and health insurers to refuse to participate in any service to which they have an objection on religious, moral, or ethical grounds. Moreover, the statute limits the steps that a facility that offers the service can take to overcome the refusal, such as transferring the refuser or reassignment to a different shift, by framing the issue as one of “discrimination” against the refusing individual. For example, the statute allows a clerk to refuse to admit a patient for a service to which the clerk objects. In 2008, a number of new refusal statutes were introduced across the country: 8 states introduced statutes allowing health care workers to refuse to provide medical care generally (only Oklahoma’s law was enacted), 5 states pertaining to insurers, 11 for pharmacists, and 5 for facilities.<sup>33</sup>

In December 2008, under former President George W. Bush, the Department of Health and Human Services issued final regulations that would expand the legal protections afforded to a wide range of participants in the health care workforce including volunteers, framing any limitation on refusals as “discrimination.”<sup>34</sup> The regulations would allow health care workers in over 500,000 entities to refuse to participate in even tangential activities such as admitting, billing, and janitorial services. In February 2009, President Obama issued a proposed regulation to rescind the HHS regulations.<sup>35</sup> As of this printing, no decision has been made on the rescission.

At the federal level, The Weldon Amendment,<sup>36</sup> enacted in 2005 as an appropriation rider, prohibits “discrimination” by any federal agency or state or local government against an entity or individual who refuses to provide, pay for, provide coverage for, or provide referrals for abortion services. The Weldon Amendment attempts to limit the ability of federal, state, and local laws to increase access to and referral for abortion services.

a The Church Amendment also prohibits institutions from discriminating against providers who *do* perform abortions and sterilizations.

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## POLICIES ALLOWING PROVIDERS TO REFUSE

STATE	ABORTION		CONTRACEPTION				STERILIZATION	
	Individual Providers	Institutions	Individual Providers	Pharmacists	Pharmacies	Institutions	Individual Providers	Institutions
Alaska	X	Private						
Arizona	X <sup>ψ</sup>	X <sup>ψ</sup>	§	§	§	§		
Arkansas	X	X	X	X	*	Private	X	X
California	X	Religious		†				
Colorado	X	X	X	*	*	Private		
Connecticut	X							
Delaware	X	X						
Florida	X	X	X	*				
Georgia	X	X		X			X	X
Hawaii	X	X						
Idaho	X	X					X	X
Illinois	X	Private	X	*	‡	X	X	X
Indiana	X	Private						
Iowa	X	Private						
Kansas	X	X					X	X
Kentucky	X	X					X	
Louisiana	X	X						
Maine	X	X	X	*	*	Private		
Maryland	X	X					X	X
Massachusetts	X	X				Private	X	Private
Michigan	X	X						
Minnesota	X	Private						
Mississippi	X	X	X	X	X	X	X	X
Missouri	X	X						
Montana	X	Private					X	Private
Nebraska	X	X						
Nevada	X	Private						
New Jersey	X	Private			Φ	Private	X	Private
New Mexico	X	X						X
New York	X							
North Carolina	X	X						
North Dakota	X	X						
Ohio	X	X						
Oklahoma	X	X						
Oregon	X	Private						
Pennsylvania	X	Private					X	Private
Rhode Island	X						X	
South Carolina	X	Private						
South Dakota	X	X		X				
Tennessee	X	X	X	*	*	Private		
Texas	X	Private						
Utah	X	Private						
Virginia	X	X						
Washington	X	X	X		Ω	X	X	X
West Virginia							X	X
Wisconsin	X	X			‡		X	X
Wyoming	X	Private						
<b>TOTAL</b>	<b>46</b>	<b>43</b>	<b>8</b>	<b>4</b>	<b>1</b>	<b>9</b>	<b>16</b>	<b>15</b>

Source: Guttmacher Institute, printed with permission

Note: Unless indicated, the right to refuse applies to all institutions— private, religious and public.

§ Temporarily enjoined; law not in effect pending the outcome of litigation.

ψ An expansion of the state's abortion refusal clause is temporarily enjoined pending the outcome of litigation; the prior law is in effect.

\* A broadly worded refusal clause may apply.

† Pharmacists have a duty to dispense valid prescriptions and can only refuse to dispense a prescription, including contraceptives, when their employer approves the refusal and the woman can still access her prescription in a timely manner.

‡ State law requires pharmacies to fill valid contraceptive prescriptions.

Φ Pharmacies have a duty to fill valid prescriptions.

Ω The policy in Washington requires pharmacies to dispense valid prescriptions and deliver FDA-approved drugs, such as Plan B. Only the plaintiffs in an ongoing court case are exempt from the policy with regard to emergency contraception.

Refusal clauses related to contraception have been highly publicized. A number of states have introduced and are enacting laws requiring emergency rooms (ERs) to offer and provide emergency contraception (EC) to survivors of sexual assault. EC can prevent pregnancy if taken within 120 hours of unprotected sex. Although the provision of EC is the accepted medical standard of care in rape treatment, not all hospitals are meeting that standard. A number of states have enacted legislation to enforce the standard of care. At the same time, however, many of these “EC in the ER” bills include refusal clauses which range from very narrow exceptions that include requirements for counseling and referral, to very expansive “opt-out” provisions for both individual providers and institutions.<sup>37, 38</sup>

The newest wave of refusal clauses are laws that allow pharmacists to refuse to fill prescriptions for contraceptives, both regular birth control designed to prevent pregnancy prior to sexual intercourse and emergency contraception which prevents pregnancy after unprotected sex.<sup>39</sup>

### Institutional Restrictions

The largest group of restrictions, and the ones that have the greatest impact on access to care, are imposed by institutions controlled by religious entities. Several religions’ doctrines restrict the provision of reproductive health services. The largest religiously-controlled health systems are Catholic, Adventist, Baptist, Lutheran, and Methodist.

The Catholic health systems are the only ones to have a hierarchical system of rule-making and enforcement which is maintained through their relationship to the local Bishop, the United States Conference of Catholic Bishops, and ultimately to the Vatican.<sup>40</sup>

As such, the broadest religiously-based health care restrictions are those imposed by Catholic health systems which control 15 percent of the hospital beds in the United States, and 20 percent of hospital admissions in 20 states and the District of Columbia.<sup>41</sup> The four largest Catholic hospital systems reported nearly \$29 billion in net patient revenues in 2006.<sup>42</sup> Most of the patients served in these facilities are not themselves of the Catholic faith or adhere to the doctrine as enforced by the Catholic bishops.

Catholic health facilities are governed by the Ethical and Religious Directives for Catholic Health Care Services (The Religious Directives), promulgated by the U.S. Conference of Catholic Bishops. The Directives present “a theological basis for the Catholic health care ministry.”<sup>40</sup> The Directives govern the way health care is delivered in Catholic health facilities and systems, and apply in Catholic hospitals, clinics, and managed care organizations. They are also often incorporated into lease agreements for medical offices owned

*Kathleen Brownfield was raped. She was taken to Daniel Freeman Marina Hospital in Los Angeles, then operated by the Sisters of Carondelet, whose staff did not provide her information about or offer her any means to prevent becoming pregnant from the rape. She sued the hospital, and the hospital argued that emergency contraception is an abortion and that they were shielded from liability under California’s abortion refusal clause. In *Brownfield v. Daniel Freeman Marina Hospital*, the Court found that emergency contraception is not an abortifacient, and that the hospital would have been liable if Ms. Brownfield had become pregnant (which fortunately for her, she did not).<sup>43</sup>*

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**1 in 6 Americans  
are treated in  
Catholic Hospitals  
each year.**

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by Catholic entities, restricting the services private physicians can offer in their offices. Physicians must agree to abide by the Directives to obtain admitting privileges at Catholic hospitals, and other health care workers are contractually bound by them as a condition of employment. The Religious Directives specify a range of services that are prohibited including abortion, contraceptives, sterilization, and most forms of assisted reproductive technology such as in vitro fertilization (IVF). The Directives also limit the treatment options for ectopic pregnancy and to prevent pregnancy as a result of sexual assault.

The Directives substitute religious doctrine for the standard of care, and there are no exceptions for rape, incest, the health or life of the person, medical necessity, or the informed decision of the patient. The prohibition on abortion extends beyond elective abortions, and applies to the direct termination of any pregnancy, even when the pregnancy is putting the woman's health or life at risk. Under the Directives, treatment options are not subject to patient control or physician recommendation.

There is considerable variation among hospitals in how the Directives are applied; some are quite literal in interpreting the Directives, while others are less restrictive in their enforcement. Most of the variations are driven by the local Bishop, others by market forces. Some result from disagreement among theologians about the proper interpretation of the Directives, and some by the quiet provision of some prohibited services on a case by case basis.

For example, in some Catholic hospitals, physicians may perform sterilizations if they document a medical necessity in the patient's medical record. In those hospitals, it is often known that some physicians may construct a medical reason in order to obtain permission to perform a voluntary sterilization.<sup>44</sup> At St. Louise Medical Center in Gilroy, California, a very small number of sterilizations are allowed but only if the physician applies for approval directly to the Archdiocese.<sup>45</sup>

Other religious restrictions may apply at some Adventist and Mormon institutions. The Adventist position on abortion is to generally discourage abortion but not to prohibit it in all cases. "Abortion is never an action of little moral consequence. Thus prenatal life must not be thoughtlessly destroyed. Abortion should be performed only for the most serious reasons."<sup>46</sup> Similar guidance is offered on pre-implantation genetic diagnosis (PGD) and abortion following prenatal diagnosis.<sup>46</sup> On this basis, many Adventist hospitals do not provide abortions.

Patients and communities are further disadvantaged when institutions fail to provide accurate information about the services that are restricted. There are no requirements that health facilities inform patients, and the names of hospitals often do not indicate their religious affiliation, for example West Suburban Medical Center in Chicago or Santa Rosa Memorial Hospital in California, which are Catholic-owned. California is the only state that requires managed care organizations to inform their members that some institutions restrict services, but the patient still has to contact the plan in order to get specific information.<sup>47</sup>

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Patient care in religiously-based institutions, therefore, is largely unpredictable and is ultimately compromised when neither patients nor communities have accurate information about available services and access to medical interventions according to the standards of care.

Other types of institutional refusal clauses allow insurers and managed care organizations to refuse to provide coverage for services. Several states prohibit insurance coverage of abortion unless the buyer has purchased a separate rider for abortion care. In 2007, Michigan lawmakers considered a refusal clause that would allow insurers to refuse to provide coverage for any service to which the insurer objects.<sup>48</sup> Deseret Mutual Benefit Administration, controlled by the Mormon Church, will not cover sterilization unless a married woman already has five children.<sup>49</sup> Managed care refusals are especially problematic when refusing organizations are part of state-funded health care such as Medicaid. In New York, FidelisCare is a Catholic managed care organization contracted to provide Medicaid.<sup>50</sup> Due to its religious affiliation, the organization is allowed to legally refuse to provide family planning services or to offer referrals. These refusals limit women's access to services they need and to which they are entitled under Medicaid.

Recognizing that abortion services are essential to quality patient care, the Accreditation Council for Graduate Medical Education (ACGME) requires OB/GYN residency programs to offer abortion training. Typically, Congress supports the accrediting bodies like the ACGME by refusing to provide funding to training programs that do not meet their program requirements. In this case, however, a federal refusal clause prohibits the federal government from withholding funding if a program is not accredited solely because it does not offer abortion training. The refusal clause undermines the ACGME's ability to enforce a professional standard and treats abortion training differently than other aspects of professional development.

### **Political Restrictions**

Many restrictions on access to health care, particularly when it comes to reproductive health, are enacted by federal and state legislatures and agencies. These restrictions derive from political ideology, electoral politics, and other political considerations that have nothing to do with evidence-based medicine. These restrictions are seen most often in abortion services.

Laws and regulations impose particular burdens on abortion clinics such as what types of equipment they must have or how wide the hallways may be, that are not imposed on other health clinics and facilities.<sup>51</sup> Other laws interfere with the doctor-patient relationship<sup>52</sup> by requiring physicians to perform unnecessary ultrasounds on abortion patients, or imposing waiting periods that are not governed by medical necessity. Laws impede low income women's access to care by restricting public funding for reproductive services.<sup>53</sup> For example, the federal Hyde Amendment severely limits Medicaid funding for abortions, while Oklahoma state law prohibits abortions in hospitals that receive public funding.<sup>54</sup>

## Informed Consent

Informed consent - disclosure of information about what will happen to the patient so that s/he can competently and voluntarily make a decision about whether or not to undergo the advised intervention<sup>55,56</sup> – is at the core of the individual's right to make his or her own decisions about medically appropriate health care.<sup>57</sup> This right relies on two factors: access to relevant and medically accurate information about treatment choices and alternatives, and provider guidance 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."<sup>58</sup>

***Refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent...***

In recent decades, the U.S. medical community has primarily looked to informed consent as key to assuring patient autonomy in making decisions.<sup>55,59</sup> Informed consent is intended to help balance the relationship between health providers and patients, in which only patients authorize specific interventions. Moreover, consent is not a yes or no question but rather is dependent upon the patient's understanding of the procedure that is to be conducted. Disclosure of medical information is an essential component of the provider-patient relationship, and is embedded in medical and research codes.<sup>55</sup> Various state and federal laws require that health care professionals inform and counsel patients on specific issues such as preventing the spread of HIV/AIDS, non-directional information on family planning and abortion options, and emergency contraception to prevent pregnancy from rape.<sup>60</sup> Informed consent involves providing the patient with a range of options that fall within professionally-defined standards of care. The patient uses this information to select from the available options or refuse treatment altogether.<sup>61,62</sup> The principle of informed consent does not require providers to render services that fall outside accepted standards of care or draw on limited resources, even if patients request them.<sup>63</sup>

Informed consent has come to be associated with disclosure of the following six items to the patient or their guardian: 1) diagnosis, 2) nature and purpose of the proposed treatment, 3) risks and consequences of the proposed treatment, 4) probability that the proposed treatment will be successful, 5) feasible treatment alternatives, and 6) prognosis if the proposed treatment is not given.

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."<sup>55</sup>

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.”<sup>64</sup>

The American Pharmaceutical Association code of ethics specifically calls on the pharmacist to respect the autonomy and dignity of each patient.<sup>65</sup>

## Restrictions on Patients’ Ability to Give Informed Consent

Refusal clauses and institutional restrictions can operate to deprive patients of the complete and accurate information necessary to give informed consent, and as a consequence can rob patients of their autonomy. Informed consent under the Catholic Religious Directives acknowledges the responsibility of health care providers to discuss treatment options with their patients, but limits the information about treatment alternatives to those considered “morally legitimate” within Catholic religious teachings.<sup>40</sup>

### **DIRECTIVE 26.**

**Free and informed consent requires that the person or the person’s surrogate receive all reasonable information about the essential nature of the proposed treatment and its benefits; its risks, side-effects, consequences, and cost; and any reasonable and morally legitimate alternatives, including no treatment at all.**<sup>40</sup>

### **DIRECTIVE 27.**

**Each person or the person’s surrogate should have access to medical and moral information and counseling so as to be able to form his or her conscience. The free and informed health care decision of the person or the person’s surrogate is to be followed so long as it does not contradict Catholic principles.**<sup>40</sup>

Referrals for prohibited services are also at issue. Fr. Kevin O’Rourke, a Catholic bio-ethicist, emphasizes that to make a referral for an abortion, for example, is to cooperate in “the performance of an evil act.”<sup>66</sup> Similarly, Karen Brauer, president of Pharmacists for Life International, says referring a patient for emergency contraceptive pills is “...like saying, ‘I don’t kill people myself but let me tell you about the guy down the street who does.’” She equates referring a patient, a crucial part of health care, to being an accessory to a crime.<sup>67</sup>

A recent survey by researchers Curlin et. al. asked 2000 physicians their opinions regarding their ethical rights and obligations when conflicts arise over treatments to which they object on moral grounds. In stark contrast to the American Medical Association’s ethical standards on informed consent, the researchers found that 63 percent of physicians thought it ethically permissible to tell patients about their personal objections to a particular health care service. Given the imbalance of power between physicians and patients,

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such disclosures violate the requirement to present medical facts that are unbiased and evidence-based. In addition, many physicians do not believe they are obligated to inform patients about services to which the physician has a personal objection. Fourteen percent did not think a doctor had an obligation to present all options to a patient or were undecided; only 56 percent of self-described “religious” physicians felt that physicians are obligated to disclose all possible options. Finally, 29 percent did not think a physician had an obligation to make a referral for the objected service or were undecided.<sup>19</sup>

In the *Brownfield* case, noted above, the Court also addressed access to information about emergency contraception. The Court found that:

“The duty to disclose such information arises from the fact that an adult of sound mind has ‘the right, in the exercise of control over [her] own body, to determine whether or not to submit to lawful medical treatment.’ [citation omitted] Meaningful exercise of this right is possible only to the extent that patients are provided with adequate information upon which to base an intelligent decision with regard to the option available.”<sup>68</sup>

Some statutory refusal clauses also allow providers to opt out of providing counseling, information, and referrals. These refusals shield providers from complying with legal and ethical mandates regarding informed consent and the requirement to inform patients of all reasonable treatment options. The Mississippi refusal clause prohibits “discrimination” against medical personnel who refuse to “counsel, advise...refer” for a service to which they object.

The Balanced Budget Act of 1997 prohibits “gag rules” in which Medicaid managed care organizations prohibit providers from discussing treatment options that might not be covered by the plan, but it also contains a broad refusal clause that essentially allows managed care organizations that serve the Medicaid population to impose their own gag rules by opting out of “provid[ing], reimburs[ing] for, or provid[ing] coverage of, a counseling or referral service if the organization objects to the provision of such service on moral or religious grounds.”<sup>69</sup> As a result, many women of childbearing age are mandatorily enrolled in Medicaid plans that refuse to provide Medicaid-covered services that are central to their health care, and most importantly, they are not given information or referrals on how to obtain these services. Low-income women in particular are harmed by denials of care because they may be unable to locate or pay for alternative sources of care, or to afford transportation, child care, or time off of work to travel to another location where care might be available.

The American Bar Association (ABA) has adopted a 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.”<sup>70</sup>

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## Political Restrictions on Informed Consent

Some states require physicians to tell women that abortion has negative psychological effects,<sup>71</sup> a claim that contradicts the American Psychological Association's empirically-grounded position on abortion outcomes.<sup>72</sup> These restrictions subvert the critical legal and ethical principles of informed consent by requiring physicians to provide biased and misleading information to patients about the abortion procedure and its health effects.<sup>52</sup>

## Conclusion

The Institute of Medicine's influential *Crossing the Quality Chasm* report (2001) identifies the new paradigms of evidence-based medicine and patient-centered care as explicit means for achieving better health outcomes among individual patients and the U.S. population. Complementing these approaches is the commitment to prevention that has moved from public health to mainstream medicine. Quality of care is undermined when a full range of medically appropriate services are not available to patients because institutions or individuals object to providing a particular service based on religious doctrine or ideology. Longstanding legal and ethical requirements for informed consent go unmet when patients are denied full and accurate information.

Contrary to the trends in modern health care delivery, health care refusals and institutional denials of care grounded in personal and religious beliefs rather than scientific evidence negate evidence-based practice, patient-centered care, and prevention. The patient's needs and preferences are made invisible, and she may lack the information necessary to make informed decisions. Last, institutional restrictions prohibit health care professionals from meeting the standards of their profession and their patients' needs.

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***Contrary to the trends in modern health care delivery, health care refusals and institutional denials of care... negate evidence-based practice, patient-centered care, and prevention.***

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## Research Methodology

The research for this project comes from a number of sources including the medical practice guidelines and consensus documents of major professional medical associations, the policies adopted by religiously-owned health care institutions, and writings of major relevant content experts and ethicists. All errors are those of the authors.

### Advisory Board

The Standards of Care Project assembled a national Advisory Board composed of renowned medical professionals from around the country who have expertise in a range of medical specialties related to reproductive health. A full list of Advisory Board members is found in the Acknowledgments. The Advisory Board provided input and advice in developing the framework, medical conditions to be addressed, and other aspects of the content of the report. They also offered their expertise and suggested additional resources as needed.

### Selection of Medical Conditions

The medical conditions addressed in this report were chosen based on several factors. Issues related to reproductive health were selected since these conditions are most often contested in the public arena. Specific conditions where conflicts over care have been reported were prioritized. In addition, conditions were selected where substantive reviews of the evidence in the medical literature had been undertaken by professional organizations.

### Review of the Medical Literature

The focus of this report is on standards of care, or professionally agreed-upon practices. Unlike “best practices” that focus on the highest level of care a patient can receive, standards of care establish a baseline of health care provision that is accepted by the profession and codified in professional policies and position statements. This report contains examples of conditions for which pregnancy is a major risk factor and for which abortion and contraception are necessary to meet standards of care. Undertaking an exhaustive search of the published literature regarding each of these conditions is beyond the scope of this report. Rather, this report compares institutional and personal refusals with the professionally-determined standard of care for specific medical conditions. To determine the standards of care, the authors reviewed published guidelines of the leading health professional and medical societies in the U.S. and Western Europe:

- The American College of Obstetricians and Gynecologists ([www.acog.org](http://www.acog.org))
- The American Medical Association ([www.ama-assn.org](http://www.ama-assn.org))
- The Royal College of Obstetricians and Gynaecologists of the United Kingdom ([www.rcog.org.uk](http://www.rcog.org.uk))
- The World Health Organization ([www.who.int/en](http://www.who.int/en))
- The Cochrane Collaboration (which provides reviews of evidence-based medical interventions) ([www.cochrane.org](http://www.cochrane.org))
- The U.S. Preventative Health Services Task Force ([www.ahrq.gov/CLINIC/uspstfix.htm](http://www.ahrq.gov/CLINIC/uspstfix.htm))

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- The Centers for Disease Control and Prevention ([www.cdc.gov](http://www.cdc.gov))
  - Additional medical association guidelines relevant to reproductive health

To establish guidelines, professional associations conduct a thorough review of the published literature using Medline and various searchable databases. Several independent reviewers then aggregate those studies by conducting a sort of meta-analysis in which they weigh each study's findings based on the strength of the study design. The associations distribute guidelines to their members and to the public on their websites and as part of professional membership.

A summary of the accepted standard of care for treatment of the medical conditions was drafted and presented to the project's Advisory Board for review and feedback. As directed, the summary was modified and additional resources were reviewed. In addition, Advisory Board members reviewed subsequent drafts of the report for accuracy, clarity, and completeness. Additional external reviewers provided their input and expertise.

### **Review of the Literature on Refusal Clauses**

To determine the type of restrictions imposed on medical practice, the authors reviewed official policy of the U.S. Conference of Catholic Bishops, essays by respected theologians about the way in which religious restrictions are interpreted, and health care policies of health systems as posted on their websites. To examine the laws and regulations that include refusal clauses, the authors reviewed publications of national organizations with expertise in this area.

Information was drawn from the policies, publications and writings of the following sources:

- The largest secular and religiously-owned health care systems as determined by Modern Health Care ([www.modernhealthcare.com](http://www.modernhealthcare.com))
- Catholic Health Association of the United States ([www.chausa.org](http://www.chausa.org))
- United States Conference of Catholic Bishops ([www.usccb.org](http://www.usccb.org))
- National Catholic Bioethics Center ([www.ncbcenter.org](http://www.ncbcenter.org))
- Theological scholars of the Ethical and Religious Directives for Catholic Health Care Services (see Frs. Kevin O'Rourke and Thomas J. O'Donnell)
- The Protection of Conscience Project ([www.consciencelaws.org](http://www.consciencelaws.org))
- The Guttmacher Institute ([www.guttmacher.org](http://www.guttmacher.org))
- The Reproductive Freedom Project of the American Civil Liberties Union ([www.aclu.org/reproductiverights](http://www.aclu.org/reproductiverights))
- Catholics for Choice ([www.catholicsforchoice.org](http://www.catholicsforchoice.org))
- MergerWatch ([www.mergerwatch.org](http://www.mergerwatch.org))
- National Women's Law Center ([www.nwlc.org](http://www.nwlc.org))

In addition, the experiences of patients confronted with denials of care and of health care providers barred from providing various health care services were documented through ongoing research projects, or drawn from news publications and other published writings.

## Chapter Two **Pregnancy Prevention**

### Overview

In 2006, nearly half of all American women were at risk of an unintended pregnancy: that is,<sup>73</sup> 2 million women were between the ages of 13 – 44, sexually active with a male, capable of becoming pregnant, and neither pregnant nor seeking to become pregnant. Seventeen and a half million women needed publicly-funded contraceptive services because of their age or income.<sup>73</sup> According to the Centers for Disease Control and Prevention (CDC), contraceptive use is nearly universal in women who are sexually active with a male partner. In 2002, 90 percent of women had, at some time, a male partner who used a condom, and 82 percent had used oral contraceptives in their lifetime.<sup>74</sup>

**There are many medical conditions for which pregnancy prevention is an important component of disease management.**

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, or some forms of cardiovascular disease, pregnancy may worsen a woman's condition. The CDC reports that three percent of the women who could potentially become pregnant are taking teratogens, drugs that can cause severe fetal impairments.<sup>75</sup> Medical practice guidelines for the use of many pharmaceuticals require that women not become pregnant during their course of treatment.

Standards of care require that providers offer women with some health conditions or those taking teratogenic medications the information and services necessary to prevent pregnancy. Institutional prohibitions and individual denials interfere with patient care and may result in adverse medical consequences and health care that violates medical standards.

### Women's Decisions to Prevent Pregnancy

Women decide to prevent or postpone pregnancy for many reasons. The U.S. Supreme Court in *Planned Parenthood v. Casey*<sup>76</sup> recognized the importance of women's ability to make decisions about when and whether to have a child: "The ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives."

The ability to control their reproductive lives and to become a parent when they have made an affirmative decision to become pregnant is fundamental to women's ability to get an education and to be economically self-sufficient. Children also benefit from women's control over reproduction; children born from wanted pregnancies tend to be more healthy than those born from unwanted pregnancies.<sup>77</sup> In addition, women take into account factors such as age, the presence of a partner, medical condition, mental health, and whether they are taking medications that are contra-indicated for pregnancy.

The importance of women's ability to prevent pregnancy for many reasons is well-established within the medical guidelines across a range of practice areas. In 2001, 49% of pregnancies in the United States were unintended – meaning that they were

either unwanted or mistimed.<sup>78</sup> Unintended pregnancy is often a consequence of poverty. Low-income women have higher rates of unintended pregnancy as they are least likely to have the resources to obtain reliable methods of family planning, and yet, they are most likely to be impacted negatively by unintended pregnancy.<sup>79</sup> The Institute of Medicine has documented negative health effects of unwanted pregnancy for mothers and children. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors as well as low-birth weight babies and insufficient prenatal care.<sup>80</sup>

Access to family planning information and supplies is essential to optimal women's health. Family planning is a focus area of the Healthy People 2010 health promotion objectives set out by the U.S. Department of Health and Human Services. Goal 9 of Healthy People 2010 is, "Improve pregnancy planning and spacing and prevent unintended pregnancy." Specific indicators include increasing intended pregnancies from 51 percent to 70 percent; increasing pregnancy spacing to 24 months; increasing the proportion of women at risk for unintended pregnancy who use contraceptives to 100 percent, and increasing the proportion of teens who use contraceptive methods that both prevent pregnancy and prevent sexually transmitted disease.<sup>25</sup>

The World Health Organization recommends that pregnancies should be spaced at least two years apart.<sup>81</sup> Pregnancy spacing allows the woman's body to recover from the pregnancy, and if she becomes pregnant while breastfeeding, the health of both her baby and fetus may be compromised as her body shares nutrients between them. According to the American College of Obstetricians and Gynecologists (ACOG), women who become pregnant less than six months after their previous pregnancy are 70 percent more likely to have membranes rupture prematurely and are at a significantly higher risk of other complications.<sup>82</sup> The CDC/Agency for Toxic Substances and Disease Registry(ATSDR) Preconception Care Work Group and the Select Panel on Preconception Care highlighted the numerous poor health outcomes including low birthweight, premature birth, and infant mortality which result when health conditions are not optimized prior to pregnancy.<sup>75</sup> To maximize preconception health, the ACOG Guidelines for Women's Health Care recommend that every physician encounter with a patient should include a reproductive health screen including counseling about the need for family planning and options for contraception.<sup>83</sup>

Although contested in the field of politics, pregnancy in the field of medicine has long been defined as "the implantation of a fertilized ovum."<sup>84</sup> Current methods for preventing pregnancy include hormonal contraceptives (such as pills, patches, rings, injectables, implants, and emergency contraception), barrier methods (such as male and female condoms, cervical caps, contraceptive sponges, and diaphragms), intrauterine contraception (IUC), and male and female sterilization. The mechanisms of action differ between methods with some methods working in multiple ways. These mechanisms include preventing ovulation, fertilization of the egg, and/or implantation of the fertilized egg. The wide range of pregnancy prevention options allows a woman to choose the most effective method for her lifestyle and health status.<sup>85</sup> Pregnancy can also be prevented through sustained abstinence.

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***Unwanted pregnancy is associated with maternal morbidity... low-birth weight babies and insufficient prenatal care.***

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## Drugs that Significantly Impair the Developing Fetus

A number of commonly prescribed pharmaceuticals are known to cause impairments in the developing fetus or to create adverse health conditions if a woman becomes pregnant while taking them. 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.

The FDA has categorized drugs as Pregnancy Classes A and B (there is no evidence of harm to the fetus in humans), Class C (there are not adequate studies on harm to the fetus in humans), Class D (there is evidence of fetal harm, but the potential benefit may be acceptable despite the harm), and Class X (contraindicated in women who are or may become pregnant).<sup>86</sup> 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 a significant women of reproductive age in the U.S. every year.<sup>87,b</sup> See Appendix A for a list, which is not exhaustive, of 168 of these drugs.

Following are some examples of commonly prescribed drugs for which pregnancy is a serious risk factor for maternal health and/or the health of the fetus. In these cases practice guidelines and medical standards dictate that physicians should provide their patients with complete and accurate information about the risks of pregnancy and advise them on effective methods to prevent pregnancy.

### Drugs to treat severe acne: Isotretinoin (Accutane®)

The CDC considers use of the drug isotretinoin as a risk for adverse pregnancy outcomes. Isotretinoin is a manufactured form of Vitamin A available only by prescription to treat severe, disfiguring cystic acne that has not responded to other treatments.<sup>88</sup> Isotretinoin, the generic name, is sold under the brand name Accutane® or as a generic under the names Amnesteem, Claravis, and Sotret.<sup>89</sup>

Isotretinoin is a known human teratogen – an element that can cause multiple major fetal impairments, such as craniofacial, cardiac, thymic, and central nervous system malformations.<sup>90</sup> Isotretinoin is associated with a pattern of fetal impairment in more than 35 percent of infants whose mothers take the drug during pregnancy. Many children who were exposed in utero also will have moderate to severe mental disabilities, and the long term effects on an exposed child are still unknown.<sup>88</sup> Isotretinoin is also associated with up to a 40 percent risk of having a miscarriage, and premature births have also been reported.<sup>91</sup> While not every fetal exposure to isotretinoin has resulted in a fetal impairment, there is no accurate way to determine whether an exposed fetus has been affected.<sup>91</sup>

The concerns about Accutane® are so significant that the FDA initially posted this strong warning to women on its website:

b In May 2008, the FDA issued a proposed rule to replace the A-X system with an analysis of each drug in the context of pregnancy and lactation by addressing (1) fetal risk summary, (2) clinical considerations, and (3) data.

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“You must not become pregnant while taking Accutane, or for 1 month after you stop taking Accutane. Accutane can cause severe birth defects in babies of women who take it while they are pregnant, even if they take Accutane for only a short time. There is an extremely high risk that your baby will be deformed or will die if you are pregnant while taking Accutane. Taking Accutane also increases the chance of miscarriage and premature births.”<sup>92</sup>

The FDA later determined that warning was not sufficient, and approved a strengthened risk management plan, called iPLEDGE, to ensure that female patients do not become pregnant while taking this drug.<sup>93</sup> As of March 1, 2006, only registered and active iPledge providers and pharmacists are able to prescribe and dispense isotretinoin and only patients registered and qualified in iPLEDGE can receive the medication. Female patients of childbearing potential 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.<sup>91</sup>

### **Drugs to treat cardiovascular disease: Warfarin (Coumadin®)**

Warfarin is a medication used to prevent blood clots from forming or growing larger in the blood and blood vessels. Warfarin is in a class of medications called anticoagulants (known as “blood thinners”). It is prescribed for people with certain types of irregular heartbeat, people with prosthetic (replacement or mechanical) heart valves, and people who have suffered a heart attack. Warfarin is also used to treat or prevent venous thrombosis (swelling and blood clot in a vein) and pulmonary embolism (a blood clot in the lung). It works by decreasing the clotting ability of the blood.

Warfarin is not recommended for pregnant women because it crosses the placenta (is transmitted from mother to child) resulting in an increased risk of developmental disorders in the embryo, or spontaneous abortion, prematurity and stillbirth.<sup>94</sup> An alternative to Warfarin may be Heparin, but Heparin comes with risks as well including an increased risk of maternal hemorrhage or prosthetic valve thrombosis. The American College of Cardiologists (ACC) and the American Heart Association (AHA) recommend that Warfarin therapy be avoided during the first trimester of pregnancy and, except in special circumstances, that it be avoided entirely throughout pregnancy.<sup>95</sup> Physicians and patients are advised to discuss these associated risks before conception because some women may decide to terminate their pregnancies.<sup>96</sup>

### **Drugs to treat epilepsy**

Epilepsy is defined by the presence of recurrent unprovoked seizures, and treatment typically consists of a daily anti-epileptic drug regime.<sup>97</sup> An estimated one half million U.S. women with epilepsy are of childbearing age<sup>98</sup> and anti-epileptic/anti-seizure drugs have the potential to affect an estimated 75,000 pregnancies.<sup>99</sup> Because certain anti-epileptic drugs are known teratogens, the Centers for Disease Control and Prevention recommends that before conception, women who are on a regimen of these drugs and who are

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contemplating pregnancy should be prescribed a lower dosage of these drugs.<sup>75</sup> Caring for pregnant women with epilepsy thus requires carefully balancing the need to prevent seizures while also minimizing fetal exposure to drugs used to treat pregnancy.<sup>100</sup> The American Academy of Neurology recommends that women be informed that being seizure free for nine months prior to pregnancy is associated with high likelihood of remaining seizure free during pregnancy.<sup>96</sup> A review article published in BJOG, the international journal of the Royal College of Obstetricians and Gynaecologists argues that pre-pregnancy planning must address reliable contraception.<sup>101</sup>

### **Drugs to treat thyroid disease**

Thyroid disease is the second most common endocrine disease facing women of reproductive age. It affects over two million Americans, most of whom are women.<sup>102</sup> 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. 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.<sup>102</sup>

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. The 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.<sup>102</sup>

### **Drugs to treat major depression**

Pregnancy prevention plays an important role in pre-conception care of women with depressive disorders. The American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients with Major Depression recognizes that major depressive disorders occurring during pregnancy are difficult therapeutic problems. Consequently they conclude that whenever possible, a pregnancy should be planned in consultation with the psychiatrist so that, if feasible, medication may be discontinued before conception.<sup>103</sup> The Expert Consensus Guideline Series recommendations, developed by a survey of leading experts in the area of women's mental health regarding the management of depression during conception and pregnancy, state that a woman with a history of mild depression who is taking antidepressants should avoid pregnancy for several weeks while tapering off the medication.<sup>104</sup> The APA Practice Guidelines concur.<sup>103</sup>

Notably, none of the commonly used antidepressant medications fall in the FDA's Pregnancy Risk Category A (controlled studies with human subjects showed no risk), and most antidepressants are classed in Category C (human studies are not available and animal studies either show risk or are unavailable) or X (contraindicated). Due to

the ethical problems in conducting clinical trials with pregnant human subjects, information regarding the safety of antidepressants during pregnancy and lactation is limited. As such, information and services to prevent unintended pregnancy are an integral component of patient care for women being treated with antidepressant medications.

The concerns about the drug paroxetine (Paxil® and Paxil CR®) illustrate the caution necessary in prescribing antidepressants for women seeking to conceive, in their first trimester of pregnancy, or at risk for unintended pregnancy. In December 2005, the FDA issued a public health advisory concerning paroxetine in pregnancy. According to the advisory, evidence from Swedish and American sources showed a 1.8 to 2-fold increase in congenital malformations (particularly cardiac malformations) among infants who were exposed to paroxetine in utero in the first trimester.<sup>105</sup> In 2006, the FDA issued another alert about selective serotonin reuptake inhibitors (SSRIs), including paroxetine, noting that infants born to mothers who took SSRIs after the 20th week of pregnancy were six times more likely to have persistent pulmonary hypertension than infants whose mothers did not take antidepressants while they were pregnant.<sup>106</sup>

## Preconception Management of Chronic Conditions

Millions of women live with chronic conditions such as cardiovascular disease, diabetes, lupus, and epilepsy, which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy. In 2005 the Centers for Disease Control and Prevention (CDC) hosted the first national summit on preconception health to address ways to improve birth outcomes and maternal health.<sup>107</sup> Subsequently the CDC released its *Recommendations to Improve Preconception Health and Health Care* which identified a range of conditions that should be addressed before pregnancy to improve pregnancy outcomes.<sup>99</sup> During “preconception care” (care prior to pregnancy) and “interconception care” (care between pregnancies) 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.<sup>99</sup> The following are examples of common chronic conditions for which pregnancy prevention is an essential element of preconception care.

### Pregestational Diabetes

People with diabetes either produce insufficient insulin or cannot properly use insulin. Insulin is a naturally occurring hormone in our bodies which helps glucose move from the blood stream into the cells to be used for energy production. This causes a build-up of glucose in the blood stream which can lead to damaged organs, blood vessels or nerves.<sup>108</sup> There are two types of diabetes, Type I and Type II. Type I diabetes typically occurs early in life and is caused by an auto immune defect. Type II has been associated with onset later in life in which a person does not produce sufficient insulin or whose insulin does not effectively transfer the glucose into the cells from the blood stream. Obesity and family history are among the major risk factors for Type II diabetes.<sup>109</sup>

***Millions of women live with chronic conditions... which if not properly controlled, can lead to health risks to the pregnant woman or even death during pregnancy.***

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The rate of diabetes among women under the age of 45 is 20.6 per 1,000, compared to 17.6 per 1,000 men of the same age, and large racial and ethnic disparities exist in rates of diabetes.<sup>109</sup> Diabetes in women that develops before they become pregnant is called pregestational diabetes mellitus. An estimated 10-18 percent of nonpregnant women of reproductive age have some type of abnormal glucose tolerance that would be associated with fetal or maternal risks if they became pregnant.<sup>110</sup> Pregestational diabetes occurs in approximately 1 – 14 percent of all pregnancies, relative to the prevalence of diabetes in the particular community.<sup>111</sup>

The failure to manage glucose levels during pregnancy can lead to serious complications for maternal and infant health. For women, this can mean an increased risk of hypoglycemia, blindness (from acute acceleration of diabetic retinopathy), renal failure (from diabetic nephropathy), complications from chronic hypertension, and life-threatening complications from coronary heart disease. Diabetic ketoacidosis, a life threatening condition, affects five to ten percent of all pregnancies in women with pregestational diabetes mellitus.<sup>111</sup> In addition, diabetic nephropathy occurs in 20-40 percent of patients with diabetes, and affects five to ten percent of pregnancies in women with diabetes.<sup>112</sup> It is one of the most significant complications of diabetes, and the leading cause of renal failure.

The American College of Obstetricians and Gynecologists and the American Diabetes Association have developed practice guidelines for the preconception care for women with pregestational diabetes. According to the American Diabetes Association, planned pregnancies greatly facilitate diabetes care. Their recommendations for diabetic women with childbearing potential include: 1) Use of effective contraception at all times, unless the patient is in good metabolic control and actively trying to conceive; 2) Counseling about the risk of fetal impairment associated with unplanned pregnancies and poor metabolic control; and 3) Maintain blood glucose levels as close to normal as possible for at least two to three months prior to conception.<sup>113</sup> New guidelines from the National Institute for Health and Clinical Excellence in the UK concurs: from adolescence onwards, women should be advised of the importance of avoiding unplanned pregnancy.<sup>114</sup> The American College of Obstetricians and Gynecologists further recommends that “[a]dequate maternal glucose control should be maintained near physiological levels before conception and throughout pregnancy to decrease the likelihood of spontaneous abortion, fetal malformation, fetal macrosomia [excessive birthweight], intrauterine fetal death, and neonatal morbidity.”<sup>111</sup>

The American Diabetes Association guidelines for preconception care of women with diabetes state that women with incipient renal failure should be counseled that more than 40 percent of patients experience permanent worsening of renal failure if they become pregnant.<sup>115</sup> Women with severe diabetic nephropathy can progress to end-stage renal disease. Worsening renal function is related to significantly higher risks for hypertensive disorders, uteroplacental insufficiency, and iatrogenic preterm birth for women with pre-existing diabetic nephropathy.<sup>111</sup> Poor preconception glucose control has been linked to congenital fetal impairment and to spontaneous abortion.<sup>111, 115</sup> Major impairments are the leading cause of perinatal mortality in pregnancies complicated by pregestational diabetes.

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## Cardiovascular Heart Disease

Heart disease is the number one cause of death for women in the United States.<sup>116</sup> Using data from the National Health Interview study, an estimated 2.5 million women ages 18-44 have some form of heart disease.<sup>117</sup> Cardiovascular disease is any disorder in the cardiovascular system, which consists of the heart and all the blood vessels in the body. Valvular heart disease embodies any dysfunction or abnormality of one or more of the heart's four valves (mitral, aortic, tricuspid, and pulmonic). These valves are a vital part of the heart and allow for the efficient flow of blood progressively forward through the heart's chambers, maximizing the efficiency of the heart muscles. Valvular disease may increase the maternal and fetal risks associated with pregnancy.<sup>96</sup>

The American College of Cardiology and the American Heart Association Task Force on Practice Guidelines issued specific recommendations for management of women with valvular heart disease.<sup>118</sup> They conclude that individualized preconception management should provide the patient with information about contraception as well as the maternal and fetal risks of pregnancy. Some cardiac conditions in which the physiological changes brought about in pregnancy are poorly tolerated include valvular heart lesions such as severe aortic stenosis, aortic regurgitation, mitral stenosis, and mitral regurgitation all with III-IV<sup>c</sup> symptoms, aortic or mitral valve disease, mechanical prosthetic valve requiring anticoagulation and aortic regurgitation in Marfan syndrome.

The European Society of Cardiology Guidelines recommend the use of contraception to avoid pregnancy while and until symptomatic and severe cardiovascular conditions can be addressed and rectified before a woman becomes pregnant. For example, cardiac valve surgery has significant risks during pregnancy. Replacement of a valve requires the use of anticoagulation drugs which present significant risks and problems to the mother and the fetus of either hemorrhage or thrombosis with the use of either warfarin or heparin. See the earlier discussion of the effect of these medications on fetal development.

Marfan syndrome is an inheritable disorder. It can cause spontaneous aortic dissection and/or rupture which can lead to death, and is the most feared cardiovascular complication associated with pregnancy. The American College of Cardiology and the American Heart Association Task Force on Practice Guidelines strongly recommend that any woman with Marfan Syndrome should be counseled against pregnancy.<sup>118</sup> The European Society of Cardiology Guidelines recommend that women with Marfan Syndrome who want to become pregnant should first be screened and carefully assessed with special testing and that the pros and cons of pregnancy should be fully discussed as well as alternatives including childlessness, adoption and surrogate pregnancy.<sup>119</sup>

Given the medical complexity associated with caring for women with heart disease, pregnancy prevention information, referral, and services are necessary components of clinical management for these patients.

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<sup>c</sup> Class III denotes conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful and in some cases may be harmful.

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## Major Depressive Disorder

Major depressive disorder affects approximately 14.8 million American adults.<sup>120</sup> It is the leading cause of disability in the U.S. for ages 15-44.<sup>121</sup> Major depressive disorder is also more prevalent in women than in men,<sup>122</sup> thus necessitating a greater concern for women of reproductive age. The lifetime risk of major depression is 20% to 26% for women and 8% to 12% for men.<sup>123</sup> Patients who experience one episode of major depression have a 60 percent chance of a second episode, and those who experience two episodes have a 70 percent chance of a third episode.<sup>124</sup>

For many women, pregnancy can be complicated by the occurrence or reoccurrence of a psychiatric condition. Experts agree that “Psychiatric disorders during pregnancy are associated with poor obstetric outcomes, higher risk of postpartum psychiatric illness, increased rates of substance abuse, lower participation in prenatal care, and adverse infant and family outcomes.”<sup>125</sup> As both depressive symptoms and antidepressant exposure are associated with poorer pregnancy and fetal outcomes, the presence of a depressive diagnosis must be considered separately from concerns simply about the teratogenic effect of the drugs.<sup>126</sup>

The Preconception Guidelines from the Centers for Disease Control and Prevention explicitly state that quality preconception care requires the screening for depression.<sup>99</sup> And new guidelines in the management of depression during pregnancy from the American Psychiatric Association and the American College of Obstetricians and Gynecologists conclude that it is ideal to evaluate a woman with a past or current depressive illness prior to conception.<sup>126</sup>

## Lupus

Lupus is an auto-immune disorder of unknown etiology which can affect multiple parts of the body such as the skin, joints, blood, and kidneys and with multiple end-organ involvement.<sup>127</sup> Lupus is a chronic inflammatory disease and causes the immune system to lose its ability to differentiate between its own cells and tissues and antigens. The body’s immune system responds by making antibodies directed against itself. For most people, lupus is a mild disease affecting just a few organs, but for others, it may cause serious and even life-threatening problems. Lupus symptoms typically vary over the course of the disease; a person can experience periods where her lupus is under control and she is relatively free of symptoms, and other periods called “lupus flares,” a worsening of symptoms signaling that the disease has become more active.<sup>128</sup>

Between 161,000 and 322,000 adults in the U.S. have lupus. Often labeled a “woman’s disease,” nine of 10 people with lupus are women. The incidence rate for African-American women is three times higher than for Caucasian women. Most women develop lupus during their childbearing years.<sup>128</sup>

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Women with lupus who become pregnant face particularly increased risks. A large review of U.S. hospital data found the risk of maternal death for women with lupus is 20 times the risk of non-lupus pregnant women. These women were 3-7 times more likely to suffer from thrombosis, thrombocytopenia, infection, renal failure, hypertension, and preeclampsia.<sup>129</sup> Women who suffer from moderate or severe organ involvement due to lupus are at significantly higher risk for developing complications during pregnancy, and the guidelines cited in the chronic disease sections of this report apply to women with those co-morbidities. As noted, this should be taken into consideration in the decision to become pregnant or to carry a pregnancy to term.<sup>130</sup>

Contraception plays a critical role in preparing a woman with lupus for pregnancy. Nearly one-fourth of pregnant women with lupus decide to terminate their pregnancies.<sup>131</sup> Historically, women with lupus were discouraged by the medical community from bearing children. While this is no longer always true, pregnancy for women with lupus is always considered high risk, and should be undertaken when, if at all possible, the disease is under control. The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) recommends that a woman should have no signs or symptoms of lupus and be taking no medications for six months before she becomes pregnant. In addition, NIAMS directs patients, “Do not stop using your method of birth control until you have discussed the possibility of pregnancy with your doctor and he or she has determined that you are healthy enough to become pregnant.”<sup>130</sup>

### **Obesity**

Obesity is defined as having a Body Mass Index (BMI) greater than 30.<sup>132</sup> Adverse perinatal outcomes associated with maternal obesity include neural tube defects, preterm delivery, diabetes, cesarean section, and hypertensive and thromboembolic disease. As a result, the Centers for Disease Control and Prevention Recommendations to Improve Preconception Health and Health Care recommends appropriate weight loss and nutritional intake before pregnancy to reduce these risks.<sup>99</sup> New recommendations from the Institute of Medicine state that to improve maternal and child health outcomes, women should be within a normal BMI range when they conceive.<sup>133</sup> Access to contraceptive services is an integral part of health care for the obese patient.

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***Women with lupus who become pregnant face particularly increased risks.***

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## Ideological Restrictions on Pregnancy Prevention

Although many practice guidelines require that women be given information about and access to contraceptives to prevent pregnancy, women face many barriers to contraceptive use including institutional restrictions, physician denials of care, cost, and pharmacists' refusals to fill prescriptions. Institutional restrictions and refusal clauses in particular operate to prevent women from obtaining complete and accurate contraceptive counseling, devices, and supplies.

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### Contraception

#### Institutional Restrictions

The Ethical and Religious Directives for Catholic Health Care Services (Religious Directives) directly prohibit any form of artificial contraception. "The Church cannot approve contraceptive interventions that 'either in anticipation of the marital act, or in its accomplishment or in the development of its natural consequences, have the purpose, whether as an end or a means, to render procreation impossible.'"<sup>40</sup> This prohibition extends to all forms of contraception including condoms, hormonal contraceptives, and permanent sterilization.

Vatican doctrine also prohibits sexual activity outside of marriage, and therefore all references to sexual activity are framed in terms of the "marital act." Within marriage, contraception is forbidden based on the view that the purpose of marriage is procreation. As the Rev. Paul F. deLadurantaye explains, "the conjugal union must take place with respect for its openness to procreation; and the procreation of a person must be the fruit and the result of married love."<sup>134</sup>

#### **DIRECTIVE 52:**

**Catholic health institutions may not promote or condone contraceptive practices but should provide, for married couples and the medical staff who counsel them, instruction on the Church's teaching on responsible parenthood and in methods of natural family planning.<sup>40</sup>**

In addition to a general prohibition on the provision of contraceptives by Catholic-controlled health entities, the Catholic hierarchy teaches that life, and, by implication, pregnancy, begins at the time of fertilization of the egg. As noted earlier, this is contrary to the medical definition of pregnancy as beginning at implantation of the egg in the uterus. By promoting a definition that does not conform with medical guidelines, the Bishops describe some forms of contraception as early abortions because they prevent the implantation of a fertilized egg.

The Religious Directives do not comport with medical standards that recommend pregnancy prevention for certain medical conditions. For example, a physician at Fidelis-Care, a Catholic HMO that abides by the Religious Directives, may tell a patient in the

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midst of a lupus flare that she should avoid pregnancy, but would be prohibited from also providing contraceptives or contraceptive counseling as required by medical guidelines. By shifting the burden to the patient to find a source of information about contraception and access to contraceptive services and supplies, the medical provider has not met the standard of care.

While one may not usually consider hospitals sources of contraception, hospital refusals to provide information about and access to contraception impact women on two levels: women are unable to directly obtain treatment they require, and health care professionals are unable to provide women the treatment they have deemed medically necessary. Examples include:

- Women who are hospitalized for any reason may not have access to their oral contraceptives while they are in hospital, putting them at risk for unintended pregnancy when they are discharged.
- Catholic hospitals that own and operate community clinics serving low-income women may refuse to allow counseling about contraceptive use and to provide family planning services or contraceptive commodities.
- Hospitals may prohibit nursing and other staff from providing medically accurate information about post-partum family planning. This undermines the professional ethic of informed consent by truncating the medical options available to patients.
- Physicians who lease offices in medical buildings owned by Catholic hospitals often have to agree to abide by the Ethical and Religious Directives on the premises as part of their office leases, and are thereby prohibited from prescribing contraceptives within the private practice setting.

All of these examples demonstrate how the institutional restrictions undermine providers' ability to uphold standards of care and meet patient needs.

### **Individual Refusals**

Health care providers – physicians, nurse practitioners and others with prescriptive authority may refuse to write prescriptions for contraceptives for women who need and want them. Women at risk for unintended pregnancy rely on their health providers for counseling on the appropriate means to avoid pregnancy.

Women may not be able to access the contraceptives they need at the pharmacy counter. A small but vocal national group of pharmacists are refusing to fill prescriptions for contraception and emergency contraception. Pharmacists For Life International organizes pharmacists to advocate for laws and policies that allow them to refuse to fill prescriptions for contraception, and to oppose laws and regulations that make contraceptives more widely available. They join with pro-life physicians in a belief that the pill acts to prevent implantation of an already created human being.<sup>135</sup>

There are several high profile reports of women being harassed, insulted, demeaned, and refused when they have tried to fill a prescription for birth control. The pharmacist's imposition of personal religious beliefs on the patient undermines the health and well-being of women seeking contraception. Since pharmacists counsel women about drug interactions, their input is especially important to quality health care for women with concurrent medical conditions. Inability to access contraceptive products and information from pharmacists compromises a key component of women's health care.

### Refusal to Provide Insurance Coverage

One of the major barriers to universal contraceptive access is the high out-of-pocket cost for women whose health plans do not cover contraception, or for women who are uninsured and do not qualify for public programs. Twenty-seven states have enacted statutes requiring insurance plans that include prescription drug coverage to include prescription contraceptives. Twenty of these states allow employers to refuse to provide contraceptive

*Elizabeth Dotts went to a new doctor for a routine examination. When she asked for a refill of her birth control pills, the doctor refused, stating he was opposed to birth control. She was shocked and very upset because her health insurance only pays for one OB/GYN visit per year; meaning that in order to get a prescription, she was going to have to find another physician and pay for that visit out of pocket.<sup>2</sup>*

coverage based on religious or moral beliefs, although some states, like California and New York, have very narrow refusal clauses that pertain only to institutions such as churches or religious schools.<sup>136</sup> Catholic Charities of Sacramento sued the state of California arguing that they are a religious employer and should be exempt from providing contraceptive coverage to their employees.<sup>137</sup> A similar lawsuit was filed in New York.<sup>138</sup> In both cases, the courts found that the organizations were sufficiently secular that they could not impose their religious beliefs on their employees' ability to access contraceptives.

### Sterilization

Female sterilization is the second most common method of contraception in the United States with 10.3 million women using it as their primary method of birth control.<sup>139</sup> In 2002, sterilization accounted for 51 percent of contraceptors 40-44 years of age.<sup>139</sup> Tubal sterilization is more effective than short-term contraceptive methods and equal in effectiveness to Intrauterine Contraception (IUC).<sup>85</sup> The American College of Obstetricians and Gynecologists recommends that women with certain complications associated with pregestational diabetes (i.e. serious vasculopathy) or who have completed their families consider sterilization.<sup>83,111</sup> Immediately post-partum may be a convenient time for women to undergo voluntary sterilization, and 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.<sup>140</sup> 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 the patient's consent is given voluntarily.

Timing of sterilization is also important. Key factors affecting the choice and timing of sterilization are a mix of individual patient preference, medical assessment of acute risk, and access to services.<sup>141</sup>

## Religious restrictions on sterilization

### **DIRECTIVE 53:**

**Direct sterilization of either men or women, whether permanent or temporary, is not permitted in a Catholic health care institution. Procedures which induce sterility are permitted when their direct effect is the cure or alleviation of a present and serious pathology and a simpler treatment is not available.<sup>40</sup>**

In addition to the broad prohibition on contraceptives, the Religious Directives specifically prohibit sterilization. In 2001, the U.S. Catholic Bishops revised the Directives and added a footnote to include sterilization among the list of “intrinsically evil” procedures with abortion, euthanasia, and assisted suicide.<sup>142</sup> This prohibition is especially damaging because nearly half of all tubal ligations are done in the immediate post-partum period, but physicians practicing in Catholic hospitals are prohibited from meeting those health care needs. With Catholic hospitals controlling 15 percent of all hospital beds in the United States and 20 percent of all admissions in 21 states and the District of Columbia,<sup>41</sup> the prohibition against sterilization imposes significant obstacles to meeting the standard of care for women who need permanent contraceptive services.

The Religious restrictions disproportionately impact low income women as they may be least able to seek alternative sources of care. They also impact physicians who are prohibited from providing voluntary sterilizations for their patients. In Gilroy, California, when the community hospital, Valley Medical Center, was taken over by St. Louise Medical Center, the five obstetricians/gynecologists in the community were suddenly told they could no longer provide sterilizations in the hospital, and there was no other local surgical site that could accommodate them. The doctors tried to negotiate with the new hospital owner, Catholic Healthcare West, and even wrote a letter to the Bishop, but to no avail. Zena Campos, who had decided to have a sterilization because she could not care for another child, became pregnant with her 10th child because the barriers to care became too difficult for her to surmount.<sup>143</sup>

The second part of Directive 53 allows medical interventions that cause infertility, so long as the purpose of the treatment is not contraceptive. For example, it is known that a potential side effect of certain chemotherapy treatments is the loss of fertility. The Religious Directives do not appear to prohibit such treatments, however, there are reports of physicians refusing to administer treatments that could cause harm to a developing fetus, regardless of the detrimental health consequences to the woman.<sup>d</sup>

<sup>d</sup> See the story of “Cary” described in Chapter 1.

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## Emergency Contraception

Emergency contraception can prevent pregnancy after unprotected or inadequately protected intercourse if used within 72 to 120 hours. Emergency contraception does not interfere with an established pregnancy, and, therefore, is not an abortifacient.<sup>144</sup> In the United States, the FDA-approved dedicated emergency contraceptive pills are Plan B<sup>®</sup> (a two-pill regimen of levonorgestrel, a progestin-only formula), Plan B<sup>®</sup> One-Step (one pill of levonorgestrel), Preven<sup>™</sup> and Next Choice<sup>®</sup> (a generic two-pill form of levonorgestrel). Other emergency contraceptive therapies include insertion of a copper intrauterine device (IUD) and regimens of multiple oral contraceptives (combination progestin and estrogen). Emergency contraceptives and combined oral contraceptive regimens are more effective the sooner they are taken. The mechanisms of action of emergency contraceptive pills and IUDs are not definitively understood, but research suggests that both methods prevent pregnancy by inhibiting or delaying ovulation or inhibiting fertilization rather than preventing implantation of a fertilized egg.<sup>145, 146</sup>

Emergency contraception can reduce the risk of an unwanted pregnancy by 75 percent or more if used correctly after having unprotected or unwanted sex.<sup>147</sup> The American Academy of Pediatrics Policy Statement on Emergency Contraception finds that use of emergency contraception could prevent half of all unintended pregnancies and abortions in the United States.<sup>148</sup>

Many professional medical and health associations have adopted medical practice guidelines and policies that require medical professionals to provide information about and access to emergency contraception. These include the American Medical Association,<sup>149</sup> the American Medical Women's Association,<sup>150</sup> the American Academy of Pediatrics,<sup>148</sup> the American College of Emergency Physicians,<sup>151</sup> the Association for Reproductive Health Professionals,<sup>152</sup> and the American Public Health Association.<sup>153</sup> American College of Obstetricians and Gynecologists practice guidelines recommend the use of emergency contraception for women and adolescents who have unprotected sex, experience condom breakage or slippage, miss a scheduled oral contraceptive pill or shot, or are victims of sexual assault. ACOG also notes that no clinician examination or pregnancy testing is necessary before emergency contraception is given.<sup>154</sup>

Prior to August 2006, when Plan B<sup>®</sup> was a prescription-only product, many of these organizations adopted recommendations to make emergency contraception available over-the-counter.<sup>155</sup> For example, in 2000, the American Medical Association adopted a resolution supporting FDA approval of EC as an over-the-counter product,<sup>156</sup> as did the American College of Emergency Physicians.<sup>157</sup> The Association of Women's Health Obstetric, and Neonatal Nurses published a call for over-the-counter approval.<sup>158</sup> The Society for Adolescent Medicine "strongly supports efforts to change the status of ECPs [emergency contraceptive pills] from prescription-only to over-the-counter without an age restriction."<sup>159</sup>

In the interim, professional medical associations recommended that providers write advance prescriptions for their patients. American College of Obstetricians and

Gynecologists launched the Ask Me campaign which is aimed at educating women about emergency contraception and encouraging them to get advance prescriptions of emergency contraception from their providers. The Cochrane Review found that women who had advance prescriptions were more likely to use emergency contraception, and to use it sooner after sex, thereby increasing its effectiveness. In addition they found that having emergency contraception on hand did not change the use of other kinds of contraception nor did it change sexual behavior.<sup>160</sup>

In August 2006, the FDA approved Plan B<sup>®</sup> for behind-the-counter sale without a prescription for women aged 18 and over, meaning that it could only be kept behind the pharmacy counter, not out on open shelves with other over-the-counter products. The FDA approval also required that Plan B<sup>®</sup> only be sold in licensed pharmacies and health clinics, and that it may not be sold in other facilities where over the counter drugs are commonly found such as convenience stores and gas stations. In most states, however, adult women on Medicaid are still required to have a prescription to cover the costs.<sup>161</sup>

Under the terms of the FDA approval, adolescents aged 17 or younger could only obtain Plan B<sup>®</sup> with a prescription. As a result of litigation brought against the FDA by reproductive health and reproductive rights organizations, in March 2009 the District Court ordered the FDA to allow over the counter access for adolescents age 17 and older, and to review all of the restrictions.<sup>162</sup>

### **Emergency Contraception for Victims of Sexual Assault**

In 2005, survivors reported 191,670 sexual assaults and rapes.<sup>163</sup> Using estimated rates from a prior study<sup>164</sup> when applied to the 2005 data, 12,677 resulting pregnancies could have been prevented with timely access to emergency contraception.<sup>165</sup> These numbers do not account for the numerous sexual assaults and rapes that go unreported. One study has explored the relationship between rape and emergency contraceptive use. Findings demonstrated that use of emergency contraception prevented 22,000 pregnancies out of 333,000 rapes.<sup>164</sup>

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. The American College of Obstetricians and Gynecologists recommends that, “Emergency contraception should be offered to all victims of sexual assault if they are at risk of pregnancy.”<sup>166</sup> 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.”<sup>151</sup> 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.”<sup>149</sup>

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To enforce compliance with these medical standards, 17 states and the District of Columbia have enacted legislation requiring emergency rooms that treat victims of sexual assault to offer and provide emergency contraception. Sixteen states and the District of Columbia require them to provide information about emergency contraception.<sup>37</sup> These laws and regulations establish a statutory standard of care. Some of these laws, however, include refusal clauses that limit the obligation of religiously-controlled hospitals.

### **Religious Directives on Emergency Contraception**

Emergency contraception is addressed by the Catholic Religious Directives in several ways. First, emergency contraception is generally prohibited under Catholic teachings under the same analysis as contraception. Additionally, since the mechanism of action of emergency contraception is not definitively known, emergency contraception is also prohibited under the abortion restriction. Contrary to the medical definition of contraception as preventing pregnancy, the analysis by the Catholic Bishops considers any interference with the implantation of a fertilized egg to be an abortion.

Emergency contraception for victims of sexual assault has become controversial within Catholic-controlled health care. Directive 36 differentiates between consensual sex for which contraception is prohibited and forced intercourse, but it also reinforces the Catholic view that pregnancy occurs at fertilization. In doing so, what appears to be a limited exception to allow contraception for sexual assault, in reality, denies emergency contraception to women who are at the highest risk for pregnancy, and fails to comply with the standard of care.

#### **DIRECTIVE 36:**

**Compassionate and understanding care should be given to a person who is the victim of sexual assault. Health Care providers should cooperate with law enforcement officials and offer the person psychological and spiritual support as well as accurate medical information. A female who has been raped should be able to defend herself against a potential conception from the sexual assault. If, after appropriate testing, there is no evidence that conception has occurred already, she may be treated with medications that would prevent ovulation, sperm capacitation, or fertilization. It is not permissible, however, to initiate or to recommend treatments that have as their purpose or direct effect the removal, destruction, or interference with the implantation of a fertilized ovum.**<sup>40</sup>

Many Catholic hospitals refuse to provide emergency contraception to anyone because of the possibility that an egg has been fertilized, and their religious belief that to interfere with its implantation is an abortion. There is no medical test for whether an egg has been fertilized, however, so other Catholic hospital emergency rooms replace the medical standard of care to provide emergency contraception with their own procedure known as the Peoria Protocol. Under this protocol, women are tested for ovulation with a luteinizing hormone (LH) urine dip test, or a progesterone blood level test. If a woman is ovulating or approaching ovulation, the time of highest fertility and likelihood of becoming pregnant, the Catholic hospital will not provide emergency contraception. If she is not ovulating and less likely to become pregnant, then EC may be provided. The result, in direct conflict with accepted medical practice, is to deny emergency contraception to women who are at the greatest risk for pregnancy from sexual assault.

The prohibition on the use of emergency contraception to prevent pregnancy from sexual assault was reiterated during the war in Kosovo when thousands of Kosovan women were raped as an act of war. The Vatican objected to the provision of emergency contraception to refugees by the United Nations Population Fund (UNFPA) with a statement by Monsignor Elio Sgreccia, “Every post-coital contraception is by definition abortive.”<sup>167</sup> In a letter to Cardinal Vinko Puljic of Sarajevo, Pope John Paul II called on women who had been raped to “transform the act of violence into an act of love and welcome” and to carry their pregnancies to term.<sup>168</sup>

Contrary to medical guidelines that require providers to offer emergency contraception to prevent unwanted pregnancy to women who have been raped, a recent national survey of 597 Catholic hospitals with emergency rooms conducted by Ibis Reproductive Health on behalf of Catholics for Choice, found that 55 percent would not dispense emergency contraception under any circumstances, only 28 percent provided emergency contraception at all, and 23 percent of the hospitals limited EC to victims of sexual assault (many first requiring pregnancy testing and/or police reports).<sup>169</sup> In other words, 77 percent of Catholic Hospitals did not meet the standards of care for providing emergency contraception.

The American College of Emergency Physicians notes that in the case of a physician refusal or institutional denial, at the very least, a referral is required, “Physicians and allied health practitioners who find this practice morally objectionable or who practice at hospitals that prohibit prophylaxis or contraception should offer to refer victims of sexual assault to another provider who can provide these services in a timely fashion.”<sup>151</sup> The Ibis Reproductive Health/Catholics for Choice study found that less than half of the hospitals that never provide EC would provide a referral, and two-thirds of those referrals proved to be “dead ends,”<sup>169</sup> violating even the minimal requirement set by the American College of Emergency Physicians.

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***The American College of Emergency Physicians notes that in the case of a physician refusal or institutional denial, at the very least, a referral is required...***

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*“Fearing that she was pregnant after a romantic night with her husband, Michelle Crider asked for help. Instead, she faced a dead end with pharmacist John Boling. When her doctor, Myron Schonbrun, asked Boling to supply Crider with Ovral birth control pills – take two pills immediately, then two more within 12 hours – the pharmacy manager at Longs Drug Store in Temecula refused. ‘I kind of understood immediately,’ Schonbrun recalled. At that dosage, Ovral was a morning-after pill, meant to prevent a fertilized egg from implanting in the uterus, and Boling disapproved. But Schonbrun knew that though Crider deeply wanted another child, pregnancy made her deathly ill. So the doctor tried to finesse the problem. He asked Boling to provide a month’s supply of Ovral, to be taken one a day, like any contraceptive. Boling again refused. He said he ‘knew what it was going to be given for,’ Schonbrun recalled.”<sup>170</sup>*

## Individual Refusals

Timely access to emergency contraception is also restricted when pharmacists refuse to fill valid prescriptions or to dispense emergency contraception over-the-counter. These refusals interfere with the ability of physicians to deliver quality patient care, and with the ability of patients to access the care they need. The FDA’s decision to keep Plan B<sup>®</sup> behind the pharmacy counter and to include an age restriction means that women and adolescents need the cooperation of pharmacists and pharmacy staff in order to obtain Plan B<sup>®</sup>. This is a particular barrier for low-income women because most state Medicaid plans that cover Plan B<sup>®</sup> still require that women obtain a prescription.<sup>161</sup>

## Political Restrictions

For many years, the FDA resisted designating Plan B<sup>®</sup> as an over the counter drug due to ideological and political interference that stymied the organization’s normal scientific and evidence-based evaluation of the drug. The delay compromised patient care and limited women’s ability to obtain emergency contraception within

the required timeframe. A report prepared by the Committee on Government Reform for Representative Henry Waxman documents that two FDA committees jointly reviewed the safety and effectiveness data on Plan B<sup>®</sup>, and both recommended full over-the-counter status without any age restrictions.<sup>171</sup> Many professional medical associations attested to the safety of Plan B<sup>®</sup> and called on the FDA to approve full over-the-counter status without an age restriction including the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, the American Medical Association and others.<sup>155</sup>

The Court decision in *Tummino v. Torti*, which ordered the FDA to lower the age restriction to 17 and to review the other limitations on EC access, describes in detail how the Bush White House interfered in the FDA’s decision-making, insisting on appointing to the Advisory Committee for Reproductive Health Drugs a “right to life anti-abortion physician” with few scientific qualifications and major opposition to abortion and contraception. Political pressure forced FDA Directors Mark McClellan and Andrew C. von Eschenbach to stall the decision for over 5 years, and to eventually override the regular scientific review which recommended over-the-counter status to women of all ages without a prescription in order to “appease the [prior] administration’s constituents.”<sup>172</sup>

In 2005, the United States Department of Justice released a National Protocol for Sexual Assault Medical Forensic Examination which did not include any reference to counseling or provision of emergency contraception.<sup>173</sup> In response, the AMA adopted

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additional policy on EC in cases of rape: “Our AMA will urge that the United States Justice Department’s new National Protocol for Sexual Assault Medical Forensic Examination be amended to include a full discussion and recommendations on the use of emergency contraception to prevent unwanted pregnancy in sexual assault victims, in line with established recommendations by the American College of Obstetricians and Gynecologists and other relevant medical organizations.”<sup>174</sup>

### The Decision to Terminate a Pregnancy

In 1995, the Institute of Medicine urged a new national norm establishing every pregnancy as a wanted pregnancy.<sup>80</sup> 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 one of the most common surgical procedures for women. In 2005, 1.21 million abortions were performed; 22 percent of all pregnancies ended in abortion.<sup>175</sup> In 2003, nearly 20,000 women needed abortion care after the 21st week of pregnancy. Over the course of their lifetime, one-third of all women will have an abortion.<sup>177</sup>

Women who obtain abortions reflect the diversity of the American population across age, race, ethnicity, religious affiliation, and geographic location.<sup>178</sup> Thirty-four percent of abortions were provided to white women. Among women of color, 37 percent of abortions were to African American women; 22 percent to Hispanic women; and 8 percent to women of other races. Over sixty percent of abortions are obtained by 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 above 300 percent of poverty.

**Over the course of their lifetime, one-third of all women will have an abortion.**

There are many reasons women seek abortions. In studies of women's need for abortion services, women give three main reasons for choosing abortion: having a child would interfere with a woman's education, work or ability to care for dependents (74%); that she could not afford a baby now (73%); and that she did not want to be a single mother or was having relationship problems (48%).<sup>179</sup> The American Psychiatric Association position statement on abortion "affirms that the freedom to interrupt pregnancy must be considered a mental health imperative with major social and mental health implications. It has also been shown that the children of unwanted, as opposed to mistimed, pregnancies are at high risk for abuse, neglect, illness, and deprivation of a high quality of life."<sup>180</sup>

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. For example, in the National Center of Health Statistics 2002 National Survey of Family Growth, eight percent of abortions were for intended pregnancies.<sup>78</sup> However, because abortions are substantially underreported in the National Survey of Family Growth, analyses based on these reports are likely to be unreliable. Thus while the exact percentage of women who undergo abortions for medical or fetal indications is unknown, it is important to explore the extent to which denials of care specifically affect these populations.

## Terminating a Pregnancy When the Health of a Woman or Her Fetus is at Serious Risk

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 the American College of Obstetricians and Gynecologists, Royal College of Obstetricians and Gynaecologists, and Cochrane Collaboration all recognize that in these situations, the patient must make a serious decision about balancing her health and life with the prospects for fetal survival. Universally, these practice guidelines place that decision in the hands of the patient, but this decision requires a full understanding of potential medical consequences. Therefore, professional guidelines also charge the physician with giving the patient complete and accurate medical information about her treatment options.<sup>e</sup>

### Abortion: Emergent conditions

#### Premature Rupture of Membranes (PROM)

Premature rupture of membranes (PROM) occurs when the amniotic membranes surrounding a pregnancy rupture before the pregnancy has reached term (at 37 weeks). PROM is a complication in one-third of premature births.<sup>181</sup> 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. Data on the frequency of intraamniotic infection vary; various studies have found that anywhere from 13-60 percent of women with preterm PROM also suffer from infection. 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. The incidence of infection increases for women whose pregnancies are at lower gestational ages. Risk to the fetus is infection, compression of the umbilical cord reducing nutrients and oxygen, and neurological impairment.<sup>181</sup>

Mid-trimester PROM occurs between 16 and 26 weeks gestation and complicates approximately one percent of all pregnancies in this stage. Management of patients with PROM hinges on evaluation of the relative risks of interventions and the gestational age of the fetus. Mid-trimester PROM at less than 24 weeks gestation is

*Dr. Smits<sup>3</sup> was a physician at St. Mary's hospital in a large Eastern city. The patient was 19 weeks pregnant and her membranes had ruptured. The fetus was not yet viable and the patient was septic 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. The patient was in ICU for ten days, and nearly died. The fetus died in utero. The woman had substantial internal bleeding, and developed pulmonary disease, resulting in lifetime oxygen dependency.<sup>182</sup>*

<sup>e</sup> In the medical literature, the decision to terminate a pregnancy either pre- or post-viability is often referred to as "delivery" or "early delivery." The literature rarely uses the term "abortion" in these cases. This report recognizes that the "delivery" of a fetus pre-viability is an abortion.

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also called EPPROM (extremely premature preterm rupture of the membranes). The poor survival rates for fetuses at this gestational age<sup>183</sup> shift the focus from efforts to promote the well-being of the fetus to efforts to safeguard the health and well-being of the pregnant woman.

The American College of Obstetricians and Gynecologists and the American Academy of Pediatrics Guidelines for Perinatal Care recognize that some women will elect induction of labor with no expectation of fetal survival (i.e. to terminate their pregnancies). Consequently the guidelines strongly advise that women whose fetuses are pre-viable (less than 24 weeks) should be counseled by an obstetrician and a pediatrician to understand the maternal health risks and the low likelihood of delivering a healthy infant.<sup>184</sup> ACOG practice guidelines require that the pregnant woman should be counseled about the risks and benefits of expectant management.<sup>181</sup>

### **Preeclampsia and Eclampsia**

Preeclampsia and eclampsia are serious and related pregnancy complications, responsible for 17 percent of maternal deaths in the U.S.<sup>185</sup> In the U.S., preeclampsia complicated 3.9% of live births, and eclampsia affected an additional 2 of every 1000 live births.<sup>186</sup> The cause of these conditions is unknown and the rate of pregnancy related morbidity from severe preeclampsia is increasing.<sup>187</sup> Significant racial disparities exist in rates of and complications associated with these diagnoses.<sup>188</sup>

Preeclampsia ranges from mild to severe, and is defined by hypertension and proteinuria (an abnormally high amount of protein in the urine) and may be associated with other symptoms including edema and visual disturbances. Risk factors may include preeclampsia in a previous pregnancy, multi-fetus pregnancies, chronic hypertension, gestational diabetes, vascular and connective tissue disease, nephropathy, antiphospholipid antibody syndrome, obesity, age over 35, and being African-American. Eclampsia is defined as the presence of new-onset maternal grand mal seizures.<sup>185</sup> The maternal risks of pre-eclampsia and eclampsia may continue for as long as four weeks past delivery.

Preeclampsia and eclampsia can affect the kidney, liver, and brain of the pregnant woman. If left untreated, it can lead to long-term health problems and even death of the fetus and/or the pregnant woman.<sup>189</sup> Women with severe preeclampsia and liver involvement may develop HELLP (hemolysis, elevated liver enzymes, and low platelet count syndrome) which is associated with placental abruption, renal failure, preterm delivery and fetal and maternal death.<sup>185</sup>

The only treatment of preeclampsia and eclampsia is delivery of the pregnancy.<sup>189, 190</sup> The American College of Obstetricians and Gynecologists and the American Academy of Pediatrics guidelines state that the risks to the woman from persistent severe pre-eclampsia are such that delivery (abortion) is usually suggested regardless of fetal age or potential for survival.<sup>184</sup> The guidelines further recommend that the decision to terminate a

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pregnancy take into consideration factors such as severity of preeclampsia, gestational age, maternal condition, fetal condition and prospect for fetal survival. The American College of Obstetricians and Gynecologists recommends that expectant management should only be considered for those women remote from term who have mild preeclampsia.<sup>185</sup> The Royal College of Obstetricians and Gynaecologists guidelines are clear that prolonging pregnancy can only be considered when the woman's condition is stable, and that "the woman's condition will always take priority over the fetal condition."<sup>191</sup>

### **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.<sup>192</sup> 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.<sup>193</sup>

There is no treatment for anencephaly.<sup>194</sup> Many physicians recommend abortion to reduce the potential of complications for the woman carrying the pregnancy and to alleviate maternal distress and anxiety. One patient advocacy group explains the process in this way: "A detailed scan will be done to confirm the diagnosis. After this, most Consultants will recommend that the pregnancy is terminated. It is important that you understand that whenever your baby is born, the outlook is the same, he or she will not survive. For this reason, it may make the decision easier if you view the termination of this pregnancy as an early delivery."<sup>195</sup>

### **Chronic conditions for which pregnancy termination may be medically appropriate**

Many women with chronic conditions experience safe pregnancies by utilizing appropriate preconception care and using contraception to plan a pregnancy when their conditions and symptoms are under control. However, 50 percent of pregnancies are unintended, and an unplanned pregnancy may present significant risks to women with chronic conditions such as lupus, heart disease, and diabetes, or while they are taking drugs that can cause fetal impairment.

If a woman with one of these conditions becomes pregnant unexpectedly, numerous professional associations' practice guidelines advise particular caution, often suggesting that she be seen by a high-risk obstetrician and that she be carefully monitored for medical complications that may indicate she should consider whether to terminate the pregnancy. In all cases, the standard of care is for the physician to discuss all medically accurate and appropriate treatment options with the patient, and for the patient to decide whether to continue or terminate the pregnancy.

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***There are numerous genetic disorders that result in significant problems in fetal development or in conditions that are incompatible with sustained life after birth.***

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### **Drugs that may cause significant impairment of the fetus**

Drugs that can cause significant fetal impairment include Accutane® – treatment for severe acne; Warfarin (Coumadin®) – treatment for cardiovascular disease; anti-convulsive drugs – treatment for epilepsy; Iodine 131 – treatment for thyroid disease; and some anti-depressants (see earlier discussion in this report on reasons for pregnancy prevention in these cases). In all of these cases, medical practice guidelines require that the health care provider must discuss the potential outcomes with the pregnant woman so that she can decide whether to continue her pregnancy to term. The American College of Obstetricians and Gynecologists specifically recommends that if a woman taking Iodine 131 becomes pregnant, her physician should caution her to consider the serious risks to the fetus, and consider termination.<sup>102</sup>

### **Cardiovascular Disease**

There are some cardiac conditions in which the physiological changes brought about in pregnancy are poorly tolerated. These conditions include valvular heart lesions such as severe aortic stenosis, aortic regurgitation, mitral stenosis, and mitral regurgitation all with III-IV<sup>196</sup> symptoms, aortic or mitral valve disease, mechanical prosthetic valve requiring anticoagulation and aortic regurgitation in Marfan Syndrome. The Task Force on the Management of Cardiovascular Diseases During Pregnancy of the European Society of Cardiology is clear on the importance of abortion as an option for some high risk patients: “Pregnancy is not recommended. If pregnancy occurs, termination should be advised as the risks to the mother are high (mortality 8-35%, morbidity 50%).”<sup>119</sup> The Guidelines from the American College of Cardiology/American Heart Association concur that pregnancy should be avoided altogether or terminated if a woman has cyanotic congenital heart disease, Eisenmenger syndrome, or severe pulmonary hypertension.<sup>197</sup> Additionally as Marfan Syndrome can cause spontaneous dissection or rupture of the aorta, the most feared cardiovascular complications associated with pregnancy, the guidelines recommend pregnancy termination if a woman’s aortic root enlargement is greater than 4.0 cm.<sup>197</sup>

### **Genetic Conditions for which Abortion is an Option**

There are numerous genetic disorders that result in significant problems in fetal development or in conditions that are incompatible with sustained life after birth.<sup>198</sup> Consequently patients receiving these diagnoses may choose to terminate a pregnancy. In 1987, the National Society for Genetic Counselors adopted a resolution supporting a woman’s right to prenatal diagnosis and access to safe and legal abortion.<sup>199</sup> In 2005 the Society further elaborated that while screening is ideally performed prior to conception, it should also be offered “as early as possible once pregnancy is confirmed in order to maximize reproductive options” recognizing that access to abortion is a key component of the proper care for women with some genetic conditions.<sup>200</sup>

## Ideological Restrictions on Pregnancy Termination

### Institutional Restrictions

The Ethical and Religious Directives for Catholic Health Care Services (Religious Directives)<sup>40</sup> explicitly state that abortion is never permitted. Even when the abortion is intended to protect the health of the pregnant woman, or to save her life, abortion is prohibited.

#### **DIRECTIVE 45:**

**Abortion (that is, the directly intended termination of pregnancy before viability or the directly intended destruction of a viable fetus) is never permitted. Every procedure whose sole immediate effect is the termination of pregnancy before viability is an abortion, which, in its moral context, includes the interval between conception and implantation of the embryo. Catholic health care institutions are not to provide abortion services, even based upon the principle of material cooperation.**<sup>40</sup>

For institutions like Catholic-controlled hospitals or managed care plans, religious doctrine trumps any consideration of patient wishes, and overrides provider expertise, evidence, and medical standards. The prohibition on abortion is not individualized nor is it nuanced. There are no exceptions for the medical condition of the patient, even if her life is in danger, or for pregnancies due to rape or incest.

#### **DIRECTIVE 47:**

**Operations, treatments, and medications that have as their direct purpose the cure of a proportionately serious pathological condition of a pregnant woman are permitted when they cannot be safely postponed until the unborn child is viable, even if they will result in the death of the unborn child.**<sup>40</sup>

Some procedures do not intend to cause an abortion, but they may have the foreseen but unintended consequence of ending a pregnancy. Chemotherapy or radiation treatments on a pregnant woman may cause her to miscarry. Such treatments might be allowed under limited circumstances in some Catholic hospitals.

This is known as the “principle of double effect.” When an action that is good has two effects - the intended good effect and an unintended evil effect, the action may be morally acceptable if: 1) the action is good in its intention, 2) it is not reasonably possible to achieve the good effect without the evil consequence, 3) the evil consequence is not the means to the good end, and (4) the good effect is equal or greater than the evil effect.<sup>201</sup> For example, if a woman needs surgery as treatment of a disease that cannot wait until

*Dr. Ramesh Raghavan writes in the Journal of the American Medical Association of his personal experience when his pregnant wife went into premature labor with their twins. Faced with the potential of infection that could permanently damage his wife's future fertility, and fetuses that might not survive outside the womb, he and his wife made the difficult decision not to risk infection, and to terminate the pregnancy. He describes his experience in the third person:*

*“And at this point their personal decision-making runs afoul of their hospital's policies. Inducing labor before membranes have ruptured, or before there is a maternal indication such as infection, is technically an “elective abortion,” and the hospital will not allow the termination of this pregnancy.”<sup>203</sup>*

her child is born without gravely endangering her health, it might be permissible to perform the surgery even if the surgery puts the fetus at risk, so long as the intention is not to terminate the pregnancy.<sup>202</sup> Direct abortion is never justified under the principle of double effect. Therefore, if a pregnant woman with Marfan Syndrome or lupus developed complications that could seriously compromise her health or even threaten her life, abortion would still not be permissible for the sole purpose of preserving her health or life.

The American College of Obstetricians and Gynecologists require in the case of premature rupture of membranes that the physician counsel the pregnant woman about the medical risks and benefits of expectant management or pregnancy termination, and for the woman to decide her course of treatment. The Religious Directives, on the other hand, require a treatment decision based on the ideological analysis of “double effect.” In that analysis, a woman's decision to protect her health and future fertility by preventing a serious infection would not justify early induction

of labor. If, however, the mother actually develops an infection or other life threatening condition, it might be permissible to treat that condition, even if the result would be the death of the fetus. Some hospitals still will not permit the termination of the pregnancy - even if the woman developed an infection, as long as the fetus still had a heartbeat.

### **How restrictions affect care for preeclampsia/eclampsia/HELLP syndrome**

In direct contradiction of medical guidelines, the Religious Directives apply the same analysis to severe preeclampsia, eclampsia or HELLP syndrome. According to Fr. Thomas O'Donnell, a leading Catholic theologian on health care issues, pregnancy termination in eclampsia when there is no hope that the fetus can survive outside the uterus “must be viewed as a direct abortion and in violation of the uniquely divine prerogative of absolute dominion over human life.”<sup>202</sup> He comes to this conclusion despite his acknowledgment that the disease is very serious and can cause damage to many organs of the body and maternal death. Fr. O'Donnell explains that early pregnancy termination cannot be justified under the principle of double effect because the removal of the fetus from the uterus (the evil effect) is the intended act, and even though it will result in controlling the preeclampsia and could protect the health of the woman or even save her life, it is not permissible.<sup>202</sup> Only if the fetus dies in utero due to eclampsia, is it morally permissible to remove the dead fetus from the woman's uterus.

### **How restrictions affect abortion for anencephaly**

The U.S. Bishops issued a statement in 1996 directly addressing abortion in the case of an anencephalic fetus, saying, “It is permitted to treat directly a pathology of the mother even if this has the unintended side-effect of causing the death of her child,

if this pathology left untreated would have life-threatening effects on both mother and child, but it is not permitted to terminate or gravely risk the child's life as a *means* of treating or protecting the mother" [emphasis original]. They clarify that anencephaly is a pathology of the fetus, not of the mother, and therefore abortion of an anencephalic fetus does not fall under Directive 47 and is never permitted. According to the Bishops, the fetus is not at risk so long as it is in the uterus, therefore it is not permitted to terminate the pregnancy because to do so would cause the early death of the fetus.<sup>204</sup> Even though the child will die soon after birth, the mental health of the mother is not a consideration.

### Individual Refusals

Individual refusals undermine the standard of care in two ways: first, they interfere with patients receiving complete medically accurate and unbiased information about their treatment options, and second, they inhibit the ability of patients to access medically appropriate treatment options. Shielded by refusal protection laws, physicians can opt not to follow the standard of care for women for whom abortion is one alternative. For example, a woman experiencing a lupus flare may be told of her increased health risks to both herself and her child but not offered the opportunity to select abortion as one treatment option.

### Political Restrictions on Abortion Care

*Planned Parenthood of Southeastern Pennsylvania v. Casey*<sup>205</sup> limited the constitutional protection for abortion allowing for the regulation of abortion, as long as such regulation did not impose an "undue burden" on women. Since then, nearly every state has enacted laws that limit the availability of abortion. Some of these laws require that women receive information that is scientifically inaccurate. Others prohibit the kind of abortion a woman can receive regardless of medical need and the location where abortions are performed. These laws have reduced the availability of abortion care for women.

### Misinformation Laws

Basic ethical principles of informed consent require that a health care provider give medically accurate, unbiased and adequate information to a patient regarding the patient's condition, treatment options, and potential risks and benefits so that the patient can make an informed decision about her treatment.<sup>206</sup> Professional commitment to informed consent has been compromised by state laws that require health providers to give inaccurate, often non-germane, and misleading information about abortion to their patients.<sup>207</sup> Laws that mandate that health care professionals provide misinformation to their patients violate the standard of care.

*Dr. Brill described another doctor at the hospital at which he worked. The patient had placental abruption, where the placenta separates from the uterus and puts the patient at extreme risk for internal bleeding. If left untreated, the patient may need transfusions or even bleed to death. The treating physician was a "fundamental Christian." The patient was 20 weeks pregnant. The physician refused to terminate the pregnancy. Instead he tried to stop the bleeding and to stop the labor. She continued to bleed. A week or two later, she spontaneously aborted, but not until she required several blood transfusions.<sup>182</sup>*

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According to the Guttmacher Institute, 23 states have specific laws requiring information that must be given to women who are seeking abortions that does not conform to the ethical standards of informed consent. Six states require that women be informed of the unsubstantiated link between abortion and breast cancer, nine states the unsupported ability of a fetus to feel pain at a certain point in gestation, and seven states the supposed long-term negative mental health consequences.<sup>71</sup> Each of these claims is contrary to recognized science. In 2004, the Collaborative Group on Hormonal Factors in Breast Cancer published the results of a review of the worldwide epidemiological evidence on the possible relation between breast cancer and previous spontaneous and induced abortions. After reanalysis of data on individual women from 53 studies from 16 countries with liberal abortion laws, the Group concluded that pregnancies that end as a spontaneous or induced abortion do not increase a woman's risk of developing breast cancer.<sup>208</sup> In 2005, a summary of the state of the science concluded that a human fetus probably does not have the functional capacity to experience pain until the 29th week of pregnancy at the earliest.<sup>209</sup> In 2008, the American Psychological Association Task Force on Mental Health and Abortion reaffirmed its early position on the lack of evidence that abortion causes negative psychological harms for women.<sup>72</sup>

### **The Federal Abortion Procedure Ban**

Congress enacted the federal *Partial-Birth Abortion Ban Act of 2003*<sup>210</sup> prohibiting an abortion provider from intentionally drawing the fetal trunk or fetal head outside the woman's body prior to fetal demise and then taking an action, other than delivering the fetus, which causes fetal demise. The federal ban does not specify a gestational age or viability status of the fetus and has no exception to protect the woman's health. In 2007, the Supreme Court upheld the law in *Gonzales v. Carhart*.<sup>211</sup> The Court generally construed the ban to apply only to intact procedures and not to dilation and evacuation abortion (D&E) with disarticulation, which the Court referred to as "standard" second-trimester abortions. The decision, like the law, lacks articulation of any clear delineation between legal, "standard" D&E abortions and illegal "partial birth abortions." In addition, the Court held that such bans need not contain a health exception because differences of opinion exist in the medical community as to whether an intact D&E is ever medically necessary to preserve the health of the pregnant woman. There is, however, an exception in the law to save the life of the woman.

The scientific evidence, however, points to a different conclusion than that reached by the Court. Clinical experts in the *Gonzales v. Carhart* trials testified that intact dilation and evacuation may be the safest abortion technique for some women with medical conditions such as uterine scars, bleeding disorders, heart disease, or compromised immune systems, as well as for women with pregnancy-related conditions such as placenta previa and accreta (placental growth over the cervix or embedded in the uterine muscle) and for women carrying fetuses with abnormalities such as severe hydrocephaly. In addition, experts testified that intact dilation and evacuation may be generally a safer technique than disarticulation dilation and evacuation later in the second trimester because it involves less instrumentation in the uterus and therefore less risk of uterine

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perforation.<sup>212</sup> Data from a small research study that examined differences in outcomes between techniques support this claim.<sup>213</sup>

Immediately after the Court's decision upholding the ban, experts in second-trimester abortion raised concerns about how physicians might alter the care they provide in an effort to continue offering second-trimester abortions without running afoul of the law, while continuing to provide safe care. These changes include decreasing the amount of cervical dilation and using medications to cause fetal demise prior to initiation of the abortion which were not otherwise clinically indicated. Data from abortion providers in one state seeking to adhere to the new law supports these concerns. Following the *Carhart* decision, access to abortion care declined as a provider stopped offering services, another limited the number of abortions performed, and many implemented clinical interventions necessary only to adhere to the law but which did not enhance patient care.<sup>214</sup>

### **Abortion Facilities Restrictions**

Laws known as Targeted Regulations of Abortion Providers (TRAP) laws single out facilities at which abortions are performed and subject them to requirements not applied to other physician's offices or outpatient clinics. These regulations vary in degree of burden they impose, the facilities they govern, and the stages of abortion to which they apply. In general, TRAP laws require licensing of facilities that provide abortions and then authorize the state health department to inspect those facilities and to ensure compliance with a range of statutory or regulatory requirements. Criminal and civil penalties may be imposed on those facilities not in compliance. TRAP schemes differ by state and vary as to whether they apply to abortions performed during any stage of pregnancy, whether they exempt private medical practices, whether they apply only to providers who perform more than a certain number of abortion procedures, whether they apply to both surgical and medical abortions, and the degree of governmental oversight they impose.

One new TRAP scheme of concern is the requirement that abortions be performed in ambulatory surgical centers (ASC) set up for more sophisticated and intrusive surgical procedures. ASC regulations are generally quite extensive, encompassing standards for the facility's physical plant, staffing, administration, and quality improvement, and consequently, compliance is extremely costly. The costs and burdens stemming from the imposition of ASC requirements have hindered or prevented physicians in some states from providing abortions. These targeted laws do not require the use of ASCs for the performance of other procedures of comparable complexity and risk such as hysteroscopy, surgical completion of miscarriage, vasectomy, or sigmoidoscopy. ASC regulations also go far beyond the guidelines for abortion provision issued by professional organizations such as the American College of Obstetricians and Gynecologists<sup>215</sup> and the National Abortion Federation.<sup>216</sup> These restrictions can have profound effect on access to care as an analysis of Texas's requirement for ACS compliance<sup>217</sup> demonstrates. When the 2004 state law went into effect requiring that abortions after 16 weeks' gestation be performed in ASCs or hospitals, no existing abortion provider was able to comply, and the number of

abortions performed after 16 weeks in the state dropped 85 percent from the previous year. In 2006, the number of abortions performed later than 16 weeks in Texas was still less than half the number performed in 2003.<sup>51</sup>

## Ectopic Pregnancy

***In the United States, ectopic pregnancies occur in 2 percent of all first trimester pregnancies, and are the leading cause of maternal death in the first trimester.***

Ectopic pregnancy, a potentially life-threatening condition, occurs when a fertilized egg implants outside of the uterus, most commonly in the fallopian tube. It is also known as a “tubal pregnancy.” In the United States, ectopic pregnancies occur in 2 percent of all first trimester pregnancies, and are the leading cause of maternal death in the first trimester.<sup>218</sup> If the ectopic pregnancy is not removed, it may rupture the fallopian tube and cause permanent damage to the woman’s future fertility, and even death. A rupture or imminent rupture of the fallopian tube is a medical emergency. Due to advances in diagnostic methods and increased patient and clinician knowledge of risk factors, ectopic pregnancies can now be detected earlier and with greater accuracy. Early diagnosis allows for a wider range of treatment options.

### Treatment Options for Ectopic Pregnancy

Care guidelines for women with ectopic pregnancies are established by the American College of Obstetricians and Gynecologists<sup>27</sup> and the Royal College of Obstetricians and Gynaecologists.<sup>29</sup> In addition the Cochrane Collaboration’s review of evidence<sup>28</sup> provides a synopsis of the randomly-controlled trials of treatment for tubal pregnancy and assessed both short-term and long-term outcome measures.

There are now a range of treatment and management options for non-ruptured ectopic pregnancy: salpingectomy (removal of all or part of the fallopian tube through laparotomy or open surgery), salpingostomy (use of a small incision done by laparoscopic surgery), medical treatment (using a pharmaceutical agent), and expectant management (observing and waiting for spontaneous resolution). The Royal College guideline states that the option chosen “must be tailored to the clinical condition and future fertility requirements of the woman.”

American College of Obstetricians and Gynecologists guidelines recommend lower levels of intervention—medication and tube-sparing surgery—when clinically possible. Methotrexate can be used successfully in early, non-ruptured ectopic pregnancy. When compared with tube-sparing laparoscopic surgery, methotrexate shows no difference in overall tubal preservation, tubal patency, repeat ectopic pregnancy, or future pregnancies.<sup>27</sup>

The Cochrane Review also finds that for some women, medical management may be an alternative to surgical intervention. Medical management involves treatment with the drug methotrexate which eliminates the pregnancy without surgery. This route is recommended by Cochrane for women with an unruptured tubal pregnancy who are medically

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stable, have no signs of active bleeding and have low levels of the pregnancy hormone in their blood.<sup>28</sup> Methotrexate has been used in single and in multiple dose injections. Close follow-up is necessary to ensure that the methotrexate has effectively removed the ectopic pregnancy. Failure necessitates surgical intervention to treat the ectopic pregnancy. Women should be counseled carefully about the risks and benefits and the need and protocol for follow-up care.

Cochrane and the Royal College guidelines identify laparoscopy (small incision surgery) also as an effective treatment for most women.<sup>28,29</sup> Cochrane concludes that compared to laparotomy (open surgery), laparoscopy is feasible in almost all patients, and is safe and less costly. It is also associated with less blood loss and requires less medical intervention, a shorter duration of operation time, and a shorter hospital stay and convalescence time. Although patients undergoing laparoscopic conservative (non-removal) surgery were slightly more likely to need additional treatment (either surgical or medical) to fully remove the ectopic pregnancy, long-term follow-up studies demonstrate that the two methods result in similar rates of unobstructed fallopian tubes and subsequent normal pregnancy rates. For women with ectopic pregnancies, especially those without a second healthy fallopian tube, laparoscopic conservative surgery should be considered the primary treatment to preserve future fertility.

In addition to the medical risks and benefits, other factors may affect women's choice of intervention method. In one study, women indicated a willingness to trade off the increased treatment burden of systemic methotrexate for the benefits of a totally noninvasive management of tubal pregnancy.<sup>219</sup>

Expectant management involves closely monitoring a woman in hopes that the ectopic pregnancy will spontaneously resolve itself in order to avoid unnecessary treatment. All of the guidelines conclude that, while there may be a role for expectant management in rare cases, women must be willing to accept the potential risks of tubal rupture. Expectant management is not effective for all ectopic pregnancies.

### **Ideological Restrictions on Treatment for Ectopic Pregnancy**

While the medical literature analyzes ectopic pregnancy as a medical condition and recommends guidelines for appropriate treatment options based on individualized assessment of the patient's medical condition, the Religious Directives analyze ectopic pregnancy treatment as a prohibited abortion.

In a footnote, Directive 48 refers to Directive 45 which says: Abortion (that is, the directly intended termination of pregnancy before viability or the directly intended destruction of a viable fetus) is never permitted.

**DIRECTIVE 48:**

**In case of extrauterine pregnancy, no intervention is morally licit which constitutes a direct abortion.<sup>40</sup>**

On the other hand, a treatment for which ending a pregnancy is only a side effect may be permissible. Instead of focusing on the best medical treatment for the patient, debate among Catholic theologians, bio-ethicists, and health systems focuses on whether the removal of an ectopic pregnancy, which by definition cannot be brought to term and result in the birth of a child, is an abortion or the treatment of a pathological condition. Some argue that the use of methotrexate and salpingostomy (removal of the embryo through laparoscopy) constitutes a direct abortion because the embryo is attacked directly. Therefore, “the death of the embryo is not the unintended evil effect, but rather the very means used to bring about the intended good effect.”<sup>220</sup> This procedure also is characterized as “gravely evil” and “murder.” An even more conservative approach also limits the use of salpingectomy (removal of the fallopian tube through surgery) to wait until the tube *“is at present gravely dangerous to the mother, or if putting off the operation would involve grave danger”* (emphasis added).<sup>221</sup>

**DIRECTIVE 47:**

**Operations, treatments, and medications that have as their direct purpose the cure of a proportionately serious pathological condition of a pregnant woman are permitted when they cannot be safely postponed until the unborn child is viable, even if they will result in the death of the unborn child.<sup>40</sup>**

The Sisters of St. Francis Health Services, Inc., have corporate policy to permit the use of methotrexate in the treatment of ectopic pregnancy only in certain circumstances. The drug can be used if, in addition to the other clinical criteria, an ultrasound indicates a gestational sac without a living embryo. The policy also states that in the case of a viable extrauterine pregnancy, the criteria for double effect are met by salpingectomy but not salpingostomy that evacuates the living embryo or fetus in the tube.<sup>222</sup> In the medical literature, however, there is no such thing as viable ectopic pregnancy.

Catholic Health East, one of the largest non-profit health systems in the United States, refers directly to Religious Directive 48 regarding extrauterine pregnancies and abortion on its Ethics Tools webpage.<sup>223</sup>

Thomas O’Donnell, a leading Catholic theologian on health care, argues that no intervention is allowed unless, or until, the fallopian tube is so pathologically affected to justify ending the tubal pregnancy. In his words, “to distinguish between removing a non-viable fetus from the uterus and from the fallopian tube is patently (from a theological viewpoint) to make a distinction without a difference.”<sup>224</sup>

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The Catholic bio-ethicist Fr. Kevin O'Rourke, whose interpretations of canon law are influential in health care, argues that all treatment options should be allowed.<sup>220</sup> In his analysis, a salpingectomy (removing the tube) is justified by the principle of double effect because the physician's direct intention is to save the mother's life, even though the ensuing death of the fetus is an unintended and unwanted effect. Similarly, he believes that the use of a salpingostomy (non-removal of the tube) is also defensible because this procedure aims to remove damaged tubal tissue as well as damage-causing trophoblastic tissue, not to cause death or destruction of the embryo. With respect to use of methotrexate, Fr. O'Rourke further explains, "[g]iven that in an ectopic pregnancy the fallopian tube is pathological (e.g., will bleed or rupture) because of the manner in which the trophoblast has imbedded itself in the tube's inner wall, it seems well within moral probity for the obstetrician to intend the removal of the trophoblast and to employ the means to fulfill the intention [e.g. methotrexate], even though that means the death of the fetus will result."<sup>225</sup>

While there is no definitive data on the manner in which these Directives are interpreted and applied to treatment of ectopic pregnancy, anecdotal reports suggest that the availability of treatment options varies between institutions and may be based on unwritten policies and practices. Such variation leads to disparities in quality of care, and subjects all women to the risk of care that does not meet medical standards.

## Chapter Four **Pregnancy Attainment**

### Overview

Although the National Center for Health Statistics reports declining rates of infertility in the United States,<sup>226</sup> the impact of infertility on the long-term quality of life has not diminished.<sup>227</sup> More than seven million women, 12 percent of women of child-bearing age, suffer from some form of impaired fertility. The psychosocial effects of infertility range from unresolved grief and depression to reduced life satisfaction and increased anxiety.<sup>228</sup> Patients suffering from a health condition leading to infertility may feel such distress just as acutely, if not more so. Advanced fertility planning may serve as a positive coping factor when dealing with proposed treatment that could result in infertility.

Increasing prevalence of sexually transmitted infections is also contributing to infertility. If left untreated, 40 percent of women with Chlamydia or gonorrhea will develop pelvic inflammatory disease. 100,000 women per year become infertile due to Chlamydia.<sup>229</sup>

The American College of Obstetricians and Gynecologists defines infertility as the inability of an individual to achieve pregnancy after one year of intercourse without the use of any form of birth control, or the inability to carry a pregnancy to term.<sup>230</sup> Infertility may arise from anatomical or physiological defects, and may have many causes including environmental factors. Forty to sixty percent of infertility cases in heterosexual couples result from infertility in the female. Congenital or acquired infertility accounts for approximately 40 percent of these cases. Physiologically, endocrine system dysfunctions account for an additional 40 percent of infertility in women. The remaining cases likely stem from endometriosis or other immunologic disorders.<sup>231</sup> The definition of infertility depends on the discipline—demographers focus on actual childbearing while reproductive medicine is concerned with conception.

In male infertility, the underlying cause of abnormal sperm production is unknown in about 50 percent of all cases. Although the available evidence points largely to genetic defects as the root cause of infertility in men, testicular cancer and hypogonadism are particularly prevalent in infertile men. As in women, endocrine disorders also affect male fertility.<sup>231</sup>

Some of the most common medical conditions adversely affecting reproductive capabilities in men and women include cancer, pelvic inflammatory disease, diabetes, epilepsy, and coronary artery disease. Infertility may be caused by the underlying condition itself, or by its treatment.

Some causes of infertility are temporary and can be reversed, and not all causes of infertility preclude all future reproduction. Most infertility is treated with medication and/or surgery of the reproductive organs. Advances in assisted reproductive technologies (ART) have allowed many patients to bypass physiological limitations and to achieve pregnancy. Assisted Reproductive Technology (ART) generally refers to a variety of procedures that involve surgically removing eggs from a woman and mixing them with sperm to achieve fertilization in the laboratory. The resulting embryos are then implanted in the woman's uterus. ARTs can be performed with the eggs and sperm of the intended

**More than seven million women, 12 percent of women of child-bearing age, suffer from some form of impaired fertility.**

parent(s) or from donors.<sup>232</sup> Eggs and sperm can be harvested from patients prior to undergoing treatments such as chemotherapy or radiation that would otherwise destroy the person's future fertility, and frozen for future use.

Professional recommendations now suggest that physicians discuss fertility preservation with all patients presenting with medical conditions that may complicate future reproduction.<sup>233, 234</sup> While not encompassed in the medical definition of infertility, people seeking to form biological families such as lesbians, heterosexual single women, and surrogates may also be in need of assisted reproductive technologies to become pregnant.

## Cancer

In 2005, approximately 1,372,910 people were diagnosed with some form of cancer. Approximately 1 in 1000 adult Americans is a cancer survivor.<sup>235</sup> The increase in survival has induced new considerations about preserving fertility potential. The permanence or impermanence of infertility in cancer patients depends on factors such as disease, treatment type and dosage, pre-treatment fertility preservation options, and age.

The American Society for Clinical Oncology guidelines clearly state:

“As part of education and informed consent prior to cancer therapy, oncologists should be prepared to discuss possible fertility preservation options or refer appropriate and interested patients to reproductive specialists. Clinician judgment should be employed in the timing of raising this issue, but discussion at the earliest possible opportunity is encouraged. Sperm and embryo cryopreservation should address the possibility of infertility with patients treated during their reproductive years and be considered standard practice and widely available; other available fertility preservation methods should be considered investigational and be performed in centers with the necessary expertise.”<sup>228</sup>

The Oncology Nursing Society guidelines and recommendations for practice require that nurses “explore fertility options prior to initiation of cancer treatment.” Except when the urgency of cancer treatment makes fertility treatment unfeasible, female patients should be referred to a reproductive gynecologist to explore options such as in vitro fertilization, gamete intrafallopian transfer, use of donor oocytes, surrogacy, cryopreservation, embryo donation, embryo banking, adoption, and child-free living. Male patients, including adolescent males who have just achieved puberty, should be informed about semen cryopreservation and sperm banking.<sup>236</sup>

## Ideological Restrictions on Pregnancy Attainment

### Institutional Restrictions

The Catholic Religious Directives base the decision of whether health providers can offer fertility treatments on a distinction between (1) whether the treatment “assists marital intercourse in achieving its procreative potential,” in which case the treatment is allowed; or (2) whether the treatment “substitutes a laboratory procedure for intercourse” or involves a third party in the act of conception, in which case the treatment is prohibited.<sup>237</sup> The decision to provide a treatment is not particular to individual patient needs, but rather is generalized based on religious teaching. In 1987, the Congregation for the Doctrine of the Faith, which is the Vatican office that promotes Catholic doctrine, issued a statement on reproduction and assisted reproductive technologies. This document, *Donum Vitae*, is the basis for health care restrictions in these areas.<sup>238</sup>

*Guadalupe Benitez sought artificial insemination to start a family with her partner of 15 years. She went to the North Coast Women’s Care Medical Group in San Diego where the treating physician told her she would provide her with the preliminary treatments, but that she had a religious objection to the actual insemination. However, she assured Benitez that another physician in the practice would do the procedure. North Coast is the only fertility practice covered by Benitez’s insurance plan. After many months, the doctors informed her that they would not provide IVF to her based on their religious beliefs. The California Supreme Court determined that religious beliefs do not exempt a medical provider from complying with California’s civil rights laws that prohibit discrimination based on sexual orientation.<sup>240</sup>*

The Religious Directives state, “Reproductive technologies that substitute for the marriage act are not consistent with human dignity.<sup>142</sup> Directives 38-43 address which fertility treatments are allowed and which are prohibited. Fertility treatments that involve actual intercourse are allowed; all others are prohibited. Therefore, medications, counseling, and surgical interventions to repair the reproductive organs are allowed. Any procedure that collects sperm and eggs separate from an act of intercourse or creates embryos is prohibited. One morally acceptable process is the use of a perforated condom which retains the “marital act” (intercourse) and also allows for the collection of sperm for testing for possible causes of infertility or for reinsertion directly into the uterus. This process creates an illusion of uncertainty about whether the pregnancy resulted from the act of intercourse or from the fertility treatment.<sup>202</sup> Masturbation for the purpose of collecting sperm is separate from the marital act and therefore not morally acceptable. In vitro fertilization is “clearly

and unequivocally immoral”<sup>239</sup> and other treatments that use donor eggs, or create embryos such as Intra-cytoplasmic Sperm Injection (ICSI) are prohibited because “lives are usually snuffed out in the process.”<sup>239</sup> Surrogacy is also prohibited by the Religious Directives.

### Individual Refusals

Individual refusals related to fertility treatments can occur in two ways. First, providers may refuse to give women and men information and referrals about fertility options. Therefore, in violation of the American Society for Clinical Oncology guidelines, a provider

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may fail to disclose information about the potential for preserving eggs or sperm prior to undergoing chemotherapy or radiation treatment.

A second type of refusal to provide fertility treatments is likely to be directed at the person seeking the fertility treatment rather than an objection to providing the service itself. Individual providers refuse to provide treatment to particular women on the basis of their personal beliefs about who should become a parent. The personal belief that only married couples should become parents leads to provider refusals to provide fertility treatment to lesbians, single women, or surrogate mothers.

### Condoms and Preventing Sexually Transmitted Diseases and Infections and HIV/AIDS

The CDC estimates that 19 million new sexually transmitted infections occur each year, almost half of them among young people ages 15 to 24.<sup>241</sup> Chlamydia remains the most commonly reported infectious disease in the United States, while HIV/AIDS remains the most life threatening. In 2007, 1,108,374 Chlamydia diagnoses were reported, an increase of 7.5 percent over 2006. Women, especially young women, and African-American women, are hit hardest by Chlamydia. Forty-eight percent of Chlamydia cases are in Blacks, which is eight times the rate in Whites. Hispanics experience three times the rate of Chlamydia than Whites.<sup>242</sup>

In 2006, there were an estimated 56,300 new cases of HIV/AIDS in the United States. Women account for 27 percent of new cases. The HIV incidence for Black women was nearly 15 times that for White women, and nearly four times that of Latinas. Eighty percent of new infections in women were transmitted through high risk heterosexual contact.<sup>243</sup>

According to the Cochrane Review, consistent use of condoms results in 80 percent reduction in the transmission of HIV.<sup>244</sup> The American Academy of Pediatrics recommends that pediatricians “actively support and encourage the correct and consistent use of reliable contraception and condoms” by adolescents who are sexually active or contemplating sexual activity.<sup>245</sup> The American College of Obstetricians and Gynecologists recommends that a condom should be used every time a woman has intercourse with a man unless it is known that neither partner is infected with an STD.<sup>184,246</sup> Furthermore, the World Health Organization states that, “Prevention is the mainstay of the response to AIDS. Condoms are an integral and essential part of comprehensive prevention and care programmes, and their promotion must be accelerated.”<sup>247</sup>

### Ideological Restrictions on the Use of Condoms

#### Religious Restrictions

The Religious Directives prohibition on contraception also extends to the use of condoms, even when condoms are used to prevent the spread of HIV/AIDS and other sexually transmitted diseases. When a Spanish Bishop suggested that condoms could be condoned when intended to prevent AIDS, Pope John Paul II responded by re-affirming the Vatican’s ban on condoms, “The Holy See . . . considers that it is necessary above all to combat this disease in a responsible way by increasing prevention, notably through education about respect of the sacred value of life and formation of the correct practice of sexuality, which presupposes chastity and fidelity.”<sup>248</sup>

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This policy is in direct contradiction of national and international standards of care that emphasize consistent use of condoms to prevent the spread of HIV/AIDS and other sexually transmitted diseases. The United Nations AIDS Coordinator for Honduras expressed concern that the Roman Catholic Church's stand against condoms was making the spread of AIDS in Latin America worse.<sup>249</sup> As recently as March, 2009, Pope Benedict stated that condoms are not the answer to solving the AIDS crisis in Africa, but, "On the contrary, [condoms] make it worse."<sup>250</sup>

### **Political Restrictions on the use of condoms**

Despite the medical guidelines and evidence that condoms substantially reduce the spread of sexually transmitted infections and HIV/AIDS, the U.S. continues to fund programs that promote abstinence only and do not promote the use of condoms. The President's Emergency Plan for AIDS Relief, a \$15 billion initiative implemented under former President George W. Bush to support countries around the world in their efforts to fight the AIDS epidemic, requires that fully one-third of the funding be spent on abstinence-until-marriage activities. The Institute of Medicine mid-term evaluation of the program found that "the abstinence-until-marriage budget allocation in the Leadership Act hampers [prevention] efforts and thus PEPFAR's ability to meet the [HIV prevention] target."<sup>251</sup>

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***Programs that promote abstinence only and that do not promote the use of condoms run contrary to medical guidelines and evidence.***

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Refusal clauses and denials of care undermine standards of care by shielding providers when they fail to deliver health care services and information that would otherwise be required by generally accepted practice guidelines. Moreover, institutional restrictions systematically prevent medical professionals from meeting standards of care, and delivering care to their patients based on sound medical evidence. The consequences of public policies that allow health care denials and prohibitions 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 initiate change in 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:** Health care decision making is based on the best scientific evidence available, and ensuring that patients receive treatments known to be effective.
- **Patient-centered:** Patients are provided culturally appropriate care, treated with dignity and respect, and given complete and medically accurate information so that patients can give fully informed consent to their treatment.
- **Prevention:** Access to information and services that allows patients to optimize their health outcomes and well-being before the onset of disease.

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

## Appendix

### Drugs Categorized as Class D and Class X in the First Trimester of Pregnancy

Appendix A includes two tables. Table 1 lists those drugs categorized as Class D in the first trimester of pregnancy, meaning that there is evidence of fetal risk, but the potential benefits of the drug may make it acceptable for use when pregnant. Table 2 lists those drugs categorized as Class X in the first trimester of pregnancy, meaning that they are contraindicated in pregnant women.<sup>86</sup>

**Table 1. Class D Drugs in the First Trimester of Pregnancy**

Alprazolam	Doxycycline calcium
Amikacin sulfate	Doxycycline hyclate
Amiodarone hydrochloride	Doxycycline monohydrate
Amitriptyline hydrochloride/chlordiazepoxide	Epirubicin hydrochloride
Anastrozole	Etoposide
Arsenic trioxide	Exemestane
Aspirin/meprobamate	Flutamide
Atenolol	Gemcitabine hydrochloride
Azathioprine	Gentamicin 14 mg/mL eye drops
Belladonna alkaloids/phenobarbital	Gentamicin fortified eye drops
Bleomycin sulfate	Gentamicin in Ocean Nasal Spray (Fleming Pharmaceuticals, Fenton, Missouri)
Busulfan	Gentamicin sulfate
Cadexomer iodine	Gentamicin sulfate/sodium chloride
Capecitabine	Gentamicin sulfate/prednisolone acetate
Carbamazepine	Hydroxyurea
Carboplatin	Idarubicin hydrochloride
Chlorambucil	Ifosfamide
Chlordiazepoxide hydrochloride	Imatinib mesylate
Cisplatin	Imipramine hydrochloride
Cladribine	Imipramine pamoate
Clidinium bromide/chlordiazepoxide	Irinotecan hydrochloride
Clonazepam	Letrozole
Clorazepate dipotassium	Lithium carbonate
Colchicine	Lorazepam
Colchicine/probenecid	Mechlorethamine 0.01% (10 mg%) in Aquaphor (Beiersdorf AG, Hamburg, Germany)
Cyclophosphamide	Mechlorethamine hydrochloride
Cytarabine	Meclofenamate sodium
Dactinomycin	Melphalan
Daunorubicin hydrochloride	Mephobarbital
Demeclocycline hydrochloride	Meprobamate
Dexamethasone/diphenhydramine/nystatin/ tetracycline solution	Mercaptopurine
Dexamethasone/diphenhydramine/ tetracycline 1:1:1	Methimazole
Diazepam	Midazolam hydrochloride
Divalproex sodium	Minocycline hydrochloride
Docetaxel	Mitoxantrone hydrochloride
Doxorubicin hydrochloride liposome	Neomycin sulfate
Doxorubicin hydrochloride	Nicotine

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Nortriptyline hydrochloride  
Oxazepam  
Paclitaxel, semisynthetic  
Pamidronate disodium  
Penicillamine  
Pentobarbital sodium  
Phenobarbital  
Phenytoin  
Phenytoin sodium extended  
Potassium iodide (for oral use)  
Potassium iodide/iodine  
Povidone-iodine  
Povidone-iodine swabs  
Primidone  
Procarbazine hydrochloride  
Propylthiouracil  
Secobarbital sodium  
Tamoxifen citrate  
Temozolomide  
Tetracycline hydrochloride  
Tetracycline, nystatin, hydrocortisone  
mouthwash  
Tetracycline, nystatin, hydrocortisone  
powder, water  
Thioguanine  
Tobramycin fortified ophthalmic drops  
Tobramycin sulfate  
Tobramycin sulfate/dexamethasone  
Tobramycin/sodium chloride  
Toremifene citrate  
Tretinoin  
Tretinoin A 0.05% cream/hydrocortisone  
1% cream  
Tretinoin  
Valproic acid  
Vinblastine sulfate  
Vincristine sulfate  
Vinorelbine tartrate

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**Table 2 . Class X Drugs in the First Trimester of Pregnancy**

Acitretin	Testosterone 2% in Eucerin cream (Beiersdorf AG, Hamburg, Germany)
Atorvastatin calcium	Testosterone 2% in Velvachol cream (DPT Laboratories, San Antonio, Texas)
Bexarotene	Testosterone 2% in White petrolatum (Penreco, Dickinson, Texas)
Cerivastatin sodium	Testosterone 3% in Velvachol cream (DPT Laboratories, San Antonio, Texas)
Danazol	Testosterone 3% in White petrolatum (Penreco, Dickinson, Texas)
Diclofenac sodium/misoprostol	Testosterone cypionate
Dienestrol	Testosterone enanthate
Dihydroergotamine mesylate	Testosterone in Aquaphor (Beiersdorf AG, Hamburg, Germany)
Ergotamine tartrate	Testosterone in triamcinolone ointment
Ergotamine tartrate/caffeine	Testosterone in Velvachol cream (DPT Laboratories, San Antonio, Texas)
Ergotamine/belladonna/phenobarbital	Thalidomide
Estazolam	Triazolam
Finasteride	Warfarin sodium
Fluorouracil	
Fluoxymesterone	
Flurazepam hydrochloride	
Fluvastatin sodium	
Goserelin acetate	
Isotretinoin	
Leflunomide	
Leuprolide acetate	
Leuprolide acetate 40	
Lovastatin	
Methotrexate 2.5 mg/mL solution	
Methotrexate sodium	
Methotrexate sodium/PF	
Methyltestosterone	
Methyltestosterone (compounded)	
Methyltestosterone/estrogens, Esteri-G1BX	
Misoprostol	
Mitomycin	
Mitomycin 0.02% ophthalmic solution	
Oxandrolone	
Pravastatin sodium	
Quazepam	
Quinine sulfate	
Raloxifene hydrochloride	
Ribavirin	
Ribavirin/interferon ALFA-2B, recombinant	
Simvastatin	
Tazarotene	
Temazepam	
Testosterone	
Testosterone 1% in Lidex ointment (Medicis, Scottsdale, Arizona)	
Testosterone 1% in White petrolatum (Penreco, Dickinson, Texas)	
Testosterone 2% in Aquaphor (Beiersdorf AG, Hamburg, Germany)	

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