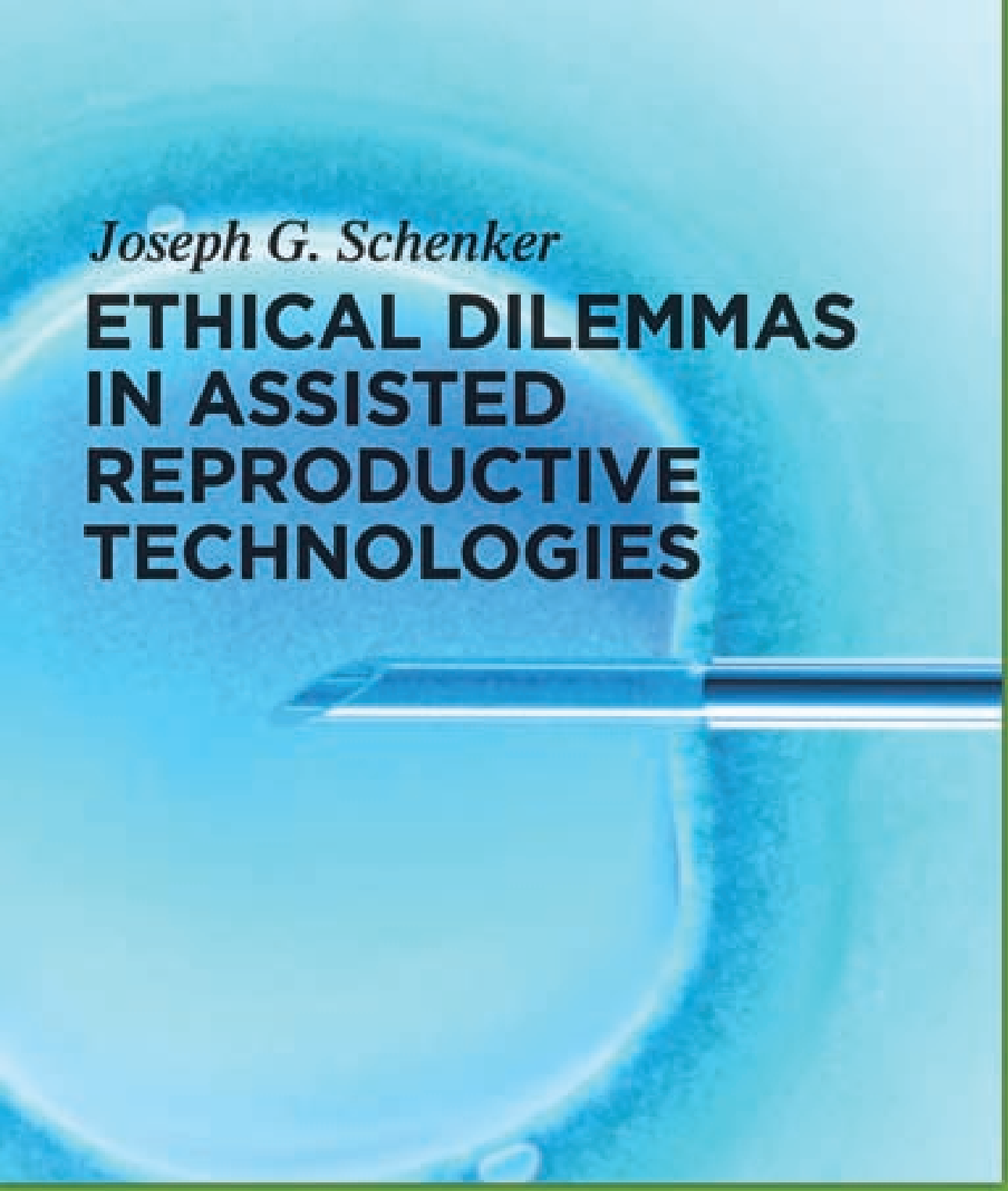

Joseph G. Schenker

ETHICAL DILEMMAS IN ASSISTED REPRODUCTIVE TECHNOLOGIES

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Edited by Joseph G. Schenker

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Preface

Medical ethics have undergone many and significant changes from antiquity to our era. In fact, it continues to change and to reshape constantly both in theory and in practice.

The role of medical ethics in individual patient-physician relationships as well as in public matters is growing along with the major and rapid changes in health and life sciences.

It is very important for caregivers and health care policymakers as well as for the public at large to be sensitive to ethical dilemmas and ethical debates and solutions. It is equally important for ethicists to be sensitive to public input and concerns. This mutual awareness and sensitivity will bring about better solutions to troublesome ethical dilemmas in modern medicine.

Infertility has been a major medical and social preoccupation since the dawn of human existence. There are many stories of women in the Bible who struggle with infertility and the pain of not having children. The Bible not only shares the stories of these "barren women" but also offers hope and comfort during these times. Though infertility is as much a male problem as it is a female problem, people throughout history have attempted to place the blame solely on the woman's womb.

At present millennium infertility affects millions people worldwide. Most of those who suffer from infertility live in developing countries where infertility services in general and assisted reproductive technology (ART) is not available. Infertility is a source of social and psychological suffering for both men and women and can place great pressures on the relationship of the couple. For a woman in developed countries the struggle with infertility can be an enormous psychological and emotional burden.

The low status of women in developing countries where womanhood is defined through motherhood reproduction is a social issue, controlled by family and religious customs, and not merely a personal choice.

A stigma of being childless puts pressure on the couple to have children, and for many infertile couples, infertility is a life crisis.

It may translate into very serious consequences, such as divorce, husbands taking second wives, difficulties with in-laws, domestic violence and economic abandonment.

Scientific advances in the field of human reproduction and genetics, the two areas of medicine that deal with infertility, have brought encouraging results. Couples who wouldn't have known the joy of being biological parents are now bringing home healthy offspring and in some cases, multiple babies,

The right to procreate has been considered to be the basic human right as was pronounced in 1948, by the United Nations Universal Declaration of Human Rights “that men and women of full age, without limits due to age, race, nationality, or religion, have the right to form a family.” Similar statements were several times reconfirmed by different international declaration and Acts during the last half century. The right to reproduce has gained importance in the modern era owing to technical advances in assisted reproduction.

ART (assisted reproductive technology) was originally developed for women with tubal factor infertility. During the last three decades there have been major advances in the development of improved drugs, individualized protocols for ovarian stimulation, the introduction of advanced laboratory techniques such as those involving embryo culturing methods, intracytoplasmic sperm injection, and enhanced egg/embryo freezing through vitrification. These have expanded the indications for IVF so that today it has become a first line of treatment for a variety of causes of infertility.

It is now estimated that 5 million infants have been born worldwide following ART treatment. In many countries ART children now account for 2–4% of all children born.

Preimplantation genetic diagnosis (PGD) is becoming an established tool in assisted reproduction for avoiding the transfer of the embryos with chromosomal abnormalities, which contributes significantly to implantation failure and pregnancy loss.

PGD may avoid distress and increase the chance of a successful pregnancy. It also avoids the ethical dilemma of abortion if the fetus is found to have a lethal or profound disorder. The use of PGD is now being extended to include gene mutations that increase the risk of late-onset disorders such as breast and ovarian cancer.

The extension of PGD raises practical ethical issues involving relative burdens, duty of care, freedom of choice, distributive justice.

To date, successful results based on pregnancy rates have been obtained with cryopreserved spermatozoa, embryos, oocytes and ovarian tissue

In cases of severe male infertility, such as non-obstructive azoospermia after testicular sperm retrieval, no sperm confirmed, and some male genetic diseases, the use of donor sperm is often the only approach for infertile couples to father children. As demand for sperm banks and sperm bank services continues to rise, health and ethical considerations on behalf of the sperm donor, the sperm recipient, and donor offspring remain critical issues to consider.

The original aim of embryo cryopreservation was to reduce the number of embryos transferred in order to limit the well documented risk of multiple gestations. It was proved that cryopreservation of embryos offers practical, financial and social benefits.

Human oocyte cryopreservation is potentially an alternative solution to the ethical legal or religious problems arising from embryo storage. Human ovarian tissue banking is proposed as a method of preserving female fertility especially in cancer patients of reproductive age. It offers the potential of restoring normal ovarian function and natural fertility.

Delayed age of childbearing is increasing in industrialized nations and is related to deferment of marriage and postponement of pregnancy in marriage, as well as frequent occurrence of divorce and remarriage. More women in their late 30s to early 40s are now seeking their first pregnancy. Oocyte donation is a common form of third-party reproduction, associated with significant success rates. It gives older couples an opportunity to bear children, almost regardless of the maternal age. Oocyte donation raises a number of ethical issues, not only for donors and recipients but also for reproductive medicine professionals, offspring, and society in general. This raises the question of whether certain limits should be imposed in applying the method in older women.

Since the introduction of IVF, advances in assisted reproduction technologies have resulted in the creation of family types that would not otherwise have existed. With IVF using the father's spermatozoa and the mothers oocyte, the child is genetically related to both parents, whereas children conceived by donor insemination are genetically

related to the mother but not the father, and children conceived using donated oocytes are genetically related to the father but not the mother. When both egg and spermatozoa are donated, the child is not genetically related to either parent. This latter group of children is similar to adopted children in that they are genetically unrelated to both parents. In the case of surrogacy, the child may be genetically related to neither one or both parents, depending on the use of a donated egg and/or spermatozoa.

Despite the changes that have occurred in society during the past few years the most widely accepted structure of the family remains that comprising two heterosexual married parents who are genetically related to their children.

Families that have resulted through assisted reproduction, although continuously increasing in number, may differ from the normal, either because of a non-genetic relationship of one or both parents with the offspring. Surrogacy enables gay couples who desire to be parents.A growing number of single heterosexual women, lesbian women and gay men are opting for assisted reproduction. Non-heterosexual adults who want to become parents may have to overcome legal, social, and /or financial barriers to achieve this goal.

Gay and lesbians endorsed the value of parenthood just as strongly as did their heterosexual peers, despite being less likely to express parenting intentions and desires. The right to reproduce is not recognized for homosexual couples in most countries.

IVF contributed to the development of human embryonic stem cell lines.

From the first derivations of permanent human embryonic stem cell lines, a huge amount of new information regarding early human development, use of pluripotent stem cells in regenerative medicine, and pharmaceutical and toxicity testing has followed.

Ethical debates have surrounded the development of human embryonic stem cell research. The ethical position of individual societies and countries on obtaining stem cells from supernumerary embryos, there by ending their capacity to develop, derives from considerations on the moral status of preimplantation embryos, status that is itself contingent on cultural, religious, or philosophical considerations on the beginning of human life.

Human reproductive for the sake of producing a child that will, in principle, grow into adulthood as a normal member of society is to be distinguished from therapeutic cloning and cloning with research aims. United Nations Declaration on Human Cloning calling for the ban of all forms of Human Cloning contrary to human dignity, was adopted

Ethical issues raised by ART have been found to be so profound that several countries have created national commissions to propose legal regulatory discipline.

In the present situation at this time the methods of legal regulation of ART may be divided into three categories: 1. Legal regulation under the law – a set of rules passed in the legislative process and containing penalties for nonobservance. 2. Legal regulation under various guidelines. 3. Without legal regulation.

In most cases, the treatments by ART are invasive and performed solely on the woman. The medical achievements that make it possible to conceive, other than naturally, via donation of gametes, surrogacy and even posthumously, mandate a different approach to fertility-treatment consent than that required for other medical treatments. This is so due to certain unique characteristics of fertility treatments: the aim of fertility treatment and the measure of its success is the creation of a live newborn infant. Hence, the good of the future child should be considered, as should the patients' capability to undertake parental responsibility.

The developments in reproductive medicine raise new ethical questions for different religions that do not always have clear answers.

It is important to those who practice reproductive techniques to learn about different religious perspectives related to reproductive-health problems. Religious groups are active in influencing the public with bioethical positions, and this is particularly evident with issues concerning procreation, abortion, and infertility therapy. Religious leaders in some countries still exert a powerful influence on the development and practice of reproductive technology.

The attitude toward ART varies among different Christian Dominations.

The Vatican statement on assisted reproduction is very clear; ART is not acceptable. The Catholic Church argues that IVF involves disregard for human life and separates human procreation from sexual intercourse.

There are basic principles in Jewish Law – Halakha, that with certain restrictions favor ART. First and foremost is the commandment in The Bible "Be fruitful and multiply". Judaism allows the practice of all techniques of assisted reproduction when the sperm originates from the husband.

The primary sources of Sharia have affirmed the importance of marriage, family formation, and procreation, as indicated in several verses of the Koran

Today, the guidelines – fatwa that are followed by most Sunni Muslims are as follows:

If assisted reproduction is indicated in a married couple as a necessary line of treatment, it is permitted within the validity of a marriage contract with no mixing of genes, but if the marriage contract has come to an end because of divorce or death of the husband, ART cannot be performed on the female partner, even when using sperm cells from her former husband.

Shia guidelines, via fatwa, are even more liberal, have opened the way to a third-party donation. This fatwa allows third-party participation, including egg donation, sperm donation, embryo donation, and surrogacy.

The book offers expert reviews and valuable scientific articles on a wide variety of controversial topics about the ethical dilemmas in ART. It presents a unique collection of 31 chapters by contributors from different countries, from a wide range of disciplines which include physicians applying assisted reproductive technologies for infertile patients, ethicists, lawyers, theologians and sociologists.

The contributing authors were chosen for recognized international authority in their respective areas and for their ability to transmit information in a manner that is lucid and interesting.

I sincerely hope that the readers of this book will find in it sufficient new information regarding ethical, legal and religious innovative approaches for ART practice.

I want to thank each and every author for the tremendous time and energy spent in writing manuscripts for this book

Joseph G Schenker

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1 The foundations and application of medical ethics

Avraham Steinberg

1.1 Introduction

Ethics is the branch of philosophy that deals with moral aspects of human behavior.[1]

Medical ethics, in the narrow historical sense, refers to a group of guidelines, such as the Oath of Hippocrates, generally written by physicians, about the physician's ideal relationship to peers and to patients.

Medical ethics, in the modern sense, refers to the application of general and fundamental ethical principles to clinical practice situations, including medical research. Individuals from various disciplines may author these principles.

In recent years, the term has been modified to biomedical ethics, which includes ethical principles relating to all branches of knowledge about life and health. Thus, fields not directly related to the practice of physicians, such as nursing, pharmacy, genetics, social work, psychology, physiotherapy, occupational therapy, speech therapy, and the like, are included. In addition, bioethics addresses issues of medical administration, medical economics, industrial medicine, epidemiology, legal medicine, and treatment of animals, as well as environmental issues.

1.2 Historical background

Since the beginning of human history, concern for medical ethics has been expressed in the form of laws, decrees, assumptions, and oaths prepared for or by physicians. Among the oldest of these are the Babylonian Code of Hammurabi (approximately 1750 BCE), Egyptian papyri, Indian and Chinese writings, and the works early Greek writers, most notably Hippocrates (460–377 BCE).

Early medical ethical codes were written by individuals or by small groups of people, usually physicians. The Oath of Hippocrates is considered historically to be the first such code written in an organized and logical way that describes the proper relationships between physician and patient. During the Middle Ages, other medical codes were written. In more recent times, Thomas Percival's writings, disseminated in 1803, represent one of the first ethical codes in the United States and the Western world (Chapman 1979).

Beginning in the second half of the 19th century, medical organizations began writing codes of medical ethics:

- The first ethics code of the American Medical Association (AMA) was published in 1847 (Baker 1997). This was the first ethical code of a professional organization that outlined the rights of patients and caregivers. Over the years, many revisions and additions to this original code have been made. The latest edition of the AMA Code of Medical Ethics (www.ama-assn.org, June 2001) contains four parts, which include general principles, opinions on specific issues, and special reports. The AMA established the Council on Ethical and Judicial Affairs to advise it on legal and ethical issues and to prepare position papers on these issues for the AMA.

- The British Medical Association published its first code of Medical Conduct of Physicians in 1858. The code has subsequently undergone numerous changes.
- The World Health Organization issued the Declaration of Geneva in 1948, the first worldwide medical ethical code, which is modeled after the Oath of Hippocrates.
- Many other medical organizations throughout the world, including those in Israel, have issued medical ethical codes.

Modern medical ethics as a separate field began to develop in the 1950s. One of the major innovations of modern Western medical ethics involves the physician-patient relationship, with a dramatic change from paternalism to autonomy and its resultant requirement for informing the patient, obtaining informed consent, and relating to the patient as an active partner in decision making.

1.3 General ethical theories and principles

The study of ethical theories provides a logical framework for the understanding of the ethical dimensions of human conduct and helps one recognize ethical dilemmas and provides tools for their resolution. Ethics examines and measures human conduct. Accepted practices of human conduct in a given country are termed normative behavior. Ethical standards are used to evaluate and ensure the appropriateness and desirability of such practices.

A value usually denotes the good and the beneficial in ethics, the truth in cognition, and the holy in religion. A value is not determined objectively. It is not a scientific term and cannot be scientifically defined. Therefore, science is neutral with respect to most bioethical values. A value represents a subjective assessment and may be measured by what a person is willing to sacrifice for it and not by what it gives to him.

Ethical dilemmas are created only in relation to human beings, within the framework of relations between one human being and another. They arise when two or more alternative actions, each of which is inherently good, yield conflicting outcomes. Alternately, an action that benefits one person may cause harm to another. In such situations, one must find the ethical justification for each course of action and have a system of prioritization to select the most appropriate one. Ethics asks what should be done, not what one ordinarily does and not what one could do.

The two central questions in ethical theories follow:

- What is the good for which we strive or should strive, and what is the evil that we would like to or must avoid?
- What is the proper or desired course of action, and what is the inappropriate or forbidden course of action?

Some people believe the two questions are interrelated and debate which comes first and which the corollary is. Others totally separate the two questions.

Sometimes, the dilemma is factual, and not one of values. In such cases, debates and discussions may result from imprecise knowledge about the facts related to the dilemma either due to lack of actual information or to lack of clarity or understanding of positions and views about the issues. Often, mere clarification of the facts may

resolve the ethical question. Good ethics starts with the correct facts. A decision is inherently unethical if it is based on erroneous or incomplete data. Therefore, the first step in adjudicating a concrete medical ethical issue is to gather the pertinent facts. Proper clarification of the facts often avoids futile ethical debates. Sometimes, debates result from differences in the fundamental positions of the people involved. Even in such cases, a clear and precise presentation of the various positions may achieve mutual respect, precision of ethical focus, and sometimes even resolution of the ethical dilemma, even if a consensus is not reached.

Ethical dilemmas would not exist if ethical principles were like parallel lines that never intersect. However, in reality, values do not function in that way. Rather, they go in different directions and involve situations where values conflict with each other. Then, one must choose between good and bad values or between values of greater or lesser utility. Sometimes, resolution of an ethical problem is easy, with a single, course of action all parties agreed on. At other times, the resolution is a compromise between opposing interests, with no one totally satisfied.

Theoretically, ethics should decide between good and bad, between proper and improper, between correct and incorrect. But a proverb says, "A wise person is not the one who knows how to choose good from bad, but he who chooses the lesser of two evils."

Ethical acts can be evaluated on four planes:

- the desire, intent, or motivation
- the ethical principle, theory, or value
- the method
- the consequences

Various ethical teachings emphasize one or more of these planes, and some utilize all four. At times, one needs to consider specific circumstances, which may be temporary or changing, or one needs to find a middle path between opposing and contradictory values.

Ethics differs from precise science in several ways:

- One cannot readily subject ethical questions to controlled experimentation and study, and one cannot separate purely ethical considerations from personal-subjective influences also affected by cultural and historical backgrounds. Since ethical decisions are influenced by historical, philosophical, sociocultural, and religious attitudes, each with strong subjective components, there are few universal objective truths. The most widely used terms in ethics are *good* or *bad, proper* or *improper,* and *correct* or *incorrect.* In contrast, in the physical and natural sciences, we arrive at specific conclusions based on objective observations or experiments with minimal human biases. Therefore, the terms used in science are *true* and *false*.
- Science arrives at conclusions, whereas ethics provides decisions or recommendations. A conclusion is the obligatory acceptance of the facts, whereas a decision or recommendation is a voluntary choice among various options. Furthermore, a scientific conclusion is based on the past (i.e., on previous studies that lead to present conclusions). Ethics, on the other hand, is future oriented: A present choice is based on a future desire, intent, or consequence. Thus, the word *cause* is a scientific term

that explains a current situation based on earlier data, whereas the words *reason* and *argument* are value terms that attempt to justify current action based on desires or motives.

- If an error is discovered in scientific knowledge, the scientist can correct it by explaining the facts differently without being required to change personal conduct. By contrast, if an error is discovered in a value judgment or in ethical conduct, repentance and a change in the person's behavior is required. In science, only success of the effort is considered significant, whereas in ethics, the effort itself in trying to resolve the dilemma is considered worthwhile. Many scholars in ethics and religion believe that the attainment of perfection should not be the ultimate goal. Rather, the goal should be the effort to gain perfection, since its actual attainment is all but an impossibility for a human being. This is also true from a religious point of view – it is erroneous to believe that a person is obligated to recognize the truth; rather, one must seek the truth, since absolute truth is only with God.

Ethics also differs from laws and religion in that the latter two provide definitive and absolute rulings. By contrast, ethics in general does not decide absolutely, but rather focuses and clarifies questions and issues and presents options and alternatives for dilemma resolution.

There have always existed various ethical schools of thought, with significant differences between them. They differ in the principal justifications and validity of the various ethical theories as well as in the terminologies, the specific principles and rules, the relative relationship between them, and their practical application.

One of the basic ethical questions is the source and validity of values. Ancient Greek philosophers debated this issue. Plato and the stoics argued that the validity of moral cognition is absolute and objective and that universal ethical laws and principles apply to all people in all places and at all times. By contrast, the Sophist and Skeptic philosophers argued that one cannot prove or justify a universal ethical law or value, and they believed that ethical principles are relative, and dependent on the place, the time, and the circumstances. An intermediate view was that of Pythagoras and his followers, who said that certain values and norms exist for certain populations but may vary in different cultures and be influenced by external circumstances.

These basic differences of opinion remain even in modern times. Some philosophers view most or even all values merely as subjective recommendations that differ from society to society and from era to era and, according to the circumstances, even from person to person. This view is based on the observation that various actions are perceived differently by various societies and various people. According to this view, ethical values are not innate but must be acquired and hence are influenced by forces that determine various types of behavior. Some philosophers define the source of ethics to be one's emotions; an action is ethical if it makes one feel content and good, and unethical if it evokes a feeling of disgust and revulsion. Others, such as David Hume, Baruch Spinoza, and Lana Stermac, espouse the view that an action is ethical if it produces joy, and unethical if it leads to sadness. According to these views, emotions and social habits are the sources for the validity of ethics.

By contrast, some philosophers recognize absolute and universal values that change neither according to external needs and circumstances nor from society to society or from era to era. The source of these values is either factual-empiric, intuitive, or

metaphysical-religious. This view is based on the thesis that certain values and conduct are universally accepted as ethical or unethical in all societies and in all eras. This view also asserts that relativism is unfounded, unjust, and empties ethics of any real content, since it changes with differing temporal circumstances and conditions. (The main proponent of this view is Immanuel Kant.)

Two basic theories exist today in the fundamental approach to normative ethics. The utilitarian (or consequential or teleologic) theory measures the value of an action by its consequences: An appropriate or good action is one that brings the most beneficial results for the most people. This view, in its classic sense, opines that the goal of ethics is to bring the most good to the most people so that ethical principles are used as vehicles to attain the highest or ultimate good. Ethics thus has a specific goal, and each action is taken to achieve that goal.

There is obviously great variability in deciding what is the ultimate good toward which attainment one is to strive. Some view a specific individual goal as the ultimate good (= a monistic view; the main proponents of this view are Epicurus, Spinoza, and Friedrich Nietzsche), be it happiness (the main proponents of this view are Aristotle, Socrates, and the Greek Stoics, and in modern times John Stuart Mill), self-fulfillment (proposed by Georg Wilhelm Friedrich Hegel and F. H. Bradley), or pleasure (= hedonism). Thus, the individual's own opinion is decisive and any action that gives that person benefit is by definition ethical and good. Others believe that the good should be a general one for society and not just for the individual. Thus, an action is ethical if it brings great pleasure to the largest possible number of people. (The main proponents of this view are Hume and Jeremy Bentham.) Some view the attainment of physical pleasure to be the ultimate good, whereas others consider mental pleasure and benefit to be the crowning ethical consideration.

By contrast, some philosophers argue that there is no single purpose that is the sole good; rather, several goals should be sought (= a pluralistic view, espoused by Richard D. Mohr). Examples of good goals are love, health, happiness, friendship, and beauty, each one of which is an ultimate good in itself. Therefore, ethical acts need to be assessed on the basis of the greatest progress that they produce toward the conglomerate of these values and not just on the pleasure and avoidance of suffering achieved.

A third utilitarian view is that the best goal is to promote individual preferences toward the fulfillment of personal desires and ambitions; the main goal is the realization of what the individual or the group view as good for them, within specific conditions and time frameworks.

Utilitarianism has been strongly criticized for many reasons, including the following:

- It is based on the ability to measure the good consequences and compare between various goods. How can one, however, measure individual ethical units of goods such as pleasure, happiness, love, etc.?
- In many concrete situations, it is very difficult to weigh the expected benefit if varying and conflicting actions are taking place.
- It is impossible to prove with certainty that a single value is the ultimate good for which one should strive. The choice of pleasure as the ultimate good is open to debate, just as is the choice of any other simple value.

- Utilitarianism lacks ethical consistency in decision making because it changes with different expected outcomes.
- It can easily lead to unjust social actions in that actions that benefit the majority of people may create serious harm to the remaining minority.

In a utilitarian system, who decides what should be the best outcome, and how does one decide? The subgroup that views individual preferences as the ultimate good resolves this question but produces a much more difficult issue, in that often other peoples' desires and preferences are ignored. Thus, utilitarianism can undermine the whole ethical foundation of universal applicability.

The main theoretical objection to utilitarianism is its premise that ethical acts themselves have no intrinsic value because their ethical validity is based on their outcomes or consequences. Thus, the goal justifies the means. Hence, some acts can be ethically wrong but are justified because their outcome produces the desired benefit as defined above.

The second theory of ethics, the deontological (*deos,* in Greek, means obligation), states that an act is considered ethically proper and good if it fulfills the basic requirements of ethical principles and values of intrinsic validity, without regard to the expected or anticipated consequences.

The main proponent of the deontological theory of ethics in its extreme form is Immanuel Kant (1724–1804) (Kant 1964). According to his theory, there exist ethical values that dictate actions categorically without compromise. The source of ethics is logical, universal, and unchanging – irrespective of time or place. The ultimate good is for decisions to be made based on one's intent to act ethically, and not on the result or outcome of that act. Only good intentions are good, without reservation. Kant's thesis is that one must act ethically because of the autonomy of one's will and not because of pressure, inclination or external forces of any kind (= heteronomy). The philosophic basis of this theory of ethics is that the ethical value of an act flows from an obligation, and the latter is the fulfillment of one's autonomous will established by the laws of understanding and wisdom. According to Kant, ethical behavior is required of all people of understanding. It is not learned by experience but is established a priori by that understanding. Therefore, ethical law is objective and absolute and nothing can restrict it or attach conditions to it. One of Kant's fundamental rules is the general formula, whereby a person must always act in a way that everyone else should act similarly.

The deontological theory of ethics has also been strongly criticized for several reasons:

- Pragmatically, it is difficult to determine who decides on absolute values and how they are implemented.
- The extreme view of this theory, which completely ignores the goals and consequences of actions, cannot be applied practically, because the absolutism often leads to impossible situations in daily living and may produce great harm.
- The deontological theory provides no mechanism to decide between two or more universal-absolute values when they are in conflict with each other. Situations frequently arise requiring a choice between two absolute values. There is no way, in Kant's approach, to apply his general principles to such specific situations.

A number of neo-Kantian theories developed trying to resolve the above difficulties. For example, some writers combine deontology with utilitarianism (the main proponent of this view is W. D. Ross (1939) and require one to pay attention to absolute and universal values which every decent human being should follow (= prima facie obligation). If, however, they conflict with equal or even stronger ethical imperatives in certain situations, the latter may have to be adopted and the universal values set aside.

Another attempt at resolving the difficulties with the Kantian approach is to emphasize the principles of honesty, equality, and social justice. In this view, ethical principles are those that all people would agree should they be evaluated freely and independently of the actual social situation, were they to examine them from an original position (Rawls 1971). In their view, social justice is the highest ethical value, and different characteristics of individual people are ignored.

Because every well-defined ethical theory has its problems, either in relation to its characteristics or in relation to its practical application, some writers speak of relativistic or situational ethics that are determined by the situation, the time, the place, the culture, etc. Thus, according to this approach, there are no universal principles applicable at all times, in all places, and for all situations. Rather, each situation is decided according to the appropriate culture, time, place, and circumstances. This view can undermine the basis of ethics and morality and leads to ethical anarchy. It is not helpful in resolving ethical questions in a consistent manner.

In recent years, several fundamental ethical principles have been formulated and widely adopted as the basis for ethical discussion in medicine:[2]

Autonomy is defined as a fundamental principle based on the worldview that every person has an intrinsic value. One may not restrict nor negate the free wishes of an individual with respect to his own body. One must facilitate any desired action acceptable to a person's own judgment and in accordance with her own choice. The granting of autonomy requires that we recognize and accept the free choice of each person even if that choice seems inappropriate or foolish or even dangerous.

A precondition for autonomy is complete freedom of the individual from outside control or pressure. Any action that derives from external control which interferes with one's expression of autonomy is termed heteronomy. By definition, proper, full autonomy cannot be exercised by the very young, the mentally retarded, or the psychotic. Also, autonomy is not to be respected if such a choice is likely to harm others.

Many ethicists view autonomy as the most important ethical principle, one that supersedes all others (Engelhardt 1986). In recent years, the tendency is to decide more and more medical ethical and legal dilemmas according to this principle. Other ethicists view autonomy as only one of several important ethical principles (Pellegrino and Thomas 1988). This view is based on the recognition that one should not totally abandon other ethical principles regarding a physician's obligations toward patients. Some writers even consider it "tyrannical" to view autonomy as the most important value with dominance over all others (Glick 1997), and believe that such a practice might lead to public ethical anarchy (Steinberg 1994). One should also recognize that the Western world's espousal of autonomy is not universally accepted in all societies and cultures. Therefore, some writers state that unrestricted autonomy is culturally dependent (Glick 1997).

Autonomy is not only the privilege of the patient. It is universally agreed that the physician's autonomy, too, must be respected. A physician may refuse a patient's request for a therapy that has no scientific or rational basis, especially if it may be harmful to the patient.

Also, a physician may refuse to implement a patient's decision for a certain treatment if it conflicts with the physician's conscience, for whatever reason. In such situations, the physician has the right not to treat the patient and to transfer such care to another physician.

Nonmaleficence (= primum non nocere) is defined as the obligation not to harm others and to remove and prevent potential harm (Frankena 1973). Thus, one must not only prevent intentional harm but must also be appropriately cautious not to cause harm. Health care workers must be properly trained so that they not inflict harm because of lack of knowledge or lack of appropriate skills.

This concept of nonmaleficence is applied to the relationship between physician and patient based on the phrase "Above all, do no harm." Some writers state that nowadays, nonmaleficence should be redefined as the principle of striving not to do harm, by balancing the benefit against the harm of any specific action. However, this ethical principle of not doing harm should not be absolute and cannot be applied fully in all diagnostic and therapeutic interventions (Brewin 1994; Gillon 1985). The cause for this change in the definition of nonmaleficence relates to the major changes in the practice of medicine today as compared to that practiced in antiquity.

Beneficence is defined as the moral obligation to do good for others, and to help them in an active way. Ethically, it is not enough to avoid doing harm; one must actively do good to others. Obviously, there are limits to the requirement that one act to help others at all times. These vary with the degree of need, the ease and ability with which the help can be rendered, and the nature of the relationship between the individual needing help and the one able to provide it.

Justice is the granting and fulfillment of legitimate rights of others, and injustice is the denial of these rights. Justice requires the division of rights and assets in an equitable and appropriate manner, but no less so the fair distribution of duties and burdens. In the simplistic sense, *justice* means "equality." However, in daily life, many variables cause unequal division of obligations and rights. Therefore, several ethical theories and techniques have been developed for distributive justice, taking into consideration needs, rights, contributions to society, and other factors.

Different theories of justice place greater priority on different factors: Marxism emphasizes economic needs, while liberalism emphasizes social needs. The differences in views and emphases make it difficult to attain ideal justice, since equality in one aspect may bring inequality in another and, hence, injustice.

Rights – Beginning in the 19th century, individual rights became a cornerstone in political, legal, and social thinking. Some believe that people have absolute moral rights unrelated to changing social conditions. These include natural universal rights such as the right to life, liberty, and privacy. Others believe that rights flow from societal consensus, customs, and laws and therefore are relative and may change according to the circumstances.

1.4 Modern medical ethics

Modern medical ethics is based on concepts derived from various disciplines, including the biomedical sciences, the behavioral sciences, philosophy, religion, and law. Modern medical ethics is essentially a form of applied ethics, which seeks to clarify ethical questions that characterize the practice of medicine and to justify and weigh the various

practical options and considerations. Thus, medical ethics is the application of general ethical principles to ethical issues. The application of such an ethic is not specific to medicine but also relates to economy, law, journalism, and their like.

In the past, only a few individuals, mostly physicians, devoted themselves to medical ethics. Beginning in the second half of the 20th century, the field underwent explosive expansion and experts from numerous disciplines entered the field.

The rapid advances in medical diagnosis and treatment and the introduction of new technologies have produced numerous new ethical dilemmas, resulting in the maturation of medical ethics as a specialty in its own right. Research institutes of medical ethics have been established. Medical ethics is now part of the curriculum in schools of the health professions at all levels. The medical-ethics literature has proliferated, and numerous books and journals have been devoted entirely to the subject. Nearly all medical periodicals devote considerable space to ethical topics. For example, at the end of 1997, Medline had 3,400 citations on bioethics (Wadman 1997). The general public is also vitally interested in this subject, and public lectures, newspaper articles, legal discussions, and legislation on medical ethical issues are numerous.

In the United States, medical ethics has emerged as a new profession. Medical ethicists generally have specialized in one or more of the fields such as philosophy, ethics, law, religion, and medicine, and serve as advisers in hospitals to physicians, patients, and their families. They attempt to resolve difficult ethical questions posed to them by the medical team or by patients and their families. According to recent studies, most of the medical staff found ethical consultation and advice to be valuable, but only half of patients or families found it to be valuable (McClung, Kamer, and DeLuca 1996; Orr, Morton, and deLeon 1996).

A number of reasons are responsible for the enormous recent interest in medical ethics:

- Significant technological and scientific advances and changes in clinical medicine and research have produced totally new ethical dilemmas and exacerbated old ones.
- The change in philosophy from paternalism to autonomy in the physician-patient relationship has removed from the physician the monopoly on decision making.
- The involvement of additional caregivers (various medical specialists and a variety of health professionals, students, administrators, and investigators), each with their own cultural and social value systems, have increased and sharpened ethical debates and discussions.
- The involvement of society at large (through the mass communication media, courts, and legislators) has created the necessity to redefine the societal parameters of the physician-patient and physician-societal relationships.
- Broad social changes throughout the world have damaged the image of the unique nobility of the physician. This change has been enhanced by the commercialization of medical services and the greater sense of consumer criticism. Moreover, in recent years, physicians have come to view medicine more in terms of their careers, honor, self-fulfillment, and income. There is a call nowadays to return to the historic principles of the medical profession, which differs from most other professions. Medicine, this opinion holds, should be viewed as service to the sick and the needy, with humility, honesty, empathy, intellectual integrity, and effacement of self-interest as guiding factors.

A number of significant socioethical changes have occurred in the portrayal by society of medical practice and the medical profession. In the past, it was thought that all illnesses had a limited number of causes, with only minor variations between people. Thus, a holistic view of people was prevalent. The limited armamentarium of diagnostic testing and therapeutic interventions enhanced close communication between the physician and the patient because a detailed history and physical examination were virtually the physician's only diagnostic tools. Scientific knowledge of medicine was limited, and the art of medicine was emphasized.

By contrast, modern medicine has traced disease causation to a multitude of processes in individual organs, tissues, or even cells. The diagnostic and therapeutic approaches focus primarily on the illness and less so on the patient, changing the physician-patient relationship dramatically. Since most diagnostic tests and many therapeutic interventions are performed in specialized laboratories and treatment centers, there is far less need for communication and interaction between the patient and the physician. Science and technology are glorified at the expense of humanism, and this is reflected in medical education. A 1984 study reported that only 3% of American medical students had majored in humanistic subjects in their premedical education (Warren 1984). Classically, medicine had been identified with the humanities. Nowadays, young physicians choose careers in narrow subspecialty areas with emphasis on clinical or basic research. This approach has led to a reduction of empathy for the sick person and loss of the individual human concern (Glick 1981).

This trend began to reverse itself in the 1980s and 1990s. Public pressure and the profound realization of the purposes of medicine and its roles resulted in attempts to balance the technological and scientific advances with the humanistic and ethical approach to medical practice. Medical ethics attempts to help resolve some of these issues.

Economic issues engendered as a result of the high cost of modern medical care have created new dilemmas that require resolution, both on individual and societal levels. Economic pressures have added a new dimension to the physician-patient relationship. The physician's responsibility to a patient often conflicts with responsibility to the physician's employer or insurance companies or the government. The physician must skillfully and ethically balance these ethical conflicts (Welch and Fisher 1992).

However, in practice, the influence of medical ethics in the United States on the formation of public policy or even the education of scientists and physicians has not been very great. Some critics regard modern medical ethical discussions as excessively academic and theoretical and insufficiently forceful. Furthermore, governmental, political, and economic considerations often influence the appointment and financing of medical ethics task forces or commissions, leading to biased results (Wadman 1997). If ethics is to have a major impact on society, there needs to be greater motivation on the part of society and intensive education toward appropriate ethical conduct and concern for one's fellow human beings.

Medicine is not an exact science. It deals with people and not objects. Therefore, its scientific and humanistic components must be combined. Better and more knowledge per se does not necessarily lead to better medical care, since the subjective feelings of the patient, which are based on personal, social, cultural, and economic value systems, must also be considered. Therefore, clinical and research medicine need to combine technical knowledge and advances with human feelings, as well as ethics and social

justice. Only optimal synthesis of these two elements can educate ideal physicians who can "serve mankind with respect, honor, and dignity."[3] Many areas in medicine do not involve pure science but are built on interpersonal relationships, feelings, morality, and appropriate psychosocial conditions. If medicine's function was only to cure illness, it would be a pure science without any relationship to morality or justice. However, since medicine's goal is to cure people of their illnesses, it has major humanistic and ethical components.

The basic concept of medial ethics is that the physician has a moral (and at times legal) obligation to act for the patient's good, using the most up-to-date information. The question is how to establish that good, who defines it, and what are the components thereof.

One of the most important areas of discussion in ethics is the doctor-patient relationship, which is portrayed in one of several ways:

Paternalism is an approach in which the physician chooses the treatment for the patient because the physician's professional knowledge, experience, and objectivity best qualify him or her to judge the ideal treatment for the patient. This attitude assumes that the physician and the patient have a common interest but that the doctor is better equipped for the necessary decision making, with minimal or no patient involvement.

A number of significant criticisms of paternalism are as follows:

- It impinges on the basic rights of patients to decide for themselves what should be done with their bodies.
- Many decisions are not purely medical, but involve personal and cultural aspects in which the physician has no particular expertise. Such decisions require the patient's input.
- Many diagnostic and therapeutic decisions involve ethics. For example, the decision as to whether or not to abort a fetus with Down's syndrome is not a medical one but an ethical, legal, and religious one. Similarly, the decision whether to attempt to resuscitate a terminally ill patient is an ethical rather than a purely medical one.

Autonomy means that only patients know what is best for them and that only they have the right to decide. In order to do so, patients need to receive from physicians all the appropriate information about their condition to permit the patient to make an informed decision. A physician's values, and his or her professional knowledge and experience, play no role in the final decision. Traditionally, the physician's role was viewed as giving orders to nurses and to patients. In the atmosphere of autonomy, physicians must use a different language, incorporating advice, recommendation, position, etc.

The main criticism of pure autonomy is the relegation of the physician to the role of a technical consultant, with little influence on the patient's decision, which is often based on a lack of full understanding of the patient's condition. Such a decision may cause unnecessary and avoidable harm to the patient.

A compromise or middle position between paternalism and autonomy is one in which the physician provides the patient with the relevant information, the physician and patient discuss the medical and ethical issues, and they then arrive at a joint decision. This approach preserves the patient's autonomy on the one hand, and the physician's obligation to advise the patient about the best decision on the other hand. This is considered to be the best system, permitting responsible decisions according to the

relevant individual circumstances while preserving the obligations and rights of both patient and physician (Emanuel and Emanuel 1992).

Beginning in the 1950s in the United States, paternalism largely began to give way in favor of autonomy throughout most of the Western world. But now there is a renewed questioning of whether the pendulum has not swung too far in favor of untrammeled autonomy and individualism. Various suggestions have been put forward to create joint frameworks for the physician and patient while establishing criteria for joint decision making, sharing of responsibilities, mutual respect, and mutual trust (Balint and Shelton 1996; Pellegrino and Thomas 1988).

Much of the literature in modern medical ethics has emerged from the English-speaking countries. These views and conclusions do not always reflect the views in other Western countries, and may conflict even more with those in Eastern European cultures and Asian and African countries. These differences are to be expected when one considers the sociocultural differences between various societies.

Generally, scientific progress in technology and in knowledge precedes discussions and debates about the ethical, religious, and legal aspects of that progress. The recent extraordinarily rapid pace of advances in knowledge, science, and technology have made it even more difficult for the ethical, legal, and religious analysis of these issues to keep pace with the scientific advances. There is a need now to change this approach so that ethical, religious, legal, and social implications of innovative scientific and technological measures will be anticipated and acted on in advance rather than post-factum.

The identification and characterization of a medical ethical dilemma is not always obvious. The goals of medical ethics include the analysis of the relative merits of alternative actions in medical ethical dilemmas. Definite and absolute decisions are not always attainable or implementable. Therefore, medical ethics is satisfied with decisions defining the relationship between what is desirable and what is practical or in the choice of the lesser of two evils. Medical ethics is generally pluralistic and multidisciplinary in its approach. Its main function is to identify and characterize the component elements of a given medical situation and to provide an analytic process for assessing and applying the relevant values and principles of ethics. In general, modern medical ethics does not see its function as providing definitive ethical directives in every case. In this respect, ethics differs from law, which establishes specific guidelines, whereas ethics provides pluralistic approaches and clarification and precision of understanding of the ethical aspects of medical questions.

The place of legislation in regard to medical ethics is debated. Some writers would like to see major involvement of the law in medical ethical issues and thereby to set ethical norms for society. This view assumes that the legal system is capable of coping with the varied ethical dilemmas created by the rapid advances in medicine. By contrast, others argue that legislators and judges should be involved minimally only as a last resort in ethical conflicts. The legislative process is by its very nature conservative and slow moving and therefore ill suited to deal with the dynamic changes occurring in medicine and the dilemmas thereby engendered.

A common alternative in a pluralistic democratic society is dealing with medical-ethical issues by multidisciplinary ethics committees, which analyze issues and recommend policy or guidelines. There is also considerable utility in the creation of national

nonpolitical commissions to study new issues in medical ethics and to recommend policies and procedures and, if necessary, legislation.

1.5 Conclusion

Medical ethics has undergone many and significant changes from antiquity to our era. In fact, it continues to change and to reshape constantly both in theory and in practice.

The role of medical ethics in individual patient-physician relationships as well as in public matters is growing along with the major and rapid changes in health and life sciences.

It is very important for health care policymakers as well as for the public at large to be sensitive to ethical dilemmas and ethical debates and solutions. It is equally important for ethicists to be sensitive to public input and concerns. This mutual awareness and sensitivity will bring about better solutions to troublesome ethical dilemmas in modern medicine.

Notes

1. The Greek word *ethike* means "habit, action, character."
2. For an in-depth discussion, see Beauchamp and Childress (1994) and Gillon (1994).
3. From the Code of Ethics of the American Medical Association (see www.ama-assn.org).

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2 Legislation for assisted reproductive technologies

Bernard M. Dickens

2.1 Introduction

Until the latter decades of the 20th century, the focus of medical interventions in human reproduction was on fertility control, particularly by developments in contraception. Studies of means to control fertility indicated means to preserve and promote fertility, but studies of means to overcome infertility by laboratory (in vitro) initiatives lay in the area of animal husbandry, pedigree enhancement of animal herds, and livestock marketing. With assistance from veterinarians, however, specialists in human reproductive biology came to pioneer developments, first in human artificial insemination and then in other assisted reproductive technologies (ARTs), and in 1978 the world's first authenticated in vitro fertilization (IVF) baby, Louise Brown, was born in England.

The advancement and refinement of ARTs added an important dimension to human reproduction, both qualitatively in furnishing improved means to overcome infertility and subfertility and in time quantitatively as increasing numbers of families, particularly in more economically advanced countries, were founded by resort to ARTs. Medical means to control fertility, protect fertility, and overcome infertility were brought together in the 1990s under the concept of reproductive health. This unifying vision took shape in the late 1980s within the World Health Organization (Fathalla 1988), and received international impetus in 1994 when the concept was adopted, in an expanded form, in the Programme of Action developed at the United Nations International Conference on Population and Development (ICPD), held in Cairo. The concept was further endorsed the following year, when the UN International Conference on Women, which met in Beijing, underscored that, whatever the source of infertility, the physical burdens of overcoming it fall primarily on women.

The full definition, elaborating on health as described in the first paragraph of the WHO Constitution, provides that

> [R]eproductive health is a state of complete physical, mental, and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when, and how often to do so. Implicit in this last condition are the right of men and women to be informed and to have access to safe, effective, affordable, and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law, and the right of access to appropriate health-care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant.

The historical emphasis in family planning has been on its negative aspects of birth control and avoidance of unwanted pregnancy, but the expression clearly includes planning to have a family, despite reproductive barriers due to infertility. This is consistent

with a key human rights principle of the modern, post-1945, world, embodied in Article 16(1) of the 1948 Universal Declaration of Human Rights – namely, "the right to marry and to found a family." Paragraph (3) of the same article adds that "[t]he family is the natural and fundamental group unit of society and is entitled to protection by society and the State."

Against this background, many countries now accept the legitimacy of reproductive health as a concept well rooted in human rights (Cook, Dickens, and Fathalla 2003), and propose laws to accommodate ARTs. Nevertheless, some conservative religious institutions oppose the idea of human rather than divine control of childbearing. The Roman Catholic church, in particular, employing the unique privilege of the Holy See (representing one religious denomination) to enjoy UN membership, was active at the UN meetings in 1994 in Cairo and 1995 in Beijing in opposing acceptance of the concept of reproductive health. At the latter meeting, it proposed what some perceive as an "unholy alliance" with reactionary Islamic countries to block recognition of the concept (Hulme 2009). Countries under Roman Catholic influence tend to accommodate ARTs restrictively; for instance, a challenge was mounted before the Inter-American Commission on Human Rights against Costa Rica's legal prohibition of IVF.

Costa Rica's approach to ARTs marks an extreme and exceptional end of the spectrum of legal responses. A more accommodating approach to lawmaking is found in many countries of western Europe, where laws are inspired by principles of consumer protection and promotion of progress in responsible employment of reproductive medical technologies. The further end of the spectrum may be in the United States, where the American Society for Reproductive Medicine (ASRM), the American Fertility Association, and, for instance, the American Congress (or College) of Obstetricians and Gynecologists, which adopted certification requirements of the American Board of Obstetrics and Gynecology, set professional standards of practice. However, governmental agencies do not exert direct legal controls, although central reporting of outcomes of interventions is required. This absence of legal control allows a de facto tariff of payments for ovum donors, exceeding the voluntary guidelines set by the ASRM, with higher rates, for instance, for athletic graduate students. It also permitted an IVF practitioner to treat an unmarried mother of six children by transferring six embryos, two of which divided, to result in birth of octuplets in January 2009. In that case, the California Medical Board subsequently took disciplinary action against the practitioner.

2.2 Legislation and regulations

Designing laws to manage applications of the assisted reproductive technologies poses challenges as the ARTs evolve and different implications become apparent regarding how they are or may be applied. An increasing number of countries and legal jurisdictions within countries have therefore decided that ARTs should not be governed by their general laws. All of these were designed for other purposes, and come to be applied to ARTs incidentally or by default. Countries and jurisdictions within countries (hereafter referred to simply as "countries") are increasingly turning to purpose-made laws (McLean 1992).

The incentive to make laws specifically to govern ARTs arises because, in the absence of such laws, countries' general laws tend to leave confusion. In codified legal systems,

where codes of civil law and/or criminal law define the scope of particular provisions, it may not be clear under which provisions, if any, the ARTs may fall. In customary or Common law systems, where precedents are expected to be followed, it may not be clear under which body of precedent, such as regarding contracts, delicts or torts, family law, and, for instance, medical professional law, the ARTs are best approached. Lawmakers may therefore decide, as many in particularly economically developed countries have, that ART practice should be brought under the control of specifically created laws. In Europe as of early 2010, only Ireland and Poland have not enacted ART legislation; the former adopted professional guidelines endorsed by its health ministry (Brown 2010).

An important legal and administrative distinction exists between legislation and regulations. Legislation is enacted by politically empowered legislatures, either as independent acts or as provisions that fit within existing codes of law. Enactments often follow political debate among members of legislatures, who among themselves may urge different preferences but decide according to their legislatures' rules, often by majority vote. Enactments resolve issues of politically contested principle, but this legislation may provide for technical matters that are not, or are less, politically controversial to be dealt with by regulations. These are sometimes described as delegated legislation. Legislatures empower a division or officer of the executive branch of government to make subordinate law through regulations that give effect to the purposes the legislature approved in enacting the originating legislation. A ministry or minister, for instance, may be given the power under particular legislation to pronounce and apply administrative regulations that detail what must be done to achieve the purposes of the legislation.

Legislative power is often very wide, but it may be limited by provisions of a country's written constitution, and, when countries have accepted the jurisdiction of courts or commissions under international treaties, such as on trade or human rights, such supranational agencies may declare national legislated enactments to be in violation. For instance in April 2009, the Constitutional Court of Italy ruled that some provisions of Italy's restrictive ART law, compelling uterine transfer of grossly abnormal embryos, were unlawful for violation of women's constitutionally protected right to health. Similarly, as observed above, complaints have been brought before the Inter-American Commission on Human Rights against Costa Rica's proposal to introduce comparably restrictive ART legislation, alleging violation of the country's commitments accepted under the American Convention on Human Rights.

Regulations are limited to the purposes intended by the legislation that empowers executive agencies or officers to make them. Regulations that are outside powers (ultra vires) are void. They may be successfully challenged for overreaching, or for being improperly developed, such as by not following due process. They may also be judicially voided for being unreasonable – that is, unsupported by the evidence claimed to justify them. The common advantage of regulations, however, is their flexibility. They can usually be introduced, amended, and revoked quickly by executive agencies empowered to make them in response to sudden developments, without having to pass through the often time-consuming political process of legislative debate and approval. As against this, however, some regulations are made subject to approval by a legislative chamber or committee, in order to preserve a measure of legislative control and accountability.