Informed Consent: Its Origin, Purpose, Problems, and Limits

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Informed Consent: Its Origins, Purpose, Problems, and Limits

Nancy M. Kettle

(Abstract)

The doctrine of informed consent, defined as respect for autonomy, is the tool used to govern the relationship between physicians and patients. Its framework relies on rights and duties that mark these relationships. The main purpose of informed consent is to promote human rights and dignity. Some researchers claim that informed consent has successfully replaced patients’ historical predispositions to accept physicians’ advice without much explicit resistance.

Although the doctrine of informed consent promotes ideals worth pursuing, a successful implementation of these ideals in practice has yet to occur. What has happened in practice is that attorneys, physicians, and hospital administrators often use consent forms mainly to protect physicians and medical facilities from liability. Consequently, ethicists, legal theorists, and physicians need to do much more to explain how human rights and human dignity relate to the practice of medicine and how the professionals can promote them in practice. This is especially important because patients' vulnerability has increased just as the complexity and power of medical science and technology have increased. Certain health care practices can shed light on the difficulties of implementing the doctrine of informed consent and explain why it is insufficient to protect patients’ rights and dignity.

Defining a normal biological event as a disease, and routinely prescribing hormone drug therapy to menopausal women for all health conditions related to menopause, does not meet the standards of free informed consent. Clinicians provide insufficient disclosure about risks related to long-term use of hormone therapies and about the absence of solid evidence to support their bias toward hormone therapies as a treatment of choice for menopause related health conditions. The contributing problem is women's failure to act as autonomous agents because they either
choose not to take an active part in their own therapy or because they fear to question physicians' medical authority. To insure that patients' autonomy and free choice are a part of every physician-patient interaction, physicians and patients need actively to promote them as values that are absolutely indispensable in physicians' offices, clinics, and hospitals.
Introduction: The Importance of Informed Consent

Serious violations of our basic rights and human dignity occur in settings where we expect others to honor the ideal of human rights. Physicians sworn to uphold the Hippocratic Oath of preventing harm and healing the sick fail to respect human rights to justify some sort of ill-conceived experiment or medical practice. The potential for scientific abuse became apparent during the Nuremberg trials of Nazi scientists in the late 1940s, which revealed horrifying instances of medical experiments in concentration camps. As a result of those trials, the notion of the informed consent was born. Some (Beauchamp, Childress, Faden) define informed consent as autonomous authorization, which relies on the principle of respect for autonomy or autonomy as self-governance. Others (Katz, Moreno) define informed consent as the right to self-determination, which is "a legal equivalent of the moral principle of respect for autonomy." The right to self-determination refers to "the right of individuals to make their own decisions without interference from others." Some define autonomy the same way. Both definitions rely on the principle of autonomy, which Immanuel Kant envisioned as the capacity for rational action and the supreme principle of morality. For the purpose of this thesis I will rely on the definition of informed consent as respect for autonomy.

Although the doctrine of informed consent is a relatively recent legal and philosophical concept, it governs the relationship between physicians and patients. Its framework relies on rights and duties that mark these relationships, in the United States in particular. The main

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purpose of informed consent is to promote human rights and dignity.\(^6\) Some researchers claim that informed consent has *successfully* replaced patients’ historical predispositions to accept physicians’ advice without much explicit resistance.\(^7\) Although the doctrine of informed consent promotes the ideals worth pursuing, a successful implementation of those ideals in practice has yet to occur. What *has* happened in practice is that attorneys, physicians, and hospital administrators often use consent forms mainly to protect physicians and medical facilities from financial liability.\(^8\) Consequently, ethicists need to do much more to explain how human rights and human dignity relate to the practice of medicine and how the professionals in the field can promote them in practice. This is especially important because the constantly increasing “complexity of power of medical science and technology has increased the patient’s vulnerability.”\(^9\) Certain health care practices can shed light on the difficulties of implementing the doctrine of informed consent and why it does not sufficiently protect patients’ rights and dignity.

Until very recently, there was a continuous, routine medical practice of the almost indiscriminate prescribing of hormone replacement therapies (HRT) to menopausal women. This practice might change because new, more reliable evidence from long-term randomized clinical trials, warns against it. Medical professionals have promoted HRT therapy as safe, before the completion of any long-term randomized controlled studies that could substantiate this claim. New reports, one published in the *Journal of American Medical Association (JAMA)* on July 17, 2002, and another, which National Institutes of Health (NIH) are to issue sometime in 2002,\(^10\) offer a radically different view of the benefits of HRT regimens. The *JAMA* article reports that the review panel of the Women's Health Initiative (WHI), a major federal study of hormone replacement therapy that the NIH oversee, abruptly halted the set of randomized controlled trials

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\(^6\) Tajima, "Informed" 271.
\(^7\) Moreno, "Informed Consent" 688.
\(^8\) Tajima, "Informed" 271.
\(^10\) The NIH originally planned to release its report, *International Position Paper on Women’s Health and Menopause: A Comprehensive Approach*, in June 2002. In March 2002 NIH released to the press only chapter 13, “Best Medical Practices.” This chapter specifies new guidelines regarding hormone replacement therapies. Given that the NIH conducts the Women's Health Initiative study, it is possible that it delayed the release of the *International Position Paper on Women’s Health and Menopause* to include the information reported in *JAMA*.  

of combined estrogen and progestin in women with a uterus. A planned duration of this segment, which included 16,608 postmenopausal women aged 50-79 with an intact uterus, was 8.5 years, but the review panel discontinued it after 5.2 years because these drugs create an unacceptable risk for heart disease, breast cancer, strokes, and blood clots. The review panel concluded that “Overall health risks exceeded benefits from use of combined estrogen plus progestin . . . The risk-benefit profile found in this trial is not consistent with the requirements for a viable intervention of chronic diseases, and the results indicate that this regimen should not be initiated or continued for primary prevention of coronary heart disease.” This is a radical departure from a previous position of the medical establishment, which recommended HRT to menopausal women as a preventive measure against heart disease and osteoporosis.

Although women appeared to be consenting to those therapies, they were reluctant to fill the prescriptions once they left their physician’s office. Their discontinuation of the HRT therapies within a year once they start HRT therapy suggested that their consent is not genuine. Even though physicians addressed some of these women's concerns, they could not meaningfully address all of them. The information on the risks and benefits of HRT was constantly changing, and there were no clear guidelines about who should or should not use these therapies. The problem began with the view of the medical establishment that menopause is a disease, a view which many women have not shared. These women viewed menopause as a natural process, a biological event in every woman's life that may or may not require medical intervention such as HRT. Still, women who saw physicians about menopause problems had to decide whether to accept their physician’s recommendation and take HRT for the rest of their lives to prevent the risk of conditions such as osteoporosis and heart disease. HRT regimens were supposed to prevent osteoporosis and heart disease, but in some cases they can lead to other serious problems for women such as blood clots, endometrial cancer and breast cancer. As women had to decide what is right for them, i.e., whether or not to use HRT long-term, there were problems with proper implementation of informed consent as it had functioned or failed to function in medical practice generally. This was often the consequence of medical professionals’ failure to

11 Women's Health Initiative Writing Group, "Risks and Benefits of Estrogen Plus Progestin in Healthy Postmenopausal Women. Principal Results From the Women's Health Initiative Randomized Controlled Trial,"
understand how human rights and dignity relate in the practice of medicine and how to promote them in practice.

My aim is to show that the doctrine of informed consent, as practiced in the relationships between physicians and patients, often does not fulfill its main purpose; i.e., it does not safeguard the interests, rights, and dignity of patients. This happens because of clinicians' scepticism about the existence of the right to informed consent, patients' disinclination to make decisions, the current nature of health care, and the absence of clear guidelines about implementing informed consent. I begin by examining the philosophical theory of rights in Hugo Grotius, Thomas Hobbes, John Locke, and Immanuel Kant, with special emphasis on Kant’s theory of autonomy, absolute worth, and human dignity. The purpose of this chapter is to trace the development of the notion of rights and dignity in moral theory from the seventeenth century when major philosophers assigned them the character they still have today, i.e., the position that every person possesses certain basic rights that they have simply because they are human. I start with the seventeenth century natural law theories and then discuss Kant’s notion of morality as autonomy and respect for human dignity. I also examine the important documents regarding rights, autonomy, and human dignity. These include the Declaration of Independence (1776), the Bill of Rights (1789), the French Declaration of the Rights of Man and of Citizens (1789), the Universal Declaration of Human Rights (1948), and less famous documents, such as the International Covenants on Economic, Social, and Cultural Rights (1966) and the International Covenants on Civil and Political Rights (1966).

Chapter three provides an account of the current theory of informed consent. It outlines the conceptual models of informed consent found in moral philosophy and law as they apply to health care. I start by discussing the principles of respect for autonomy and beneficence, the two principles of moral philosophy that are particularly relevant to informed consent as it applies to clinical settings. Next, I provide an overview of the legal theory of informed consent, providing some remarks about its strengths and weaknesses. Third, I focus on the meaning and the elements of informed consent: competence, disclosure, understanding, and voluntariness. Last, I discuss the strengths and weaknesses of the philosophical model of informed consent.
In chapter four the focus is on historical background of hormone therapies to menopausal women to illustrate a case in which informed consent needs a more precise application. First, I discuss the need to provide the necessary scientific background for a better understanding of the physiological aspects of menopause. Next, I describe the standard definition of “menopause” and how the medical profession handled health problems associated with menopause. Last, I show why some physicians, organizations, and women activists proposed an alternative view of menopause, one that is not strictly tied to physiology.

In chapter five, I address the problems and limits of informed consent in the medical field as a whole, in a physician-patient relationship, and in the prescription of hormone therapies to menopausal women. Physicians' resistance to informed consent, patients' disinclination to make decisions, and the assembly line quality of medical care, are major obstacles to the therapeutic patient-physician relationship and consequently to informed consent. To show how physicians' and patients' attitudes and other factors affect health care, I analyze clinician's practice of the routine prescription of hormone replacement therapy to menopausal women for treating all menopause related health conditions. I argue that in using this particular practice, clinicians provide insufficient disclosure about the long-term risks of hormone therapy and about the absence of solid evidence to justify their practice of prescribing hormone therapies routinely. I also argue that physicians have failed to make sure that women had adequate understanding of menopause, in part because of their view that menopause is a disease. Finally, I argue that physicians' bias toward hormone therapy as well as their presenting information about hormone therapy as positive, led to informational manipulation, which influenced women’s perception, and very likely, their response.

In chapter six I make some observations about what some philosophers believe it means to be human. Relying on Descartes, Kant, and Emerson, I argue that philosophers often regard reason and will as defining characteristics of human beings. Given this view, human beings, as autonomous, can decide and choose for themselves. I also argue that to be truly autonomous, human beings must also trust themselves and their capacity to understand what serves and what impedes their own welfare.

If for at least some important philosophers, possessing reason and will defines human beings, then something is amiss when in clinical setting patients fail to think and reason for
themselves. Granted, some physicians like authority and like to make decisions for patients. This is sometime necessary in emergency medical care but not in ordinary interactions between physicians and patients. Physicians, however, must realize that they have an obligation to help patients make autonomous choices because the success of the medical treatment depends on it. Moreover, both physicians and patients must realize that autonomy is an inseparable part of being human and that both must respect and help develop it.
Historical and Philosophical Development of Rights in Terms of Moral Theory

Moral philosophy refers to philosophical theories, including reflection on the nature and function of morality, moral problems, and moral judgments. Moral philosophy also focuses on “moral codes, moral arguments, moral experiences, the moral consciousness, or the moral point of view.” The objective of moral philosophy is “to enhance clarity, systematic order, and precision of argument in our thinking about morality.” Although the views about the meaning of morality differ, like law, religion, and social conventions, morality is a normative social practice that guides human conduct.

Philosophical writings in the seventeenth and eighteenth centuries show broader focus of moral philosophy than current theories. They provide “the study of the whole of human action undertaken with the hope of improving practice.” Up to that point the established conception of morality was that of obedience we owe to God. Reason, revelation, and clergy elucidated God’s authority to us, but all of us do not have an equal ability to see what morality required us to do. Consequently, even if the most basic laws of morality were in our conscience, most of us would

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3 Beauchamp, *Biomedical 5*.
7 Schneewind makes this important point here to differentiate morality as obligation from the later conception of morality such as Kant’s conception of morality as autonomy, and from the contemporary conception of morality, which assumes that ordinary or normal choosers are capable of knowing what morality requires of them and choose an appropriate action without guidance from others. Because Schneewind offers a historical and sustained discussion of morality as autonomy and of autonomy as self-governance, which serve as the foundation of this thesis, my reliance on him is necessarily substantive.
still need instruction from some authority about what is appropriate in specific cases. Another characteristic of the obedience view is that most of us commonly do not comprehend the reasons for action that morality instructs us to take. Threats of punishment and offers of reward are necessary to insure a sufficient compliance to maintain moral order. The dominant view of morality in the seventeenth century is the natural law view, beginning with Grotius (1583-1645) and ending with Locke (1632-1683). The scientific revolution that dramatically broadened the knowledge in natural sciences such as physics, astronomy, mathematics and medicine, by discovering the laws of nature, created a fruitful intellectual environment that stimulated a belief that human reason could discover natural law in human conduct. In *On the Law of War and Peace*, Grotius argued that natural law, whether physical or moral, existed separately from authorities and political powers and served as means of evaluation of the laws and practices of governments. Locke argued that all human beings possessed natural rights such as life, liberty, equality, and property, prior to the existence of any civil societies. The role of civil societies is to protect the natural rights of its members, not to suppress them. A theory of morality as self-governance became a self-conscious effort at the beginning of the eighteenth century. Concerns in a moral domain such as questions about the basis and function of morality, and also in a political domain such as domination of coercive, absolutist governments, led to a concern among rising number of philosophers that the “inherited conceptions of morality did not allow for proper appreciation of human dignity.”

By the end of the eighteenth century, a new view of morality arose, which focused on the belief that “all normal individuals are equally able to live together in a morality of self-governance.” The moral philosophies of Thomas Reid, Jeremy Bentham, and Immanuel Kant provided “the normative belief about the dignity and worth of the individual that led to conceptions of morality as self-governance.” According to this view, we all have “an equal

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9 Schneewind, *Invention* 11.
12 Schneewind, *Invention* 5.
ability to see for ourselves what morality calls for and are in principle equally able to move ourselves to act accordingly, regardless of threats or rewards from others.”¹⁵ The two points mentioned here, an equality in determining the demands of morality and self-motivating ability to meet those demands without fearing punishment or having expectations of rewards from others, gained wide acceptance in moral philosophy to the extent that most contemporary moral philosophy simply assumes them.¹⁶ The significance of the notion of morality as self-governance is that it supplies a conceptual structure for “a social space in which we may each rightly claim to direct our own action without interference from the state, the church, the neighbors, or those claiming to be better or wiser than we.”¹⁷

Kant took the notion of self-governance to a revolutionary level. He maintained that “we are self-governing because we are autonomous.”¹⁸ He meant that we alone legislate moral law by using our own will. It is the legislative characteristic of the will that places us under moral law and permits everyone to accept moral law. His theory is a significant part of current philosophical ethics.¹⁹ Moreover, the conception of morality as self-governance in early modern philosophy made a significant contribution to the emergence of the Western liberal image of the correct relationships between individuals and society.²⁰ This image refers to the conception that a democratic society allows room for individuals to pursue their personal goals by assigning them certain rights and freedoms that others must respect.

**Natural Law and Rights Theory of Grotius, Hobbes, and Locke**

Natural law theory has been in flux since its earliest known origin with the Stoics who believed in the life according to reason. They thought that universe gave human beings reason as

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a distinguishing feature from other animals whose nature is to act on impulse. Because humans are by nature rational beings, living according to reason means living according to the laws of nature. Although the notion of right emerged from the Stoic philosophy of natural law and Roman philosophy of law, it underwent major transformations in the seventeenth century with the influential writings of Grotius and Hobbes. Grotius was the first natural law thinker who offered a theory that natural laws were binding on moral agents independently of the existence of God. He also proposed a new way of understanding rights by claiming that all people have rights whether they belonged to any group and before being subject to any law. Additionally, Grotius’ assignment of rights to individuals introduced a new way of “understanding the sphere of control belonging to individuals that is still important.” Hobbes, on the other hand, solidly affirms the connection between the law of nature with the state of nature, as does Locke after him.

Grotius

Grotius’ interest in natural law sprang from a problem that involved an international dispute that resulted after a Dutch sea captain captured a Portugese vessel as a prize. A Dutch court decided that capturing a ship was just but the losing party objected to the court’s decision on a religious basis and requested that Grotius write a defense. As a result Grotius wrote On the Law of Prize and Booty where he identified the problem in international relations, which Schneewind calls “The Grotian problematic,” i.e., that humans are by nature self-interested as

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23 Schneewind, "Introduction" 88.
24 Schneewind, "Introduction" 89.
26 Schneewind, "Introduction" 89.
well as sociable, resulting in controversies that disrupt social life. Grotius contended that the
effort to pass judgment regarding an international dispute between fighting parties is futile,
especially in wartime, if it is based solely on written law.\textsuperscript{30} Another basis was necessary. Cicero
and other ancient philosophers claimed we have to appeal to the laws of nature, to the laws that
come from “the inmost heart of philosophy.”\textsuperscript{31} Grotius needed to find a position that would
facilitate “a reasonable settlement over a dispute over rights between warring parties of different
religions.”\textsuperscript{32}

Grotius had to consider two major issues to find a resolution to his dilemma. First, the
skeptics’ views about politics limited law and justice to a single country, and made it impossible
to settle international disputes peacefully. To make justice between nations possible, it was
necessary to show that different nations could discuss the notion of justice, and also to create
principle-based limits to justify war and prize taking. To accomplish those aims, Grotius first
needed to discredit the skepticism of his time, the philosophical view that Michel de Montaigne
and Pierre Charron advanced.\textsuperscript{33} They believed that humans ought to live according to the rules
and customs of the culture into which they are born, and to accept only those principles that God
chooses to reveal to them. Second, Grotius needed to transcend widely divergent religious views,
which made it impossible to appeal to the Bible or to particular Christian doctrines such as
Protestanism or Catholicism for assistance in resolving international disputes. The impossibility
of finding a standard for settling such disagreements is the source of strength for Pyrrhonian
skepticism in the seventeenth century.\textsuperscript{34} An openly atheistic morality also could not help resolve
public disagreements (given the religious disposition of the time). The Thomist and Calvinist

\textsuperscript{29} Schneewind, \textit{Invention} 70.
\textsuperscript{31} Grotius, Prize 7, bk.1; Schneewind, \textit{Invention} 70.
\textsuperscript{32} Schneewind, \textit{Invention} 70.
\textsuperscript{33} Schneewind, \textit{Invention} 70; Richard H. Popkin, \textit{The History of Skepticism From Erasmus to Descartes}
\textsuperscript{34} A theory that the evidence necessary to know whether any knowledge is possible is insufficient or
inadequate. The Phyrronists withhold judgment on all situations in which the evidence is conflicting. They live in
the world of appearances based on sense impressions and any other beliefs such as that nothing is certain. Richard
University Press, 1995) 741-42; Schneewind, \textit{Invention} 42-43. Academic skeptics like Carneades believe that no
knowledge is possible. Popkin, \textit{History} x; Popkin, "Skeptics" 741. Like other theorists during the seventeenth
doctrines also failed to provide the kind of help Grotius needed. The setting was thus conducive for Grotius to invent a new theory of law to settle international disputes, a theory that went beyond skepticism and beyond natural law theories of the time. *On the Law of War and Peace* is the exposition of his new theory of natural law.

Grotius focuses on the Greek philosopher Carneades, who denied the existence of natural law and justice, to sketch and then refute skeptics’ views. Carneades does not deny the existence of laws. His claim is that humans impose laws on themselves because it is advantageous for them to do so, and that these self-imposed laws vary according to the time period and customs. What Carneades denies, according to Grotius, is the existence of natural laws (laws based on common or universal traits of human nature) because he thinks that human nature is such that they gravitate toward ends that benefit them. Carneades thus concludes that justice is nonexistent because humans would violate their own interests if they concerned themselves with the needs of others.

To refute the skeptics, Grotius first argues that human beings differ from other animals in that they have specific traits that belong only to them, namely sociability and intelligence. Given those traits, humans want a peaceful social life with other humans, which they can organize according to the level of intelligence they possess. This sociability characteristic, which Stoics named “sociableness,” and which Grotius views as a universal truth, offers a view of humans as more than just self-interested. Grotius shows them to be capable of altruism, of caring for others as well as themselves. He argues that other animals and children, as well as mature people, are predisposed to helping others in addition to helping themselves.

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35 Schneewind, *Invention* 71.
36 From here on cited as Law.
37 Carneades (c. 213-128 B.C.), a Greek philosopher during the Hellenistic period, developed skeptical arguments against the Epicureans and the Stoics during his tenure as the head of the Platonic Academy Schneewind, "Introduction" 109.
38 Grotius, *Law* 90, prolegomena, sec. 5.
39 Grotius, *Law* 90, prolegomena, sec. 5.
41 Grotius offers an empiricist conception of a universal truth. For him something as universally valid if it holds true at various times and in various places Grotius, *Law* 94, prolegomena, sec. 40.
animals, for instance, take care of their offspring and other animals of their species. Grotius attributes this conduct to some external rational principle because animals do not act the same way in similar situations that require the same degree of intelligence. Children, Grotius argues, spontaneously want to do good for others before anyone has taught them to do so. Finally, human adults, according to Grotius, are privileged in having the knowledge of general principles of conduct which prompts them to similar actions in similar situations. Moreover, given humans’ compelling desire for society (and thus communication), they have the faculty of speech.\(^4^4\)

Grotius’ belief in humans’ ability to know and follow general principles of conduct and to communicate them, indicates that he also believed that they are able to understand the concept of natural law, which John Calvin and Martin Luther denied.\(^4^5\) Having read Marcus Tullius Cicero’s *On Ends* and other works that build on the writings of the Stoics, Grotius accepts Cicero’s argument that there are first principles of nature from which other, secondary principles originate.\(^4^6\) Grotius accepts Cicero’s definition of first principles of nature as those principles that assure self-preservation and preservation of things that assure human survival. It is not just a preference for humans to preserve themselves in the way nature intended; it is also their duty to do so. Grotius does not explain the origin of this duty other than to say that according to the first principles of the law of nature, all animals are born with a duty to preserve themselves.\(^4^7\) He does not discuss how those principles could be binding. We could assume that he meant that first principles create obligation by themselves, which would make God as obligating authority unnecessary. Given that Grotius' attempt is to establish morality dependent on reason rather than on God (as obedience to God), this would be consistent. Grotius’ next argument could support this claim. Cicero (and Grotius) balances the principle of self-preservation with the duty to refrain from wanton harm.\(^4^8\) In other words, humans’ desire to preserve themselves, ought not to lead to unnecessary harm of others. It could also be true that humans have a duty not to harm themselves, not only others. This is consistent with Grotius’ own beliefs given his argument that humans are by nature sociable beings.

\(^{4^5}\) Schneewind, *Invention* 42.
Grotius also accepts Cicero’s claim that the first principles conform to reason, in which moral goodness is the main object. Achieving moral goodness by employing the first principles, which then lead humans to right reason, is important to Grotius because he does not want instincts to direct human action since he believes that we are rational, not instinct-driven animals.\footnote{Grotius, Law 99, bk. 1, ch. 2, sec. 1.1.} Grotius’ idea of right reason has at its core the social side of human nature. In other words, any action must pass the sociability test if it is to be in accordance with reason.

That humans are intelligent shows them as competent to make good judgments. In other words, humans have the power to discriminate or to make decisions about what is good for them, what may harm them, and what can lead to either situation.\footnote{Grotius, Law 99, bk. 1, ch. 2, sec. 1.2.} Grotius thinks that it is in human nature to make “well-tempered” judgments and that fear or the inducement of immediate pleasure does not lead to impulsive decisions. He claims that whatever is in disagreement with a well-tempered judgment contradicts the law of nature and consequently the nature of humans.\footnote{Grotius, Law 91, prolegomena, sec. 9.} In other words, the law of nature for Grotius is a mandate of “right reason” because it obligates us to act according to our sociable, rational nature.

By mandate of right reason Grotius means an act that is either in accordance with our rational nature or is not because in either case, at its core, an act has a moral basis. God, as the creator of nature, approves or forbids such an act.\footnote{Grotius, Law 91, prolegomena, sec. 9.} For Grotius, God is another source of the law of nature, but the law of nature would be binding even if God did not exist. God permits or forbids an act that is in accord with our nature because it is God that gave humans the specific traits, such as sociability and intelligence, that distinguish them from other animals.\footnote{Grotius, Law 98, bk. 1, ch. 1, sec. 10.} It is the law of nature, not God, that obligates them to follow the mandates of reason. Nevertheless, because humans are by nature self-interested as well as sociable, controversies that disrupt social life do occur.
Humans’ need for law, for Grotius, thus comes from the need to maintain orderly social life that humans as rational beings seek.\textsuperscript{54} Controversies arise in peace time, as well as in war time, between nations and between private persons at all levels of society, thus creating the need for laws. One meaning of law for Grotius is that it refers to something that is just in a sense of being lawful.\textsuperscript{55} He explains that what is just is what accords with the nature of humans as rational beings. The second meaning of law grows out of the first and refers to the law as ”a body of rights,” where a right refers to “a moral quality of a person, making it possible to have or to do something lawfully.”\textsuperscript{56} Those rights are the rights of an individual human being and include a protection of property. The law requires a duty to respect the private ownership of property of others and return of anything that belongs to them including the gains others (other than rightful proprietors) we may have received from it. The law also requires reparations for any harm they may have caused, the obligation to fulfill promises, and impose proper penalties on those who have broken the law.\textsuperscript{57} Violations of any of those rights are basic injustices that could make life in a community difficult and are therefore out of character with human nature. Law, for Grotius, leads to what is good but he defines ‘good’ in terms of rights. This is a crucial point in Grotius’ theory of natural law, which I will address shortly. Grotius divides rights into those that are perfect and imperfect. Perfect rights are rights that are conducive to the type of law that carries strict obligations. This description of rights falls under Grotius’ third meaning of law, which he describes as “a rule of moral actions imposing obligation to what is right.”\textsuperscript{58} He divides law into statutory and natural law. Perfect rights refer to statutory law (also called legal or positive law).\textsuperscript{59} Imperfect rights, on the other hand, refer to aptitudes of a moral agent and do not carry with them strict obligation. They refer to virtues such as generosity and compassion expressed for the benefit of others.\textsuperscript{60}

Grotius’ theory of rights profoundly shapes his view of society. Rights are a part of our nature as sociable and rational beings, and we have them whether they serve us or not. God

\textsuperscript{54} Grotius, \textit{Law} 91, prolegomena, sec. 8.  
\textsuperscript{55} Grotius, \textit{Law} 97, bk. 1, ch. 1, sec. 4.  
\textsuperscript{56} Grotius, \textit{Law} 97, bk. 1, ch. 1, sec. 4.  
\textsuperscript{57} Grotius, \textit{Law} 91, prolegomena, sec. 8.  
\textsuperscript{58} Grotius, \textit{Law} 97, bk. 1, ch. 1, sec. 9.  
\textsuperscript{59} Grotius, \textit{Law} 97, bk. 1, ch. 1, sec. 9.
shows respect for those rights by approving or forbidding them. Grotius’ theory of rights differs from other theories in that he views rights as “qualities grounding law, not as derived from law.”⁶¹ In other words, Grotius sees rights as our personal possessions that we have before and independently of our being a part of any society. Having individual rights that enable human beings to pursue their own good in a society is important to Grotius. Because he also holds community life as equally important, he views laws as necessary to enable us to form communities in order to preserve our individual rights. This is a remarkable claim in light of earlier theories of rights, which claimed that they were the creation of laws. According to this view, laws prescribe to us different missions or positions, which correspond to specific duties and thus the right to do or to have what we need to do to carry out those obligations. Classical laws of nature assign duties with a purpose to promote a common good as well as the good of an individual moral agent.⁶²

In summary, Grotius suggests that ethical beliefs that people have held over time have minimal yet universal features, rights and duties, namely the right to self-preservation including the preservation of material goods needed for survival and the duty to avoid harming others except to protect one’s own life or possessions.⁶³ The obligation to follow the dictates of natural law comes from a need to bring about resolution to conflicts that arise from our “unsociable sociable” nature, i.e., from our natural need for social life that is sometimes difficult to maintain given our desire to pursue our self-interest. He views the right to pursue our self-interest as the right to self-preservation, and as independent of our being a part of any society. Consequently, rights, for Grotius, are not derivations from law. Rights ground law in the sense that they force the law to protect rights. By assigning individual rights to humans, Grotius provided them with protection from the absolute power of government. Having rights assured equal treatment of all humans regardless of religious or civil status. Grotius thus contributed to the movement in moral philosophy toward respect for human dignity and autonomy of humans as rational agents.

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⁶¹ Schneewind, *Invention* 80.
⁶² Schneewind, *Invention* 80.
The drawback of Grotius’ theory, however, is that he uses only empirical data about human conduct to find a way to resolve conflicts. By insisting on the minimal core of morality that skeptics would find difficult to refute, and by letting God play a role in morality, Grotius attempted to assuage the fears about justice of both groups. As J.B. Schneewind, however, points out, the nature of obligation and God’s role in morality posed a problem for his theory. As we have seen earlier, God is one of the sources of the law of nature, the other being reason, which calls into question the precise role of God in Grotius’ theory. In other words, it is not clear whether Grotius' God is necessary for morality. As Jean Barbeyrac pointed out, if the laws of nature impose obligation to follow those laws on their own without relying on God, then God's will has no role in morality. This position represents a radical departure from morality as obedience to God and toward morality based on moral agents' reason. Grotius is not explicit on the matter, i.e., on the role of God in morality and on the nature of obligation and this posed problems for the followers of his theory. Morality needed a more comprehensive theory to establish humans as free rational agents capable of recognizing their moral responsibilities and being motivated to fulfill them without the threat of punishment or expectation of rewards.

Grotius’ theory influenced other moral and political theorists including his contemporary, Thomas Hobbes, and later in the seventeenth century, Richard Cumberland, Samuel Pufendorf, and John Locke. For the purposes of this paper I will compare the theories of Hobbes and Locke with that of Grotius.

Hobbes

Although Hobbes accepts some precepts of Grotius’ theory in developing his own theory of moral philosophy, such as the right to self-preservation, he rejects others such as the Grotian idea of natural sociability. He thinks that although human beings have a desire for society, they do not naturally seek it. According to Hobbes, humans learn to seek community because they

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64 Schneewind, *Invention* 75.
65 Schneewind, *Invention* 75.
66 Thomas Hobbes, *De Cive: Philosophical Rudiments Concerning Government and Society*, Reprinted in:
receive some benefits from it such as honor or profit.\textsuperscript{67} Self-interest drives humans into society, but it also causes difficulties in maintaining it. While Grotius views humans as self-interested but also altruistic, Hobbes views selfishness as the main, if not the only factor, in human motivation. This is apparent in his discussion of transfer of individual rights that all human beings possess in the state of nature, to that of civil government: "For it is a voluntary act, and of the voluntary acts of every man the object is some \textit{good to himself}."\textsuperscript{68} Given his presupposition that all humans are selfish, Hobbes thinks that they distrust and dread each other, and that only fear of some coercive power, such as ruler or civil state, can mitigate those feelings.\textsuperscript{69} Human beings, therefore, necessarily have a natural right to self-preservation, which allows them to use all their resources to preserve their own lives as well as those of others: "the first foundation of natural right is . . . that \textit{every man as much as in him lies endeavor to protect his life . . .}"\textsuperscript{70} Moreover, to assure self-preservation, Hobbes has to allow humans the right to use the necessary means and actions to preserve their lives.\textsuperscript{71} Without the right to the use of necessary means, self-preservation is not possible. Hobbes, therefore, assigns humans the natural right to the means they need to preserve their own lives and the lives of others. This right to self-preservation includes making judgments about the means to do so.\textsuperscript{72} Hobbes does not allow others to be the judges of the necessary means for self-preservation because others are equally self-interested.\textsuperscript{73} This state of constant distrust and dread leads to the state of war "of all against all; . . . in that war all men have an equal right to all things."\textsuperscript{74} In this state of nature, which Hobbes identifies as the state of war, human beings are miserable and as soon as they realize this, reason and nature compels them to end this state of misery. They can do so only if they \textit{all give up the right to all things}.\textsuperscript{75}

\textit{Moral Philosophy from Montaigne to Kant}, ed. J. B. Schneewind (New York: Cambridge University Press, 1983) 116-17, ch. 1, sec. 2, 111-137. Although I use mainly \textit{Rudiments} for discussion of Hobbes' political theory, an expanded version of this theory is in the \textit{Leviathan}, chapters 14 and 15 in particular.

\textsuperscript{67} Hobbes, \textit{Rudiments} 116-17, ch. 1, sec. 2.
\textsuperscript{69} Hobbes, \textit{Rudiments} 114.
\textsuperscript{70} Hobbes, \textit{Rudiments} 118, ch. 1. sec. 7.
\textsuperscript{71} Hobbes, \textit{Rudiments} 118, ch. 1. sec. 8.
\textsuperscript{72} Hobbes, \textit{Rudiments} 119, ch. 1. sec. 9.
\textsuperscript{73} Hobbes, \textit{Rudiments} 119, ch. 1. sec. 9.
\textsuperscript{74} Hobbes, \textit{Rudiments} 115.
\textsuperscript{75} Hobbes, \textit{Rudiments} 115.
Right, for Hobbes, signifies freedom or liberty that all humans have to use their natural faculties (bodily strength, experience, reason, passion), provided it satisfies right reason. The basis for natural right, according to Hobbes, is that all humans have a right to protect their own lives. To act according to right reason in the state of nature, for Hobbes, is to act according to what each person thinks is right. In the *Leviathan*, he makes the same point somewhat differently. He claims that acting in agreement with the right of nature is to act according to the command of our will, using our right to self-preservation. This is where Grotius and Hobbes differ. As we have seen earlier, Grotius thinks that acting according to right reason is acting so as to respect our natural sociability, while Hobbes thinks in terms of self-defense.

The state of nature as the state of war cannot last because the effect of equal right to all things, coupled with equal power, is no right at all. The state of war is a result of mutual fear humans have, which is partly due to their natural equality and partly due to their mutual will to harm, even kill others [in self-defense]. Consequently, in Hobbes’ view, humans cannot expect to be safe from others; neither can they promise security to themselves. Their physical and intellectual faculties diminish and the weakest can kill the strongest. Thus human beings, for Hobbes, cannot trust their strength to consider themselves by nature above others. Hobbes thus sees all humans as equal to each other with equal ability to cause harm.

To end this unsustainable state of war where everyone has a right to all things simply because they want them, and where everyone has an equal ability to destroy each other, Hobbes proposes peace as a solution. He sees seeking peace as a necessary requirement, the fundamental law of nature, a dictate of reason to facilitate self-preservation. He thus ties the laws of nature to right reason, claiming that dictates of right reason are the laws of nature. Like Grotius, Hobbes thinks that reason gives humans “directives whose obligatory force does not depend on

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God.\textsuperscript{86} We can see this in Hobbes’ equation of natural law with the divine law because it is God who has given humans reason to guide their actions.\textsuperscript{87} To seek peace is a logical step because a perpetual state of war would lead to self-destruction. This would be in opposition to the natural human desire for what is good. Also, no one values “war of all against all,” which necessarily accompanies the state of war, as something good.\textsuperscript{88} Consequently, to prevent self-destruction in the state of war, Hobbes suggests that humans must help each other in the sense that they must consent to enter into society without any limitation.\textsuperscript{89} In other words, they must give up their rights to all things, which is a law Hobbes derives from the basic law of nature, that of seeking peace. Thus Hobbes, like Grotius, turns to the laws of nature to end fear and hostilities. Hobbes thinks that natural law requires humans to transfer or relinquish some rights to insure their own preservation.\textsuperscript{90} This is a form of social contract with a ruler or civil government to which citizens surrender all their rights except the right to defend themselves against violence.\textsuperscript{91}

Although Hobbes seems to follow and perhaps even advance Grotius’ theory, there is an important difference (among others outlined earlier) between the two. As mentioned previously, Hobbes makes each individual a judge of what constitutes their preservation, with the effect being a loss of “all the anti-skeptical advantages of Grotius’ theory.”\textsuperscript{92} In other words, if there is no general agreement about what counts as danger, and everyone decides for themselves what they should do to defend themselves, then conflict will occur. The idea of natural and universal right to self-defense as a solution to the skeptical challenge becomes obsolete.\textsuperscript{93}

By giving the right or the power to an individual, Hobbes promotes the idea of self-governance. The problem is Hobbes’ view of human beings as unruly and untrustworthy and thus as overly concerned about their preservation, which leads him to rely on their actual conduct and to conclude that they need a coercive power to keep them in line. It is this single concentration on the principle of self-preservation and self-defense that makes it difficult for

\textsuperscript{86} Schneewind, \textit{Invention} 97.  
\textsuperscript{87} Hobbes, \textit{Rudiments} 134, ch. 4, sec 1.  
\textsuperscript{88} Hobbes, \textit{Rudiments} 120, ch. 1, sec. 13.  
\textsuperscript{89} Hobbes, \textit{Rudiments} 120, ch. 1, sec. 13.  
\textsuperscript{93} Tuck, \textit{Hobbes} 64.
humans to know all the commands of natural law. Hobbes admits that passions such as “hope, fear, anger, ambition, covetousness, vain glory” hinder humans’ ability to know the laws of nature.\textsuperscript{94} He also sees humans as capable of knowing the laws of nature and thus acting according to precepts of those laws, and thus being able to evaluate their actions in relation to others in accord with natural laws. Moreover, he claims that it is easy to follow the principle that humans ought to follow in order to make considerate decisions regarding their actions. All they need to do is to follow a certain rule. This rule is a famous ancient dictum: \textit{do not do that to others, you would not have done to yourself}.\textsuperscript{95}

If Hobbes utilized this rule as the rational principle of morality and thus as universalizable, he would have contributed more to the development of the idea of morality as self-governance. His reliance on actual human nature, as he understood it, stops him from doing so. In other words, Hobbes believes that human beings are capable of and acknowledge natural laws such as seeking peace, honoring contracts, mercy, equality and humility. If humans could not know these laws, they could not be obligated to follow them. Moreover, they would not be laws. Hobbes, however, acknowledges that certain aspects of human nature like “hope, fear, anger, ambition, and covetousness” are limiting while they dominate the minds of human beings. But because all people experience tranquil time sooner or later, they can evaluate their actions before they undertake them by using the above rule, whether they do or do not involve a law of nature.\textsuperscript{96} Hobbes, however, believes that the perverse desire of humans for present advantage, stops them from observing those laws.\textsuperscript{97} Consequently, Hobbes' own view of human nature dissuades him from utilizing the ancient rule, \textit{do not do that to others, you would not have done to yourself}, as a rational principle of morality.

\textsuperscript{94} Hobbes, \textit{Rudiments} 131.
\textsuperscript{97} Hobbes, \textit{Rudiments} 132, ch.3, sec. 27.
Like Grotius and Hobbes, Locke believes in the state of nature but also sees a need for civil government. The state of nature for Locke is a natural state for people, a state of perfect freedom to act and make conclusive decisions about life and property freely, without asking permission from others. Locke draws on Richard Hooker, who believed not only that the state of nature exists but also that the laws in the state of nature are absolutely binding on humans simply because they are humans, despite the absence of any formal agreement among them. Like Grotius, Locke believes that humans are sociable beings. According to Locke, regardless of the absence of any formal fellowship among people and of any formal agreements about “what to do, or not to do,” people realize that they need others to live a complete life. Furthermore, according to Hooker and Locke, people naturally need and desire to live a life of dignity.

Human need for communion and fellowship with others originally drove them to unite themselves in political societies. This is not to say that the state of nature is not the natural state for humans to live in, but only that they may choose to be members of some political society for a mutual benefit. I will address this point shortly.

For Locke, the state of liberty or freedom is not the state of licence. He imposes certain limits. Like Grotius and Hobbes, Locke claims that humans do not have a right to destroy each other nor any creatures in their possession unless there is a need for self-preservation. Also like Grotius and Hobbes, Locke invokes the law of nature (or the law of reason) as the source of obligation. Reason, Locke says, teaches all who are willing to consult it, that everyone is equal and independent. Consequently, no one ought to harm another in his life, liberty, health, or

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99 Hooker (1554-1600) wrote Of the Laws of Ecclesiastical Politie (1593-1662), his masterpiece from which Locke quotes, in eight books of which only five were published in Hooker's lifetime.
101 Hooker, Ecclesiastical bk. 1, sec. 10; Locke, Treatise 13, bk. 2, ch. 2. sec. 15.
102 Locke, Treatise 13, bk. 2, ch. 2. sec. 15.
103 Locke, Treatise 9, bk. 2, ch.2. sec. 6.
property.\textsuperscript{104} As with Grotius and Hobbes, God also plays a role in Locke’s view of the state of nature. He claims that human beings are the creation of an “omnipotent, and infinitely wise maker,” who sent them into the world to do specific work. Moreover, Locke thinks that God provided everyone with like faculties to share in the community of nature without subordination, in a sense that humans may not destroy or use others as if they are inferior to them. Moreover, Locke says, everyone is obligated to self-preservation and even to preservation of others if their own preservation is not competing with it. Finally, in the state of nature, unless it benefits others, no one may interfere with the life, or what pertains to “preservation of the life, the liberty, health, limb, or goods of another.”\textsuperscript{105}

A state of nature is also a state of equality for Locke, which he describes as a state where all the power and jurisdiction is reciprocal, i.e., “no one having more than another.”\textsuperscript{106} He thinks that everyone of the same species and rank is entitled to have the same advantages that nature has to offer without discrimination, including the use of the same faculties. This means that everyone is equal to everyone else. Only God can appoint and give someone an undoubted right to authority and sovereignty.\textsuperscript{107} Additionally, quoting Hooker again, Locke implicitly suggests that equality is self-evident and beyond all doubt. Hooker, Locke explains, sees equality as the basis of the obligation to mutual love among people, and on this foundation he outlines the duties they owe to one another. Hooker then derives the principles of beneficence and justice from those duties.\textsuperscript{108}

Locke also emphasizes a natural right to private property in the state of nature because he sees it as necessary for self-preservation.\textsuperscript{109} He postulates that people establish private property in agreement with natural law, before the establishment of any positive civil laws. The earth and everything on it are a gift of God to all the people for their survival, which means that there is a natural right to life. As a result, people can appropriate to themselves as much property as they need to preserve their lives. To ensure fairness, Locke imposes certain limits on property.

\textsuperscript{104} Locke, \textit{Treatise} 9, bk. 2, ch. 2, sec. 6.
\textsuperscript{105} Locke, \textit{Treatise} 9, bk. 2, ch. 2, sec. 6.
\textsuperscript{106} Locke, \textit{Treatise} 8, bk. 2, ch. 2, sec. 4.
\textsuperscript{107} Locke, \textit{Treatise} 8, bk. 2, ch. 2, sec. 4.
\textsuperscript{108} Hooker, \textit{Ecclesiastical} bk. 1; Locke, \textit{Treatise} 8, bk. 2, ch. 2, sec. 5.
\textsuperscript{109} Locke, \textit{Treatise} 19, bk. 2, ch. 5, sec. 27, 33.
First, because everyone has a right to self-preservation, Locke thinks that all may appropriate individually for themselves as long as they leave enough and as good for others. Second, because God created enough to sustain all people, anyone may appropriate only as much as they can use before it spoils. Locke's requirement for appropriation of common property as private property is the use of labor: "Whatsoever . . . he removes out of the state of nature hath provided, and left it in, he hath mixed his labor with, and joined to it something that is his own, and thereby makes it his property." Locke reasons that the earth and everything on it is God’s gift to people for their support and comfort and thus he (Locke) has to exclude others from claiming the same common property. He thinks that the labor added to common property excludes others from claiming the same common property for themselves. He sets another limit within this last limit on property by suggesting that there has to be “enough, and as good, left in common for others.” These limits justified appropriation of the land and its products. They also defined a natural right to self-appropriation, which did not require the consent of others. Although Locke initially sets limits on the amount of property people can have in the state of nature, before they enter the civil society, he in effect removes those original natural law limits in the civil state when he introduces money.

The role of the law of nature, for Locke, is to foster noninterference with individual rights such as life, liberty, equality, and property, to instill restraint among individuals to prevent them from invading or harming each other. Having a right, according to Locke, means having the free use of something, whereas law prescribes or forbids performing an action. The law of nature, Locke says, requires “the peace and preservation of all mankind.” Those who break the law can expect a type of punishment to such an extent that would deter the violation of law. Moreover, the law of nature would be meaningless if no one had a “power to execute the law.”

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110 Locke, Treatise 19, bk. 2, ch. 5, sec. 27, 33.
111 Locke, Treatise 20, bk. 2, ch. 5, sec. 31.
112 Locke, Treatise 19, bk. 2, ch. 5, sec. 27.
113 Locke, Treatise 19, bk. 2, ch. 5, sec. 27.
115 Locke, Treatise 19, bk. 2, ch. 5, sec. 27.
117 Locke, Treatise 9, bk. 2, ch. 2, sec. 7.
Given that the state of nature is also the state of perfect equality, everyone has the right and the power to execute laws to protect “the innocent and restrain offenders.” Furthermore, this right to self-preservation gives people the right to acquire the possessions of the offender and to punish crimes to prevent future ones from occurring so as to preserve all mankind. This task of everyone being his or her own judge and policemen becomes burdensome. Thus even in the peaceful state of nature some form of government is still necessary to correct the inconvenience of everyone's having to be her or his own judge and policemen. Locke sees a need for a very strong government in the state of war because this is “a state of enmity, malice, violence and mutual destruction.” The state of war comes about when a violation of rights occurs in the state of nature, when someone uses might without right. People quit the state of nature when even the smallest differences end in the state of war.

That mutual benefit of becoming a member of a civil society, for Locke, is “mutual preservation.” He claims that the enjoyment of freedom, equality, and property becomes very uncertain in the state of nature and that others constantly invade this state. Unlike Hobbes, who thought that a coercive government was necessary to keep the lawbreakers in line, Locke wanted to set up a very strong but limited rather than absolute government. Locke, like Grotius, wanted to set up limited government whose role is to protect the same rights present in the state of nature, e.g., life, liberty, and unlimited property. Hobbes’ government was more coercive in enforcing rights because Hobbes anticipated frequent violations, which was consistent with his rejection of the idea of natural sociability. As we will see later, Locke’s idea of limited government gained respect in the sense that it provided Americans with the necessary reasons to overthrow its status as a British colony and served, at least partially, as a model for the US Declaration of Independence. Another reason for joining a civil state is that people’s existence becomes so threatened and “full of fears and continual dangers” that they feel “very unsafe, very

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insecure.” The reason for this unstable state is that many people do not adhere to the notions of equity and justice.\(^{123}\)

The root of the need for mutual preservation and thus for civil government in Locke’s theory is his view of human nature, which he bases on the idea that humans have excessive desires that dominate their actions. Locke thinks that moral laws are necessary to control those excessive desires. Like Grotius and Hobbes, he bases moral laws on actual human conduct. He thinks that the principles that guide human action cannot be innate moral or logical principles because they are too speculative to produce conformity. Humans have natural inclinations such as “desire of happiness and aversion to misery.”\(^{124}\) These inclinations for Locke are constantly present in all human action in people of all ages and therefore are firm and universal.\(^{125}\) Inclinations, however, express desires, not truths, and therefore cannot be innate moral principles. Punishments and rewards that the law imposes are necessary to keep these desires in check.\(^{126}\)

Locke’s emphasis on appetites and aversions as the basis of human motivation is remarkably like Hobbes’s theory of motivation in the sense that appetites, unless controlled by a law armed with the power of punishments and rewards, will override all moral behavior.\(^{127}\) Also, like Hobbes before him, Locke views human kind not only as appetitive but also as wanting the respect of others. Nevertheless, Locke concludes that human kind possesses “enough natural reasoning ability to conclude that it needs to agree on those principles of morality “that are absolutely necessary to hold society together.”\(^{128}\) Locke adds that societies usually neglect these principles of morality.\(^{129}\) Because runaway appetites would ruin any society, people must restrain those insatiable desires by a broad recognition that some minimal rules of morality are necessary.\(^{130}\) To control desires that might lead us to forgo our obligations, Locke introduces

\(^{123}\) Macpherson, “Editor's Introduction” xiv; Locke, Treatise 65, bk. 2, ch. 9, sec. 123.


\(^{125}\) Locke, Essay 67, bk. 1, ch. 3, sec. 3.

\(^{126}\) Locke, Essay 74, bk. 1, ch. 3, sec. 13.

\(^{127}\) Macpherson, "Editor's Introduction" xi.

\(^{128}\) Macpherson, "Editor's Introduction" xi; Locke, Essay 72, bk. 1, ch. 3, sec. 10.

\(^{129}\) Macpherson, "Editor's Introduction" xi; Locke, Essay bk 1, ch. 3, sec. 10.

\(^{130}\) Macpherson, “Editor's Introduction” xiii.
contracts, bargains, and a powerful, although limited, authority (government) to enforce them. This became necessary only when the distribution of property became unequal, when money became a bartering tool.\textsuperscript{131}

In summary, Locke’s theory seems Grotian without being Hobbesian. Like Grotius, Locke sees humans as sociable beings needing the fellowship of others but also being concerned about their preservation. Although the state of nature provides humans with freedom, equality, and property necessary to preserve their own lives in the way God meant for them to enjoy, conflict and even war are unavoidable because excessive desires drive human beings. The formation of civil government becomes necessary when people get tired of being in constant fear of attack on their lives and property. This government is limited in the sense that it is supposed to protect those rights that humans have in the state of nature, thus to ensure a life with dignity. The obligation for human beings to follow the law of nature, peace and preservation of all humankind comes from the simple truth that they are humans. This view established Locke for some philosophers as a father of inalienable natural rights that dominate political documents today. Although Locke’s claim that human beings have rights simply because they are human goes some distance toward establishing morality as self-governance, especially because he insists on limited government designed to protect human rights, it does not go far enough. The problem with Locke’s theory of rights is that like Grotius and Hobbes, he relies on actual human conduct to establish the universality of rights. As we will see in the next section on Kant's theory of autonomy and absolute worth, rights and morality are rational concepts that need a rational rather than empirical basis for their existence.

The dynamic climate of the time and Locke’s provocative theory of natural rights, helped inspire the intellectual movement in the eighteenth century called the Enlightenment, "the dawning of a new age of human reason and knowledge."\textsuperscript{132} The leading intellectuals of the movement, Francois Voltaire (1694-1778) David Hume (1711-1776), Jean-Jacques Rousseau (1712-1778) and Immanuel Kant (1724-1804), aspired to "develop modern conceptions of humanity by seeking to free human reason from dogma and the individual from absolute

\textsuperscript{131} Macpherson, "Editor's Introduction" xviii.
\textsuperscript{132} Lauren, \textit{Evolution} 15.
authority." Man is born free, but everywhere he is in chains," Rousseau proclaimed. Kant asserted that the categorical imperative, his principle law of morality (or a universal duty as some call it), protects the intrinsic worth of all individuals, so that humans would treat each other not only as means but also as ends in themselves. The Enlightenment thinkers concentrated "not so much on 'pure' scientific discovery and abstract system-building but instead on applied science and specific reforms relating to human nature and long fostering human problems of economic exploitation, social suppression, political despotism, torture, and ecclesiastical superstition and intolerance." They relied on the notion of natural law as discovered thorough human reason and brought it to the peak of its prestige. They believed that the fundamental rationality in the laws of nature could be applied to various aspects of the human condition, thus making humanity and society more rational and more perfectible through human effort. By extension, they said, such progress could result in greater happiness and liberty for all without distinction of race or sect, towards perfection and happiness. Other Enlightenment philosophers attempted to interconnect natural law and rights more explicitly. Denis Diderot (1713-1784), for instance, suggested that everyone understands the laws of nature and that they give the most basic justification for human society. He claims that irrespective of authorities such as kings, aristocracy, religious leaders, or of country, class, and time period, the laws of nature specify what is "naturally and universally just for all human beings." Diderot used the language of equal, individual rights for all and challenged authority by asserting, "Tell yourself often: I am a man, and I have no other true inalienable natural rights than those of humanity."

I will next examine Kant’s development of the categorical imperative, which serves as the basis for his theory of autonomy and absolute worth. These concepts, along with those of natural law and natural rights, dramatically changed the definition of morality from obedience to
morality as autonomy. The acceptance of these concepts also affected the role and the structure of governments in Europe and the United States in the sense that governments were now supposed to protect the freedom and the rights of individuals.

*Kant’s Theory of Autonomy and Absolute Worth*

In the eighteenth century the natural law theories of Grotius, Hobbes, and Locke became vulnerable to a new type of skeptical criticism which negated the importance of facts in ethical thinking. By the end of the eighteenth century the whole structure of modern philosophy underwent a critical transformation that shed the modern theory of natural law and its reliance on human psychology and culture. Hume started this transformation, Rousseau continued it, and Kant completed it. Hume viewed his natural law predecessors’ attempts to answer skeptics by relying on the universality of actual beliefs and practices (such as the humans’ disposition to defend themselves, and their belief that self-defense is morally acceptable), as mistaken. Hume found this sort of evidence completely unacceptable in the development of moral attitudes. For Hume, the mere fact that others are thinking or acting in a certain way cannot serve as a guide or evidence that all should be doing the same thing. Rousseau makes a similar although less explicit point in the *Social Contract*, Book I. He claims that humans do not have moral rights and moral obligations in the state of nature because morality is simply a human creation in political communities and as such has authority only if the invented communities were democratic republics. Consequently, naturalistic ethics (like what some see in Grotius, Hobbes, and Locke) is a contradiction in terms.

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143 Tuck, *Hobbes* 96. I will talk about democratic republics later in this section as it is a part of Kant’s philosophy.
Kant relied on Hume and Rousseau to wrap up the critique of the eighteenth century naturalism in all areas of philosophy, with special emphasis on the history of modern philosophy. Kant viewed the history of philosophy, from antiquity forward, as a competition between empiricism and rationalism, where empiricism relied on sense experience for its arguments and rationalism utilized mental concepts developed prior to experience. Kant set out to place the debate between the two in a new context and insisted that the difference between moral judgments and matters of fact is firm. Kant thought that seventeenth-century philosophers did not distinguish between the two and thus unjustifiably mixed anthropology and psychology with ethics. He based this assumption of the idea that our moral judgments must be a priori, i.e., “pure and uncontaminated by our beliefs about the material character of the world, including the character of human psychology.” In other words, Kant aimed to provide a different basis for morality from the minimal core that Grotius, Hobbes, and Locke provided as an answer to the skeptical challenge that denied a possibility of knowledge of natural law and justice. He set out to show that the ultimate principle of morality is based on rational concepts alone. For Kant, this principle establishes morality not only as self-governance but as autonomy and human beings as autonomous agents. It also establishes a universal duty to protect the inherent value of individuals so that human beings have value as ends, not only as means.

Self-governance is based on the idea that all humans are equally able to determine the demands of morality and have a self-motivating ability to meet those demands, without fearing punishment or having expectations of rewards. To advance the idea of self-obligation as a viable option to external obligating authority such as God (an idea we have seen earlier in the writings of Grotius, Hobbes, and Locke), Kant argued that a morally valid law is absolutely necessary to provide a basis for obligation. Such law has to be valid not only for human beings but for all rational beings, including God, in whom they see moral perfection. Moreover, Kant claims that the basis for the obligation of moral law cannot be the nature of humans or the circumstances of the world in which they find themselves. The basis for obligation has to be a

144 Tuck, Hobbes 96.
145 Tuck, Hobbes 96.
146 Kant, Grounding 2, Ak. 389.
147 Kant, Grounding 20, Ak. 408.
priori, and we can find it only in the concepts of pure reason. Any precepts based only on experience, even those that are in some ways universal (such as those that Grotius, Hobbes and Locke advanced), Kant considered practical rules, but never moral laws.\textsuperscript{148} In Kant’s opinion, all moral philosophy, not only moral laws and its principles, has its basis in pure rational concepts only, free of any empirical concepts. He thinks that if a moral theory is to be universally binding on all rational beings, it must be based on a universal law that originates in reason. Because everyone's experience is different, it is impossible to use experience as a guide to developing a supreme principle of morality. Once reason alone formulates the principle, a more popular practical philosophy may then accept it from this theoretical level. In order to formulate a new principle of morality, however, reason must first separate itself from ordinary knowledge and from all experience. When reason finishes the development of a new formal moral principle, it is in such form that all moral agents can accept it.\textsuperscript{149} At this point experience is necessary because it helps sharpen the power of judgment that moral law requires to determine the cases where moral laws might be applicable.\textsuperscript{150}

One of the ways that Kant arrives at the supreme principle of morality is by analyzing rational action. Like Grotius, Hobbes, and Locke, Kant believes that nature operates according to laws and that only rational beings have the ability to act according to their "conception of laws, i.e., according to principles."\textsuperscript{151} This ability to act according to principles of those laws, Kant calls "will." Because deriving actions from laws requires reason, Kant views will as practical reason. In other words, because reason always determines will’s action, the will is the faculty that chooses only that which reason, "independently of inclination, recognizes as being practically necessary, i.e., as good."\textsuperscript{152} If inclinations were to influence the will, this will be a subjectively-contingent condition rather than an objectively necessary one, as when reason determines the will. Kant cannot allow this because he wants to develop the law of morality that is necessarily true and universally applicable.\textsuperscript{153}

\begin{itemize}
\item \textsuperscript{148} Kant, \textit{Grounding} 3,22, Ak. 389, 410.
\item \textsuperscript{149} Kant, \textit{Grounding} 21, Ak. 409.
\item \textsuperscript{150} Kant, \textit{Grounding} 3, Ak. 389.
\item \textsuperscript{151} Kant, \textit{Grounding} 23, Ak. 412.
\item \textsuperscript{152} Kant, \textit{Grounding} 23, Ak. 412.
\item \textsuperscript{153} Kant, \textit{Grounding} 24, Ak. 413.
\end{itemize}
of inclinations; it is its job to interfere with them: "reason recognizes as its highest practical function the establishment of a good will, whereby in the attainment of this end reason is capable only of its own satisfaction, that of fulfilling a purpose which is in turn determined by reason, even though such fulfillment were often to interfere with the purposes of inclination."\textsuperscript{154} The role of reason is to produce \textit{a good will}, a will that is good in itself regardless of any purpose or end it may achieve, because it serves as a basis for duty, a concept that Kant uses to determine the moral worth of an action.\textsuperscript{155}

The Kantian concept of duty includes the concept of a good will, free of "certain subjective restrictions and hindrances."\textsuperscript{156} As long as the will expresses an objective principle, a principle that reason prescribes, it is a command or imperative. The command of reason to the will is a categorical imperative and its action does not depend on any other purpose but to define moral obligations of all rational beings.\textsuperscript{157} If an imperative involves a purpose such as happiness, or if it serves as a means to an end, then this is a hypothetical imperative, and as such it cannot serve as the basis for the law.\textsuperscript{158} According to Kant, "Only the law itself can be an object of respect and hence can be a command."\textsuperscript{159} The necessary attribute of law is its universality. If rational agents act out of respect for the law, their actions have moral worth.\textsuperscript{160} For Kant there is only one law of morality, the categorical imperative, and it is this: "Act only according to that maxim whereby you can a the same time will that it should become a universal law."\textsuperscript{161} According to Kant, we can deduce all other moral imperatives from this one. Moreover, given the previous discussion about the law of nature, it is important to mention another formulation of the categorical imperative, that of the law of nature, which Kant also calls the imperative of duty. For Kant, the universality of law constitutes nature, i.e., the existence of things to the extent that

\textsuperscript{154} Kant, \textit{Grounding} 9, Ak. 398.
\textsuperscript{155} Kant, \textit{Grounding} 26, Ak. 416.
\textsuperscript{156} Kant, \textit{Grounding} 9, Ak. 397.
\textsuperscript{157} Kant, \textit{Grounding} 26, Ak. 416.
\textsuperscript{158} Kant, \textit{Grounding} 25, Ak. 414-15.
\textsuperscript{159} Kant, \textit{Grounding} 13, Ak. 400.
\textsuperscript{160} Kant, \textit{Grounding} 26, Ak. 416.
\textsuperscript{161} Kant, \textit{Grounding} 30, Ak. 421.
the universal laws determine them. Accordingly, this imperative is as follows: "Act as if the maxim of your action were to become through your will a universal law of nature."\textsuperscript{162}

If humans can will the maxim (the rule rational beings give to themselves and act on), then it should become a universal law, and if not, then they should reject it the because it is not "fitting as a principle in a possible legislation of universal law."\textsuperscript{163} The purpose of the will is thus to legislate a universal law.\textsuperscript{164} The fitness of the maxim does not depend on any advantage or disadvantage that it may cause to us or to others. Moreover, "reason demands immediate respect for such legislation."\textsuperscript{165} To test the applicability of the maxim as a universal law, moral agents must envision it in the world in which the maxim is to be universalized, i.e., in which it is a law of nature.\textsuperscript{166} If moral agents cannot \textit{conceive} the maxim as a law of nature without contradiction, than it is in disagreement with strict or perfect [irremissible] duty, either to one self [inner] or to others [outer].\textsuperscript{167} If, on the other hand, moral agents cannot \textit{will} the maxim without contradiction, the maxim is in disagreement with broad or imperfect [meritorious] duty, also classified as duty either to oneself or to others.\textsuperscript{168}

Making decisions about maxims involves some end or purpose, in a positive or negative sense, i.e., as ends to achieve or as harms to avoid.\textsuperscript{169} The purpose of the categorical imperative is to assure that moral agents choose an end that has an absolute value, a value that reason determines and gives to the rational will. An absolute value cannot come from our desires because they are a source of needs that cannot be universalized, and it cannot come from objects of our desires because those objects get their value only from those who value them. Anything we use as a means cannot serve as an absolute value because it is a means to an end. The only things that have an absolute value are those things that are an end in themselves, and for Kant "Persons are . . . not merely subjective ends . . . but are objective ends, i.e., exist as ends in

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162 Kant, \textit{Grounding} 30, Ak. 421.
163 Kant, \textit{Grounding} 15, Ak. 403.
164 Kant, \textit{Grounding} 40, Ak. 434.
165 Kant, \textit{Grounding} 15, Ak. 403.
166 Kant, \textit{Grounding} 32, Ak. 424.
167 Not committing suicide is an example of perfect duty to oneself, while keeping promises is a perfect duty to others.
168 Cultivating one’s talents is an imperfect duty to oneself, while benefitting others is an imperfect duty to others. Kant, \textit{Grounding} 32, Ak. 424.
169 Kant, \textit{Grounding} 36, Ak. 428.
\end{flushright}
To transform this into an objective principle of the will, the categorical imperative, and thus into a practical law, Kant offers the rational nature of human beings as an end itself. This is a subjective principle of human actions, but it is at the same time an objective principle because all rational beings see themselves as ends. If all of us maintain that our ends are good, then we view our own humanity as a source of value. Because universality requires consistency, we have to respect the humanity of others. The principle of humanity thus gains the status of an objective end necessary for the categorical imperative to determine the will. This principle is not a purpose we must accomplish but rather a negative end or right that we cannot violate. The principle of humanity or the second version of the categorical imperative is thus: "Act so that you treat humanity, whether in your own person or in that of another, always as an end and never as a means only."

Given that the principle of humanity limits every person’s freedom of action, Kant offers another formulation of the categorical imperative, the principle of autonomy, which follows from the first and second versions of the categorical imperative, the principle of universal law and the principle of humanity, respectively:

the ground of all practical legislation lies objectively in the rule and in the form of universality, which (according to the first principle) makes the rule capable of being a law (say for example a law of nature). Subjectively, however, the ground of all practical legislation lies in the end: but (according to second principle) the subject of all ends is every rational being as an end in himself. From this there now follows the third practical principle of the will as the supreme condition of the will’s conformity with universal practical reason, viz., the will of every rational being as a will that legislates universal law.

If rational beings decide their own ends or set value on things, it follows that they must regard their rational nature as an end in itself. When they act on maxims that are to be universal laws, they keep their rational nature in mind. Because rational beings decide their own ends, they are

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170 Kant, *Grounding* 36, Ak. 428.
171 Kant, *Grounding* 36, Ak. 429.
172 Kant, *Grounding* 36, Ak. 429.
173 Kant, *Grounding* 38, Ak. 431.
the ones that give themselves this law and, therefore, are autonomous. They have a free will, which enables them to legislate universal law in the kingdom of ends, a moral community (or an ideal state) of different rational beings united through common laws.\textsuperscript{174} In other words, this is a community "in which freedom is perfectly realized, for its citizens are free both in the sense that they have made their own laws, and in the sense that the laws they made are the laws of freedom – the juridical laws of external freedom and the ethical laws of internal freedom."\textsuperscript{175} A moral community is possible because of the principle of humanity, which prescribes that rational beings treat themselves, as well as others, as ends and never only as means.\textsuperscript{176} Treating oneself and others as ends and never only as means in the kingdom of ends gives rational beings intrinsic worth, i.e., dignity.\textsuperscript{177} In this regard, autonomy serves as the basis "of the dignity of human nature and every other rational nature."\textsuperscript{178}

Kant thus describes human beings as autonomous beings having intrinsic worth and dignity, and endowed with an intrinsically good will or practical reason that enables them to legislate the universal laws of nature to which they are also subject. The possession of reason gives humans the ability to make choices. This is important because desires can influence humans and distract them from acting according to moral principles. This power to choose makes humans autonomous, as well as, rational agents. These qualities, however, do not lead to the state of peace. Living in close proximity with others is not a natural state for humans because, like his predecessors, namely Grotius, Hobbes, Locke, and Rousseau, Kant believes that they are unsociable sociable beings.

Like Hobbes, Kant views the state of nature as a state of war, consisting of open hostilities and of continuous and a persistent threat of hostilities, which necessitate creation of the civilized state. The suspension of hostilities alone does not offer the security of peace, which is possible only in a lawful or civil state.\textsuperscript{179} To achieve perpetual peace, Kant envisions that a just

\textsuperscript{174} Kant, \textit{Grounding} 39-40, Ak. 432-33.
\textsuperscript{175} Christine M. Korsgaard, \textit{Creating the Kingdom of Ends} (New York: Cambridge University Press, 1996) 23.
\textsuperscript{176} Kant, \textit{Grounding} 39-40, Ak. 432-33.
\textsuperscript{177} Kant, \textit{Grounding} 40, Ak. 435.
\textsuperscript{178} Kant, \textit{Grounding} 40-41, Ak. 435-36.
constitution of every nation, in relation to the persons who accept it, must have three important components: one that respects people's *civil rights*, one that conforms to the *rights of nations* in relation to one another, and one that conforms to the *rights of world citizenship* to the extent that people and nations are in "mutually influential relations as citizens of a universal nation of men." The last component is a prelude to the later, twentieth-century international effort to devise documents such as the Universal Declaration of Human Rights, which would protect the rights of people and nations.

Like Grotius, Hobbes, and Locke, Kant sets up a civil state to protect freedom and rights. Kant differs from Grotius, Hobbes, and Locke in that he proposes a republican constitution as the best form of government. Republics enable all citizens to express their moral autonomy in the public forum through political action. Kant proposes *republicanism* as the preferred or ideal form of civil government because its political principle is such that it separates the executive power (the government) from the legislative power. The constitution of the United States is organized in this manner in the sense that the presidency, which is the executive power, has separate powers from Congress, the legislative body.

The republican form of government has three important characteristics for Kant. First, it respects the freedom of its citizens, where freedom refers to the right not to obey any external laws but those to which citizens are able to give their consent. Second, all citizens can depend on a single source of legislation. Third, it respects the law of equality of all citizens, where equality in a nation refers to a "relation among citizens whereby no citizen can be bound by a law, unless all are subject to it simultaneously and in the very same way." Democracy, "the power of a people," in Kant’s view, is the same as despotism because the executive power is set up in such manner that all citizens make decisions about or against one. Consequently, the general will of the majority contradicts itself and the principle of autonomy.

Kant sees the republican form of government as necessary not only to end conflict and foster peace but also to bring about the kingdom of ends or the ideal state in every nation and

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180 Kant, "Peace" 112, Ak. 348.
181 Kant, "Peace" 112, Ak. 350.
182 Kant, "Peace" 112, Ak. 350.
183 Kant, "Peace" 112, Ak. 350.
184 Kant, "Peace" 112, Ak. 350.
thus preserve the status of humans as autonomous moral agents. In a state that has a republican
constitution, citizens must consent to go to war and thus "it is natural that they consider all its
calamities before committing themselves to so risky a game."\textsuperscript{185} Because citizens will not go to
war for insignificant causes, as a ruler in a nonrepublican constitution could, hostilities and wars
would eventually stop and so would the drain of resources to recover from the devastations of
war.\textsuperscript{186} In the state of peace, public freedom of discourse would cultivate enlightenment, peoples’
ability to think independently.\textsuperscript{187} To be specific, Kant thinks that people can become independent
thinkers if they rely on their own understanding provided they outgrow their self-imposed
immaturity, which he defines as "the lack of resolve and courage to use understanding, without
guidance from another."\textsuperscript{188} Kant views timidity and laziness as reasons for people’s immaturity,
even after they reach the physical age of maturity, which makes it possible for others to make
decisions for them.\textsuperscript{189} This is unacceptable to Kant because he advances the view that humans
are and ought to be self-governing agents.

Kant elevated the concept of self-governance to the revolutionary level because he
thought that humans are autonomous. He did this by showing how humans alone can legislate
moral law by using their own reason and wills, which places them under moral law, and permits
them to accept moral law. The possession of the self-legislating will makes humans autonomous
beings. Kant’s view of humans as autonomous makes him relevant in philosophical ethics today
and has influenced the content of important international documents such as the Universal
Declaration of Human Rights, which I will address next.

\textsuperscript{184} Kant, "Peace" 114, Ak. 352.
\textsuperscript{185} Kant, "Peace" 113, Ak. 351.
\textsuperscript{186} Kant, "Peace" 113, Ak. 351.
\textsuperscript{187} Immanuel Kant, "What is Enlightenment?" 1784, trans. Ted Humphrey, \textit{Perpetual Peace and Other
Essays} (Indianapolis: Hackett, 1983) 41, Ak. 35.
\textsuperscript{188} Kant, "Enlightenment" 41, Ak. 35.
\textsuperscript{189} Kant, "Enlightenment" 41, Ak. 35.
The basic principles of freedom and equality inherent in natural law philosophies, challenged the absolutist, coercive governments that dominated Britain, France, and their colonies. Their absolute power made people demand natural rights precisely because the absolutist governments denied them. The following documents emerged in response to those oppressive regimes: Virginia Declaration of Rights (1776), United States Declaration of Independence (1776), the Bill of Rights (1789), and the French Declaration of the Rights of Man and Citizen (1789). Section one of the Virginia Declaration of Rights states that "all men are by nature equally free and independent and have certain inherent rights." Similar language appears in the Declaration of Independence of the United States, a radical document that aimed to establish equality among people by establishing "certain inalienable rights for all, [among them] life, liberty, and the pursuit of happiness." The inalienable rights were to serve as basic rights that no one can violate. The role of governments was to secure these rights, “deriving their just power from the consent of the governed.”

The American Declaration of Independence and France’s own intellectuals inspired the leaders of French Revolution to introduce a declaration of rights for the world, not only for France. France’s Declaration of the Rights of Man and Citizen proclaimed “natural, inalienable, and sacred rights.” It also proclaimed that "Men are born and continue to be free by possessing equal rights," and that these rights included "liberty, property, security, and resistance to oppression." The Declaration also outlined political rights to vote and partake in the political process. It also specified certain civil rights such as equality in regards to law, the right of protection from arbitrary arrest and punishment, the right to be presumed innocent until found guilty, the right to freedom of expression, and the right to property, among others. The politicians were responsible to people and the law was designed to protect the people’s rights.

190 Lauren, Evolution 16.
192 Declarations 11.
193 Lauren, Evolution 17.
Any society that does not guarantee rights and the separation of powers, the Declaration did not consider to have a constitution. The language of the Declaration became the official language of France’s new constitution, thus transforming natural rights into positive national law. Consequently, the legitimacy of the government was now a derivation from "the guarantee of individual rights under the law." 

The Declaration of the Rights of Man and Citizen prompted other efforts to establish individual rights, among them the ratification of the ten amendments to the constitution of the United States, the Bill of Rights. The amendments were necessary “to secure some of the rights of concern to the drafters of the Declaration of Independence.” The purpose of the Bill of Rights was to limit the power of the federal government. The amendments delineated such rights as the right of freedom of speech, the right to a speedy and public trial by an impartial jury of the state, the right against “unreasonable search and seizure,” and the right against cruel and unusual punishment. The Civil War Amendments abolished slavery and enacted the equal rights for the former slaves (1865). The fourteenth amendment (1868) forbids state or government to “deprive any person of life, liberty, or property without due process of law.” The fifteenth amendment (1870) extended voting rights to black men.

At the time that the ratification of the Bill of Rights took place, Thomas Paine published the Rights of Man. Drawing on the theory of natural law and natural rights, he introduced the term "human rights, possibly for the first time" He argued that "universal natural right for individuals provided the original source of all subsequent rights for members of society." As Paine clearly expressed it, "Man did not enter into society to become worse than he was before, nor to have fewer rights than he had before, but to have these rights better secured." Moreover, he made an explicit response to the France’s Declaration that clarifies the important relationship

194 Declarations 21-24.
195 Lauren, Evolution 18.
197 Fred R. Harris, America's Democracy: The Ideal and the Reality, Third (Glenview: Scott, 1986) 100.
199 Lauren, Evolution 20.
200 Paine, Writings 464.
between rights and duties that still holds today: "A Declaration of Rights, is by reciprocity, a Declaration of Duties, also. Whatever is my right as a man is also the right of another: and it becomes my duty to guarantee as well as to possess."\(^\text{201}\)

**International Human Rights Documents**

The Universal Declaration of Human Rights, signed in Paris in 1948, is a declaration of international human rights, designed to introduce a vision of universal principles regarding human rights. The preamble introduces the concept of the inherent dignity and the equal and inalienable rights of all members of the human family as the foundation for freedom, justice, and peace in the world. It also proposes to foster creation of a world in which human beings would enjoy “freedom of speech and belief and freedom from fear.”\(^\text{202}\) Achieving this purpose has been the highest ideal of the common people because disregard and contempt for human rights have led to cruel acts that have “outraged the conscience of humankind.” The preamble also reaffirms that the people of the United Nations have faith in basic human rights, in “the dignity and worth of the human person and in the equal rights of men and women.” A part of this reaffirmation is promotion of “social progress and of better standards of life in larger freedom.” Moreover, the member states of the United Nations pledge to promote the “universal respect for and observance of human rights and fundamental freedoms.” Finally, the preamble asserts that a routine understanding of human rights and freedoms is of preeminent importance for the complete actualization of the solemn promise mentioned above.\(^\text{203}\)

The thirty articles of the Universal Declaration of Human Rights start with two basic points in the first and second articles, which promote equality. Article one proclaims that “All human beings are born free and equal in dignity and rights." Article two proclaims that “Everyone is entitled to all the rights and freedoms” presented in the Declaration without any distinction such as race, gender, color, religion, language, political or other views, national or

\(^{201}\) Paine, *Writings* 509.

\(^{202}\) Declarations 35.

\(^{203}\) Declarations 35.
social origin, property, birth or other situation. Some of the other articles speak of civil rights, such as everyone’s "right to life, liberty, and the security of person,” the right to be free from slavery or servitude, and the right to be free from "torture or cruel, inhuman or degrading treatment or punishment." Other articles of the Declaration mention important political rights such as people’s right to have nationality. Article twenty one is particularly important because it gives everyone the right to take part in the government of their nation, either directly or through freely chosen representatives. The Declaration also contained articles focusing on economic, social, and cultural rights, essential for human dignity and the independent development of personality, thus giving them the same importance as civil and political rights. These rights included rights to social security, the right to work, the right to equal pay for equal work. Finally, article twenty nine sets the important limitations regarding the one’s rights and freedoms:

In the exercise of one’s rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.

International Covenants on Economic, Social, and Cultural Rights (1966) and International Covenants on Civil and Political Rights (1966) are the progeny of the Universal Declaration of Human Rights. They perfected “the formulations of these rights and gave them the status of international law.” Article one of the International Covenants on Economic, Social, and Cultural Rights and International Covenant on Civil and Political Rights both state that “All peoples have the right to self-determination. By virtue of this right they freely determine their political status and freely pursue their economic, social and cultural development.”

These international documents regarding human rights, freedoms, and human dignity specify the ideals for nations to achieve. Many nations often do not follow those ideals, which sometimes results in gross violations of rights and freedoms of many innocent people. Nevertheless, there is a continuous effort to promote and implement those ideals in the political

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and social arenas. And although Grotius, Hobbes, Locke, and Kant wanted world peace and aimed toward it in their writings, it was Kant’s ideas for world peace in *Perpetual Peace* that appear to have found most expression in the Universal Declaration of Human Rights.

At the time that the Universal Declaration of Human Rights was developing, the Nuremberg trials of Nazi war criminals were in progress. During these trials the potential for abuse of human rights in medical research became apparent, and subsequently the idea of *consent* was born. The notion of consent has maintained a prominent position in biomedical ethics since then. In the late 1950's the term “informed consent” appeared and the doctrine became a focus of examination in the early seventies. As we will see in the next chapter, the idea of autonomy or autonomous action provided a basis for the concept of informed consent.
Chapter 3

A Theory of Informed Consent

The history of informed consent is an essential component in several fields that include law, moral philosophy, social and behavioral sciences, and health professions. Law and moral philosophy have dominated the field in recent years. Accordingly, there are two main types of informed consent: the institutional or legal form of informed consent, which Tom Beauchamp, Ruth Faden, and James Childress call *effective consent*, and informed consent as *respect for autonomy* or as *autonomous authorization*, according to the same authors. *Effective consent* defines the "social rules of consent" that must obtain legally valid consent from patients and subjects before proceeding with therapeutic procedures or research. Given these rules, informed consents are not necessarily autonomous acts, and occasionally are not substantial authorizations. In this sense, informed consent refers "only to an institutionally or legally effective authorization," according to the prevailing rules.

Informed consent as respect for autonomy or as autonomous choice refers to “an informed consent as an autonomous authorization (that individuals give) to permit medical intervention or of involvement in research." Informed consent in this sense requires more than person’s explicit agreement or compliance with a certain proposal; it requires informed and voluntary consent. The focus of the law concerning informed consent is much narrower then the philosophical model. The legal model has two main components, competence and disclosure, while the philosophical model includes understanding, voluntariness and, some suggest, consent, in addition to competence and disclosure components.

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1 Faden, *History* 3.
3 Beauchamp, *Principles* 78.
4 Beauchamp, *Principles* 78.
5 Beauchamp, *Principles* 78.
Informed consent began as a legal doctrine, which has philosophical implications and is subject to philosophical justification. The legal doctrine expresses some ideas of philosophical justification, such as the right to privacy and bodily integrity. Whether this right is primary or it originates from other more basic rights is a matter of debate, but it is a mainstay of Western liberal political philosophy. When we apply the right to privacy to a purposive practice such as medical care, it becomes the right of self-determination. In bioethics, self-determination relies on the ethical principle of autonomy in the sense discussed in the previous chapter, i.e., that moral agents are self-governing agents and others must respect them as such. As we will see later, an examination of informed consent in terms of self-determination and autonomy provides a much richer foundation than the one based on privacy, as in the law.\(^6\)

For the exposition of the theory of informed consent I will rely on two main works in the field, Ruth Faden's and Tom Beauchamp's *A History and Theory of Informed Consent*, which draws on twenty years of research on this topic “by both legal and philosophical thinkers and in the contexts of medical practice, medical research, and social-science research.”\(^7\) Also, as Stephen Wear points out, Faden and Beauchamp “have provided the most searching, sustained, and philosophically sophisticated discussion of informed consent to date.”\(^8\) I will also rely on Beauchamp's and James Childress' *Principles of Biomedical Ethics*,\(^9\) because it addresses in more detail other principles of biomedical ethics (besides the principle of autonomy) such as nonmaleficence, justice, and, in particular, the principle of beneficence, which has been the dominant principle of medical ethics for centuries.

*Main Moral Principles Regarding Informed Consent*

In moral philosophy four principles are particularly relevant to biomedical ethics: the principle for respect for autonomy (self-governance), the principle of nonmaleficence (obligation

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6 Moreno, "Informed Consent" 688-90.  
not to harm others), the principle of beneficence (obligation not to harm others and also to contribute to their welfare), and the principle of justice (fairness, equality, entitlements). For the theory of informed consent as it applies to clinical settings, the principles of respect for autonomy and beneficence are most relevant and will be the focus of my discussion of this and the subsequent chapter.

Respect for Autonomy

Literature on informed consent most often mentions respect for autonomy as the moral principle, and describes it as a principle embedded in "the liberal Western tradition of the importance of individual freedom and choice, both for political life and for personal development." From its original meaning of self-rule or self-governance of independent Hellenic city-states of Ancient Greece, autonomy has since included individuals and has picked up various meanings such as self-governance, individual choice, privacy, freedom of the will, liberty rights, being one’s own person, and directing one’s behavior.

In the context of this paper, the focus will be on the concept of individual autonomy, which refers to self-governance or self-rule explored in the previous chapter. Besides Kant, who championed the idea of autonomy as self-governance, we can find the basic idea of autonomy in writings of contemporary philosophers such as Isaiah Berlin, Joel Feinberg, and Thomas E. Hill. This definition describes individual autonomy as “self-rule that is free from both controlling interferences by others and from limitations such as inadequate understanding, that prevent meaningful choice.” In other words, the autonomous person acts freely in conformity with a self-chosen plan, similar to the way that a sovereign government determines its policies and manages its state. In contrast, a person with decreased autonomy is incapable of deciding or acting on her or his wishes or plans. Also, others might be controlling this person, at least in some respect. People in institutions such as prisons or mental hospitals have diminished

9 Fifth edition.
10 Faden, History 7.
11 Beauchamp, Principles 58.
autonomy because mental incapacity limits autonomy and coercive institutionalization obviously limit prisoners’ autonomy. This distinction between autonomy and diminished autonomy is essential because almost all theories of autonomy concur that two considerations are important for acting autonomously: liberty or independence from controlling influences and agency or the capacity for intentional action.\textsuperscript{12}

The Nature of Autonomy

Philosophers sometimes classify the principle of respect for autonomy as a positive or negative obligation. As a negative obligation, this principle states that "Autonomous action should not be subjected to controlling constraints by others."\textsuperscript{13} In this form, the principle of respect for autonomy expresses general, theoretical obligation that excludes certain clauses, such as that we must respect individuals’ views and rights to the extent that their thoughts and actions do not seriously harm others. To become a practical guide for conduct, it is necessary to adjust the principle of respect for autonomy to particular contexts, which will include well-founded exclusions.\textsuperscript{14}

On the other hand, as a positive obligation, the principle of respect for autonomy requires "respectful treatment in disclosing information and fostering autonomous decision making."\textsuperscript{15} At times we have an obligation to increase available choices to others because many autonomous actions could not happen without other peoples' tangible collaboration in increasing available options. In health care, respect for autonomy obligates professionals to involve their patients or research subjects, "to disclose information, to probe for and insure understanding and voluntariness, and to foster adequate decision making."\textsuperscript{16} As some contemporary Kantians claim, the maxim that "we treat others as ends requires that we assist persons in achieving their ends

\textsuperscript{12} Beauchamp, Principles 58.
\textsuperscript{13} Beauchamp, Principles 64.
\textsuperscript{14} Beauchamp, Principles 64.
\textsuperscript{15} Beauchamp, Principles 64.
\textsuperscript{16} Beauchamp, Principles 64.
and foster their capacities as agents, not merely that we avoid treating them solely as means to our ends."\textsuperscript{17}

This positive obligation to respect people's autonomy requires that health care professionals assist their patients in overcoming their sense of dependence and attain as much control over their lives as possible and as much as they desire. Physicians and other medical professionals are sometimes tempted to preserve patients' dependency in lieu of promoting their autonomy. This is inconsistent with professionals’ obligations to their patients or research subjects such as fiduciary duty.\textsuperscript{18}

The principle of respect for autonomy is a prima facie principle and, therefore, has the same, \textit{and only the same} prima facie claim, which allows it to override other valid moral principles of similar importance such as beneficence and justice. In other words, no moral principle has an absolute value that allows it to override other moral principles in all situations. Principles of beneficence and justice, and also some role responsibilities such as best professional care, can sometimes override the principle of autonomy when there is a sufficient cause.\textsuperscript{19} This classification of autonomy does not diminish its position in morality. Its role is to insure that we retain our main moral values such as that we treat each other with respect, that we retain our moral entitlements, and that we have protection against those who want to harm us.\textsuperscript{20} It might be difficult, however, to live in a community in which the sole goal is autonomy is an overriding principle.\textsuperscript{21} The moral community developed on other moral principles like beneficence and justice and normally on a solid commitment to the welfare of the public. Autonomy has been the central value of medical and research ethics for the past three decades and is "the single most important value for informed consent."\textsuperscript{22} Overvaluing or undervaluing

\textsuperscript{17} Barbara Herman, "Mutual Aid and Respect for Persons," \textit{Ethics} 94.4 (1984): 600-02; Beauchamp, \textit{Principles} 64.

\textsuperscript{18} Beauchamp, \textit{Principles} 64.

\textsuperscript{19} Faden, \textit{History} 18.

\textsuperscript{20} Faden, \textit{History} 18.


\textsuperscript{22} Faden, \textit{History} 18.
autonomy, however, causes serious problems for informed consent. I will address this issue in more detail in a later chapter.

**Autonomy and Informed Consent Connection**

Given that the basis of informed consent is the concern to protect and enable peoples’ autonomous or self-determining choice, it is important to show how autonomous action can adequately express what precisely informed consent protects. To do so it is important to differentiate between autonomous people's and actions, and between substantially autonomous actions and those that are less so.

**Discerning Between Persons and Actions**

"Consents and refusals are actions" in the sense that "informed consents are acts of autonomous authorizing–and in the case of refusals, of declining to authorize." There is somewhat of a paradox in the relation of autonomous people and autonomous actions. Both autonomous (those who normally but not always act autonomously) and nonautonomous people (those who normally but not always fail to act autonomously) can perform autonomous acts. Although the characteristics of an autonomous person include capacities of self-governance such as understanding, deciding, reasoning, and independent choice, for the purpose of decisionmaking it is important to concentrate on the *autonomous choice*, which is about actual self-governing instead of capacity for self-governing. Possessing certain capacities does not mean that autonomous people will always be able to control themselves in their choices. Illness or depression, ignorance, coercion, or conditions that restrict options may temporarily limit self-governing capacity. When autonomous individuals sign a consent form without reading or

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understanding the form, they fail to give informed consent even though they are qualified to act autonomously. Likewise, people who are not generally autonomous can sometimes make autonomous choices. People in mental institutions can state preferences for meals, make telephone calls to friends, and refuse medicine.  

**Degrees of Autonomous Action**

The concept of autonomy has a long history in philosophy, in which two models dominated, a *freedom* model and an *authenticity* model. Besides Kant, different German and British idealists, as well as Isaiah Berlin, advanced the freedom model of autonomy. Stanley Ben, Gerald Dworkin, and various existentialist writers advanced the authenticity model of autonomy, which refers to person’s "actions, character, beliefs, and motivation." Theories in both models depend on similarities to "the autonomy of political states, where ‘autonomy’ has variously referred to popular sovereignty, citizen participation, independent nationhood, nongovernance by alien forces, control by citizens, and the like." Other theories of autonomy do not utilize political theory as a background.

The model of autonomy advanced for the purpose of informed consent draws on preceding theories of autonomy but also differs from them in three major ways. Under this model, autonomous action is an action that normal choosers perform by acting intentionally, with understanding, and without controlling influences that determine their action. In other words, three basic conditions characterize autonomous action: intentionality, understanding, and noncontrol. "Intentionality is a conceptually necessary condition of autonomous action." It (intentionality) cannot be a matter of degree because acts are either intentional or unintentional. The two later conditions, understanding and absence of controlling influence, can be of higher or

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lesser degree. Understanding needs to be substantial or adequate, and influence needs not to be completely absent.

**Substantially Autonomous Actions**

The literature on informed often cites objections to agents’ or patients’ ability to "really understand" that to which they are consenting. Those objections often imply that only "full autonomy" represents autonomy. Under this conception of autonomy, patients’ decisions are not informed consents unless they can show complete understanding of issues and full independence from the influence of others. This is a conception of ideal rather than of adequate autonomy.33

An autonomous action requires only "a substantial degree of understanding and freedom from constraint, not a full understanding or a complete absence of influence."34 Limiting patients’ decision making to the ideal of fully autonomous decision making deprives it of any meaningful place in the practical world because people’s actions are seldom, if ever completely autonomous. In other words, the requirements for information and for the absence of controlling influences for health care should not exceed those needed for a financial investment, buying a house, hiring a new employee, or choosing a university. Those are consequential decisions and are usually substantially autonomous but not completely autonomous.35

**Beneficence**

One of the requirements of morality is that in addition to treating others as autonomous and refraining from harming them, "that we contribute to their welfare."36 Such actions are beneficial actions and moral philosophy classifies them as acts of beneficence or simply as

32 Faden, History 242.
33 Faden, History 240.
34 Beauchamp, Principles 59.
35 Beauchamp, Principles 60.
36 Beauchamp, Principles 165.
"beneficence." While many acts of beneficence do not impose obligation, the principle of beneficence imposes a moral obligation to help others advance their essential and lawful interests. In other words, the principle of beneficence requires that moral agents take positive steps to help others, not merely to avoid harming others as the principle of nonmaleficence requires.

For the purposes of this paper, the focus will be on two principles of beneficence: positive beneficence and utility. Those two principles require different actions from moral agents. The principle of positive beneficence demands that agents actively benefit others. On the other hand, the principle of utility demands that agents balance benefits and disadvantages to produce the best outcome. These distinctions are important because conflicts occur between respect for autonomy and beneficence in paternalistic refusals. The principle of utility is a necessary extension of the principle of positive beneficence because the moral life creates risks or incurs costs in addition to producing any benefits or eliminating any harm. Beneficence requires that we assess which actions produce sufficient benefits to justify their costs.

The principle of utility mentioned here is not the same principle as "the classical utilitarian principle of utility, which is an absolute or preeminent principle." This principle is one among other prima facie principles, limited to equalizing probable aftermaths of actions such as benefits, harms, and costs, to realize the highest possible benefit. The advantage of this limited principle of utility is that it delimits the charge that critics of utilitarianism advance, i.e., that it allows a society to override the interests and rights of individuals, in favor of its (societal) interests. For instance, an unconstrained principle of utility in biomedical ethics suggests that dangerous research on human subjects can and should be used, provided that the benefit to society outweighs the harm to individuals. As a prima facie principle, other principles sufficiently limit the principle of utility to avoid burdens of the classical utilitarian principle of utility.

37 Beauchamp, Principles 166.
38 Beauchamp, Principles 165.
39 Beauchamp, Principles 165.
40 Beauchamp, Biomedical 166.
41 Beauchamp, Principles 166.
42 Beauchamp, Principles 166-67.
Paternalism

In the field of medicine professionals’ obligations have always been the obligations to beneficence. The most famous expression of this responsibility is the Hippocratic Oath: "Help, or at least do no harm." The tradition allowed physicians to rely almost entirely on their own judgments about their patient’s needs for treatment, information, and consultation. Recent years, however, show increased assertions of patients’ rights to make autonomous judgments about their medical destiny. The problem of paternalism became more apparent as "the assertions of autonomy rights increased."

The central problem of biomedical ethics is the debate whether respect for autonomy of patients should have precedence over professional beneficence dedicated to those patients. According to some, the principle of respect for autonomy might be the primary (and perhaps the sole) source of "autonomy rights for patients, physicians' obligations to the patient of disclosure, seeking consent, confidentiality, and privacy." Others think that professionals’ obligatory beneficence commits physicians to act mainly for the patients’ medical benefit, not to cultivate their patients’ autonomous decision making. This debate between the autonomy model and the beneficence model relates to the failure to differentiate between two different views of principles of beneficence. Some see beneficence as competing with the principle of autonomy, while others see beneficence as inclusive of the patients' autonomous choices, "in the sense that the patient’s preferences help to determine what counts as a medical benefit."

Defending one principle against the other or designating one principle as absolute in medical field cannot resolve the debate whether one principle should override the other. Biomedical ethics has no preeminent principle, not even the obligation to act in the best interest of the patient. Additionally, no one has the overriding authority, neither the physician nor the

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44 Beauchamp, *Principles* 176.
45 Beauchamp, *Principles* 176.
46 Beauchamp, *Principles* 176.
patient. Beneficence supplies the main goal and basis of medicine and health care by advancing the best interest of the patient, while "Respect for autonomy sets moral limits on the professionals' actions in pursuit of this goal." To see that these two positions are consistent, it is necessary to look at conceptual and other aspects of paternalism.

There are different definitions of paternalism, among them that all paternalistic actions are those that restrict autonomous choice. The prevailing view in current literature on paternalism is that “Paternalism is the intentional overriding of one person’s known preferences or actions by another person, where the person who overrides justifies the action by the goal of benefitting or avoiding harm to the person whose preferences or actions are overridden.”

This definition of paternalism is not prescriptive and as such it does not presuppose that "paternalism is either justified or unjustified.” This definition assumes an act of beneficence similar to parental beneficence. It does not, however, assume that the beneficence is” justified, misplaced, (or) obligatory.”

**Moral Issues Regarding Medical Paternalism**

The history of medical ethics shows that both the principle of beneficence and nonmaleficence (an obligation not to inflict harm on others) provided the foundation for physicians’ paternalistic conduct. For instance, physicians have historically held the view that disclosing certain information can cause harm to their patients and that medical ethics obligates them to avoid causing such harm. Some philosophers would find physicians’ paternalistic conduct justified under certain conditions.

John Stuart Mill (1806-1873), for instance, strongly opposed paternalism, yet he thought that "considered beneficent interventions" in people's' actions are justified in certain situations. Mill claimed that restraining others to insure that they are acting intentionally and with sufficient knowledge of the consequences of their actions, is a justifiable action. A good example of such

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49 Beauchamp, *Principles* 177.
50 Beauchamp, *Principles* 178.
51 Beauchamp, *Principles* 178.
intervention is when others are starting to cross a hazardous bridge. Once they know the dangers of crossing an unsafe bridge, they should be free to decide what action they might take. Mill thought that this temporary intervention is not an actual interference with liberty, and thus he did not view it as paternalistic. Because Mill thought that liberty meant doing “what one desires,” he assumed that those crossing the bridge would not want to fall into the river and would want others to warn them of danger. Under the definition of paternalism cited in this paper, however, temporary interference qualifies as paternalistic.

It is much easier to justify paternalistic intervention in the absence of substantial autonomy then when such autonomy is present. Although much literature on paternalism opposes the idea of justified paternalistic intervention, others like Beauchamp and Childress claim that in some situations "beneficence . . . provides grounds for justifiably restricting autonomous actions as well as nonautonomous ones." Under the definition of paternalism cited in this paper, however, temporary interference qualifies as paternalistic.

**Weak and Strong Paternalism**

Weak paternalism refers to actions in which, "an agent intervenes on grounds of beneficence or nonmaleficence only to prevent substantially nonvoluntary conduct–that is, to protect people against their own substantially nonautonomous action(s). Substantially nonvoluntary or nonautonomous actions include cases of consent or refusal that are not adequately informed, severe depression that precludes rational deliberation, and addiction that prevents free choice and action." In other words, in weak paternalism, people's abilities are less than optimal, i.e., they are in some way compromised.

By contrast, strong paternalism refers to interventions that aim to benefit a person, regardless of the fact that "persons' risky choices and actions are informed, voluntary, and autonomous." In strong paternalism, an agent refuses to agree with others’ autonomous

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54 Beauchamp, *Principles* 181.
desires, choices, and actions when there is a need to protect that person. The strong paternalist will restrict information available to the person or will override the person’s informed and voluntary choices. These choices need not be fully informed or voluntary, but for the interventions to qualify as strong paternalism, the choices must be substantially autonomous.”

Some argue that weak paternalism is not real paternalism. This argument has merit because protecting others from the harm that certain conditions may cause to them, and that is beyond their control, is noncontroversial. Paternalism is about situations in which we can and should protect others from self-caused harm.

**Justification of Paternalism and Antipaternalism**

Philosophers have defended three main positions related to the justifiability of paternalism: antipaternalism, a justified paternalism that mainly relies on the principle of respect for autonomy, and a justified paternalism that mainly relies on the principles of beneficence. Proponents of all three positions find some actions of weak paternalism justified because substantially autonomous actions are absent. Preventing those who are under the influence of hallucinogenic drugs from committing suicides would be justified because it would protect them from self-caused harm.

Antipaternalism opposes strong paternalistic interventions because they infringe on individual rights and overly limit autonomous choice. Giving paternalistic authority to the state or to a class of people, e.g., physicians, which may result in serious adverse consequences to others, is one reason for rejecting strong paternalism. The more important reason for rejection of strong paternalism is that people retain authority over actions that may affect their lives or well-being. Strong paternalistic actions show “disrespect toward individuals as autonomous agents and fail to treat them as moral equals, treating them instead as less than independent determiners

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58 Beauchamp, *Principles* 181.
59 Beauchamp, *Principles* 182.
60 Beauchamp, *Principles* 182.
61 Beauchamp, *Principles* 182.
of their own good."\textsuperscript{62} If others are able to impose their perception of good on us, they fail to show us respect, even if they can benefit us and have a better idea of our needs than we may have.\textsuperscript{63}

Strong paternalism is perilous because people can misuse it.\textsuperscript{64} Under some conditions, however, “a narrow range of strongly paternalistic acts is justified.”\textsuperscript{65} This position excludes institutional and public policies of strong paternalism and includes only specific acts of strong paternalism.\textsuperscript{66} In healthcare strong paternalism is useful and justifiable if and only if the following provisions are present: (1) “A patient is at risk of a significant, preventable harm. (2) The paternalistic action will probably prevent the harm. (3) The projected benefits to the patient of the paternalistic action outweigh its risks to the patient. (4) The least autonomy-restrictive alternative that will secure the benefits and reduce the risks is adopted.”\textsuperscript{67} In medicine, paternalism is problematic because it is difficult correctly to specify and balance physician beneficence and patient autonomy in the physician-patient relationship. The problem of medical paternalism is messy and complicated partly because it involves coherence in judgments, which is difficult to attain. In other words, judging “which paternalistic actions are justifiable requires persons with good judgment in handling contingent conflicts.”\textsuperscript{68} I will address the difficulties of medical paternalism in physician-patient relationship more specifically in a later chapter.

\textit{Legal Theory of Informed Consent}

When did the legal theory of informed consent begin to develop?

In the late 1950's judges began to ask a new, almost revolutionary, question: Are patients entitled not only \textit{to know what} the doctor proposes to do but also \textit{to decide whether} an intervention is acceptable in light of its risks and benefits and

\begin{itemize}
  \item \textsuperscript{62} Beauchamp, \textit{Principles} 182.
  \item \textsuperscript{64} Mill, \textit{On Liberty}.
  \item \textsuperscript{65} Beauchamp, \textit{Principles} 185.
  \item \textsuperscript{66} Beauchamp, \textit{Principles} 186.
  \item \textsuperscript{67} Beauchamp, \textit{Principles} 186.
\end{itemize}
the available alternatives, including treatment. Moreover, in theory, patients had always been entitled to ask whatever questions they pleased. What judges now groped toward was the proposition, eventually formalized in the doctrine of informed consent, that physicians should be placed under an *affirmative* duty to acquaint patients with the important risks and plausible alternatives to a proposed procedure.\(^{69}\)

Since those early beginnings, the courts have used two legal theories to deal with the obligations of physicians toward their patients, the theory of battery (unconsented touching) and the theory of negligence (a failure to use reasonable or due care that results in unintentional harm). The omission to fulfill legal obligations, regardless of the legal theory on which obligation is based, leads to either liability to punishment or an obligation to compensation.

The theory of battery holds that "the defendant is liable for any unintentional act that results in physical contact for which plaintiff has not given express or implied permission."\(^{70}\) The charge of battery does not require ill intent and injury, but one of these conditions has to be true in order to make legal action worthwhile. A famous statement from a legal decision issued in 1914 seems to back the right to self-determination: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without patient’s consent, commits an assault for which he is liable in damages."\(^{71}\)

The theory of negligence holds that the defendant is liable for a careless action or omission when the defendant had an obligation toward the plaintiff and careless action or omission causes an injury.\(^{72}\) The standard of reasonable care is the level of care that a common person would view as proper conduct. On the other hand, the profession is the group that sets the standards for determining the level of due care in professional negligence or malpractice. Medical malpractice occurs when a physician violates the standard of due care, including an omission to properly disclose information about a specific procedure. In case of physicians'
negligence in informed consent, an action would have to show that a physician violated a duty of "due care to inform a patient, that this breach resulted in a financially measurable injury, and that a reasonable person would not have consented."73

In informed consent liability, negligence is a preferred legal theory because battery is inherently antisocial and lacks a credible perspective from which to evaluate physician conduct. A minority of legal critics argues that the theory of battery explains the philosophy of self-determination better than the negligence theory. For instance, an important issue is whether an omission to secure consent without resulting harm should count as "a dignitary injury to bodily integrity" that requires compensation. A battery theory implies that even for medical reasons, touching without consent would require compensation, while a negligence theory would not.74

The drawback of the legal theory of informed consent is that it began by advancing the principle of self-determination but its specific focus shifted to torts, or wrongful acts, such as battery or negligence, which may or may not require compensation. Consequently, law "provides little clear specific guidance regarding how informed consent should actually pursue such self-determination."75 Clinicians’ conduct in response to the law is counterproductive in the sense that they resort to tactics such as to hyperinform, "just to be safe," which leads to their patient’s information overload. Consequently, as many writers have pointed out, the commitment of law to self-determination is lukewarm at most.76 Additionally, insofar as clinicians accept the law’s own orientation regarding informed consent, the "damage control" form of informed consent is a mere formality in the sense that physicians do not engage patients in the decision making. If the law leans toward treating informed consent mainly as an item within malpractice actions, then it is unsurprising that clinicians’ responses are defensive. Finally, the law seldom considers the seriousness of the assault that illness might make on personal autonomy. The law thus provides clinicians with significantly unrealistic vision of patients as decision makers, and consequently weakens the credibility of its message to those whom it needs to persuade the most.77

72 Faden, History 28.
73 Faden, History 29.
74 Moreno, "Informed Consent" 688-89.
75 Wear, Consent 66.
76 Katz, Silent 48-84.
77 Wear, Consent 25.
Because the law’s purpose is to establish what is minimally necessary in our interactions with each other, it is unrealistic to expect a comprehensive standard for this interaction. Forcing lawyers to define "operationally precise standards" for evaluating competence or clinical definitions of medical facts, such as what constitutes a "medical emergency," does not seem prudent. Lawyers can provide a conceptual framework and can also identify unacceptable practices, but ultimately clinical experience and judgment, in accord with bioethical principles, must prevail. 78

Given that law falls short of providing an effective model of informed consent in clinical medicine, let look at moral philosophy and what it has to offer in terms of ethical principles that could help establish respect for patient autonomy as core value in medical care.

The Meaning and Elements of Moral Theory of Informed Consent

Informed consent as respect for autonomy is a person’s consent to a medical intervention or to an involvement as a subject in biomedical research. 79 In this sense informed consent requires more than person’s explicit agreement or compliance with a certain proposal; it necessitates informed and voluntary consent. Moreover, informed consent as respect for autonomy happens "if and only if a patient or subject, with substantial understanding and in substantial absence of control by others, intentionally authorizes a professional to do something." 80 In Mohr v. Williams, a classic case regarding informed consent, Anna Mohr consented to a surgery on her right ear. During the operation, the surgeon decided that Anna’s left ear instead needed surgery and proceeded to operate on her left ear without getting her consent. A court decided that the physician should have gotten Anna’s consent to operate on her left ear: "If a physician advises a patient to submit to a particular operation, and the patient weighs the dangers and risks incident to its performance, and finally consents, the patient

78 Wear, Consent 25.  
79 Beauchamp, Principles 78.  
80 Beauchamp, Principles 78.
thereby, in effect, enters into a contract authorizing the physician to operate to the extent of the
consent given, but no further.”

The elements of informed consent found in the philosophical, legal, medical, and
psychological literature on informed consent are competence, disclosure, understanding,
voltariness, and consent or authorization. For the purpose of analysis only the first four
elements are necessary. Some theorists use these elements to define informed consent: "One
gives informed consent to intervention if (and perhaps only if) one is competent to act, receives a
through disclosure, comprehends the disclosure, acts voluntarily, and consents to the
intervention.”

Competence

In decision making, competence (defined as "the ability to perform a task") and
autonomous decision making, as well as the validity of informed consent, are closely connected.
This is important because incompetent individuals cannot give valid informed consent. Competence does not need to be comprehensive for the purpose of valid consent. It is rather
limited to peoples’ abilities to make particular decisions because every task requires a different
degree of competence. For instance, people's’ competence to stand trial, to write checks, to raise
dogs, or to lecture students, requires radically different criteria. In the case of informed consent
in medical field, individuals need to be competent to decide about treatment or about
participating in research.

Competence may vary over time and may be intermittent. In other words, many people
are incompetent to do certain task at certain times but may be competent to execute the same task
at a different time. Some illnesses cause chronic changes in intellect, memory, or language, while
others such as ischemic (constriction of blood vessels) attack, and transient comprehensive
amnesia, cause only temporary changes in those functions that can vary from hour to hour. If a

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81 Mohr v. Williams, 95 104 N. W. 12, 15 (Minnesota 1905): 261, 265: 261, 265
82 Beauchamp, Principles 79.
83 Beauchamp, Principles 69.
84 Beauchamp, Principles 70.
persons' level of competence is questionable at first, it is prudent to evaluate his capacities such as understanding, deliberation, and coherence, over time.85

Competent people, who are normally able to make choices to help them reach their goals, will act incompetently in certain situations because they lack the necessary capacity when faced, in their view, with an assertive, powerful, and an authoritative figure such as a physician. For instance, a woman hospitalized with a severe disk problem to regulate back pain, decides to manage it by wearing a brace. This method had worked well for her and she strongly believed it would work for her again. The physician, a prominent surgeon, and the only one in her city qualified to treat her, however, asks her to sign a consent to surgery. The woman is psychologically not able to refuse because she vested her hopes for recovery in this physician, whom she views as powerful and authoritative. Because her illness amplifies her hopes and fears, and because her personality is passive, it is psychologically too risky for her to act according to her desires in this situation. Even though she is normally competent to make choices, this woman lacks the capacity to choose in this situation.86

From the above case it is apparent that the concept of competence in decision making is closely related to that of autonomy. People are competent to make certain decisions if they have the capacity to comprehend relevant information, to judge the information in light of their values, to aim for a certain result, and to communicate freely their desires to others. Although the concept of competence has a different meaning from the concept of autonomy (“autonomy” means “self-governance,” while “competence” means “the ability to perform certain tasks”), the criteria that demarcate autonomous people are strikingly similar to those of competent ones. Two credible hypotheses stem from this similarity; first, “that an autonomous person is (necessarily) a competent person (for making decisions), and second, that judgments about whether a person is competent to authorize or refuse an intervention should be based on whether that person can choose autonomously in particular circumstances.”87

Although being competent is like other abilities, like being intelligent or athletic, in the sense that they enable us to perform certain tasks, for practical and policy reasons we must have

85 Beauchamp, Principles 70.
86 Beauchamp, Principles 71.
a threshold level beneath which someone’s abilities do not pass the competency test. In an emergency room, for instance, a frightened and inexperienced patient is less qualified to give informed consent than a knowledgeable and experienced one. The range of abilities stretches from full expertise through various levels of proficiency, to complete ineptitude, which suggests that not all competent people are equally able to make autonomous decisions and not all incompetent ones are equally unable. Competence decisions divide people into those two basic groups, and thus treat people either as competent or incompetent for particular objectives. We treat those who are above the threshold as equally competent, and those that are below the threshold as equally incompetent. For the purpose of discovery of threshold level, health professionals can use the gatekeepers test (competence judgment), with a limit set at a particular task to be performed. Competence judgments distinguish between those who are competent to make decisions (and from whom medical professionals can thus solicit and accept decisions) and those who are not competent (and from whom medical professionals should not solicit or accept decisions).

Disclosure

From the moral point of view, informed consent relates more to the autonomous choices of patients than to the liability of physicians as agents of disclosure. To facilitate autonomy in decisionmaking, it is essential that both health care professionals and patients ask and answer questions, which makes this process more about finding relevant information and deciding how to shape and use it, and less about disclosing information. Even so, disclosure is a decisive issue because without an acceptable way to present information, patients will have an inferior foundation for decisionmaking. The professionals’ views, judgments, and recommendations are frequently necessary for a sound decision. Their responsibility is to disclose an essential set of

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87 Beauchamp, Principles 72.
88 Beauchamp, Principles 72.
89 Beauchamp, Principles 69.
90 Beauchamp, Principles 81.
information such as (1) the facts that patients consider relevant when deciding to refuse or consent to the proposed intervention, (2) information the professionals believe to be relevant, (3) the professionals’ recommendation, (4) the purpose for seeking consent, and (5) the purpose and the limits of consent as an authorization act.\textsuperscript{91}

Other types of disclosure might be necessary. Beauchamp and Childress credit Hunter Prillaman\textsuperscript{92} for compiling many arguments on how much information professionals should disclose about a procedure’s risks, about its nature and benefits, and about any alternative procedures, which include new drugs, devices and treatments. The main issues, they suggest, fall on the informational needs of the patients rather than on lists or classes of information.\textsuperscript{93}

Current literature on the subject of disclosure identifies three standards: the professional practice standard, the reasonable person standard, and the subjective standard. The first two standards have emerged in the courts. The courts have also proposed the subjective standard but have implemented it only as a causation standard, i.e., as a way of deciding whether a physician’s failure to disclose specific information caused injury to the patient.

The Professional Practice Standard

This standard holds that a professional community determines what the customary practices regarding adequate disclosure and proposes that the proper role of the physician is to act in the best interest of the patient. The professional community also establishes the quantity and the type of information to be disclosed to the patient. Like treatment, disclosure is a duty of physicians because their expertise and commitment are to the welfare of the patient. Consequently, the courts count only expert testimony from members of the profession as evidence that someone has violated a patient's right to information.\textsuperscript{94}

\begin{footnotes}
\footnote{Beauchamp, \textit{Principles} 81.}
\footnote{Beauchamp, \textit{Biomedical} 147.}
\end{footnotes}
The professional practice standard, also called a *reasonable doctor standard*, still dominates the informed consent law, but some have criticized it severely on the grounds that it makes implausible assumptions. It assumes that there is an actual consensus for the disclosure of information in the field of medicine. It theoretically enables physicians to withhold important information from patients if that is what the physician community endorses. Physicians could perpetuate negligence without concern for disciplinary actions against them. The main objection to the professional practice standard is that it undermines people's rights to autonomous choice because this standard is designed for medical judgments, while decisions for or against medical care are strictly in patients’ domain. Finally, it is questionable whether physicians have developed abilities to decide what type of information serves the best interests of their patients. No reliable data back the assumptions that physicians have such expertise. Thus the evaluation of risks as it relates to people's’ beliefs, hopes, and fears, is not a skill that belongs to experts. The information that medical professionals submit to patients sometimes needs to be free from their (professionals') firmly established values and aims.  

The Reasonable Person Standard

The reasonable person standard requires that information disclosure conforms to what a hypothetical reasonable person would want to know about potential risks and benefits of the proposed treatment, as well as alternatives to this treatment. This standard has made advances in becoming a standard that is more likely to insure respect for patients' autonomy, and most legal jurisdictions have accepted it. The authority to determine what information to disclose to patients thus shifts from physicians to patients, and the courts could find physicians guilty of negligent disclosure even if their conduct is in agreement with professional practice. The assumption of the reasonable person standard is that obligations to respect autonomy outweigh

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95 Beauchamp, *Principles* 82.

96 Moreno, "Informed Consent" 689.
those of beneficence, and therefore this standard serves the autonomy of patients better than the professional practice standard.\textsuperscript{97}

Several problems plague the reasonable person standard. First, no one has carefully defined the concept of the reasonable person standard or the concept of "relevant information." Second, no clear guidelines exist about how to use this standard in practice. The concept is abstract and hypothetical, and physicians find it difficult to use because they have to guess what a reasonable patient would need to know. Furthermore, very few patients actually use the information that was disclosed to them in their actual decision making. Some data indicate that patients make their decisions before and independently of the process of accepting information. Other studies show that patients often simply accept physicians’ recommendations without carefully evaluating the benefits and harms of a procedure. Many patients consent to a procedure without any consultation about risks (eighty-six percent in one study) or they agree to a procedure during the first meeting with a physician (eighty-two percent of candidates for supplementary breast cancer therapy in one study).\textsuperscript{98}

Although these data do not always show that patients’ decisions are uninformed or that disclosed information is not important because patients may believe that additional information did not change their original view regarding medical treatment, they do raise questions. For instance, the type of information that would be material for the individual patient may or may not be the same information that the reasonable patient would want. This creates a need for another standard.\textsuperscript{99}

The Subjective Standard

The subjective standard requires that physicians disclose specific information that individual patients want. Individual needs can vary because of specific beliefs, unusual health challenges, or special family health history that requires a different type of information from

\textsuperscript{97} Beauchamp, \textit{Principles} 82.
\textsuperscript{98} Beauchamp, \textit{Principles} 82.
\textsuperscript{99} Beauchamp, \textit{Principles} 82.
what the reasonable person would need. For instance, someone with a family history of reproductive problems might want information that other people would neither want nor need before becoming engaged in research on sexual and familial relations or before accepting employment in certain industries. If physicians know or have reason to think that their patients want such information, "then withholding (information) may undermine autonomy."\(^{100}\)

The difficulty here is determining the degree to which a standard should fit the individual patients' needs so that disclosure would have to include the details specific to "the patients’ needs for information” that patients could reasonably expect physicians to have.\(^{101}\) The subjective standard obligates the physician to disclose information that a specific patient needs to know, provided there is "a reasonable connection between those needs and what the physician should know about the patient’s position."\(^{102}\)

The subjective standard as a legal standard is plagued with problems. Nevertheless, some ethical theorists (Beauchamp, Childress, Faden) prefer it as a moral standard of disclosure because it is the only standard that recognizes “the independent informational needs of the persons.”\(^{103}\) The exclusive use of the subjective standard does not serve either law or ethics. For instance, patients frequently do not know what information would be pertinent to their needs and cannot reasonably expect physicians to do an extensive background and personality evaluation of each patient to determine what information would be pertinent.\(^{104}\)

In the fourth edition of the *Principles*, Beauchamp and Childress claim that active participation through mutual exchange of information provides a solution to the problem of disclosure.\(^{105}\) The professional-practice standard and the reasonable-person standard are insufficient guides because what professionals normally disclose and “what an objective reasonable person needs” frequently fail to incorporate some or all of the information essential to the person that needs to decide a course of action. The role of professional and legal rules of disclosure is thus a help only to begin the communication process. Professionals and their

\(^{100}\) Beauchamp, *Principles* 82.
\(^{101}\) Beauchamp, *Biomedical* 149.
\(^{102}\) Beauchamp, *Principles* 82.
\(^{103}\) Beauchamp, *Principles* 82.
\(^{104}\) Beauchamp, *Principles* 83.
\(^{105}\) Beauchamp, *Biomedical* 150.
institutions should not be content with a signed consent form unless they have devoted special
care to "the process that led to it," (if they are to meet the moral requirements). In the latest
edition of the Principles, the fifth edition, Beauchamp and Childress do not offer a solution to the
problems regarding disclosure, thus providing only a theoretical framework for a possible
operational model of informed consent in a medical practice.

Intentional Nondisclosure

Several noncontroversial legal exceptions to the rules of informed consent allow medical
professionals to proceed without consent. Emergency exceptions include (public health or
medical) patient incompetence, and patient waiver. A controversial exception to informed
consent is the therapeutic privilege, which in the past allowed physicians greater authority to
decide whether they should withhold information about the conditions of the patients for their
well-being. This exception allowed physicians to withhold information from “a depressed,
emotionally drained, or unstable patient.” Some of the possible outcomes in such situations are
anxiety and stress, irrational decisions, and life endangerment. In 1986, United States Supreme
Court Justice Byron White, however, vigorously opposed the idea of therapeutic privilege,
suggesting that its legal status is not so secure as in the past. He claimed that “It is the very
nature of informed consent provisions that they may produce some anxiety in the patient and
influence her in her choice. This is in fact their reason for existence, and . . . it is an entirely
salutary reason.”

Although different legal jurisdictions have their own formulations of therapeutic
privilege, the narrowest formula is consistent with the principle of respect for autonomy. Some
formulations allow physicians to withhold information if disclosure would cause any

106 Beauchamp, Biomedical 150.
107 Beauchamp, Principles 84; Moreno, "Informed Consent" 689.
108 Beauchamp, Principles 84.
109 Beauchamp, Principles 84.
110 Beauchamp, Principles 84; Thornburgh v. American College of Obstetricians, 106 S. Ct. 2169, at 2199-200 (1986) (White, J., dissenting)
countertherapeutic worsening in their patients' condition, while others let clinicians withhold information “if and only if the patient's knowledge of the information would have serious health-related consequences, (e.g., by jeopardizing the treatment's success or by critically impairing relevant decision making processes).”\textsuperscript{112} The narrowest form of the therapeutic privilege is similar to an occurrence of incompetence, which allows physicians to withhold information only if they have sufficient reason to think that disclosure would make patients incompetent to refuse or to consent to medical intervention. Under these circumstances the therapeutic privilege would not conflict with respect for autonomy because the patient would not be able to decide autonomously at the critical point.\textsuperscript{113}

The purpose of disclosure is to make certain that patients understand the relevant information regarding their medical conditions and thus give valid consent. There is, however, much debate and resistance among physicians to the idea that patients are able to understand such information. It is thus important to show the conceptual basis for this requirement, as well as some obstacles to achieving substantial understanding.

Understanding

No consensus exists on the nature of understanding as a philosophical concept, but for the purpose of analysis in biomedical ethics it is sufficient to say that we understand something if we have material information and justified,\textsuperscript{114} relevant beliefs about consequences of our actions.\textsuperscript{115} Both clinical experience and empirical data show that patients’ understanding of information about "diagnoses, procedures, risks, and prognoses" varies widely.\textsuperscript{116} While some patients are calm, attentive, and interested in discussion, others are anxious or distracted in ways that limit or impede their understanding. Illness, immaturity, and irrationality among many other things, limit

\begin{footnotesize}
\textsuperscript{111}Beauchamp, \textit{Principles} 84.
\textsuperscript{112}Beauchamp, \textit{Principles} 84.
\textsuperscript{113}Beauchamp, \textit{Principles} 84.
\textsuperscript{115}Beauchamp, \textit{Principles} 88.
\end{footnotesize}
patients’ understanding.\textsuperscript{117} It is not necessary that one’s understanding of relevant information be complete, but only substantial since some facts are trivial, while others are essential. Lacking knowledge of even a single risk, restriction, or missing detail can rob us of adequate understanding. For instance, some but not all, prostate surgeries cause sterilization. In the case of \textit{Bang v. Miller Hospital}, the patient, Bang, consented to prostate surgery, but he did not understand that sterilization was inevitable in his particular case. His failure to understand this particular consequence undermined his otherwise adequate comprehension of the nature of surgery and also negated the validity of his consent.\textsuperscript{118}

Assuming that we understand if we have material information and “have justified, relevant beliefs about the nature and consequences of our actions,”\textsuperscript{119} what constitutes material information, can patients or research subjects understand it, and what medical professionals can do to enhance understanding? Patients need to understand at least the essential information that physicians believe patients need to understand to consent to a procedure. The essential information includes diagnoses, the nature and purpose of intervention, prognoses, alternatives, risks and benefits, and physicians’ recommendations. Additionally, patients need to make sure they understand the terms of the authorization before permitting intervention. Without agreement about the essential elements of authorization, there is no certainty that patients made autonomous decisions because interpretations of the terms might be different. For instance, physicians and patients may have different interpretations of medical terms such as hernia or stroke if patients do not understand common medical definitions and conceptions.\textsuperscript{120}

Some object (especially physicians) that patients and research subjects cannot fully understand relevant medical information or sufficiently value its importance in making decisions about medical care or about participating in research.\textsuperscript{121} This objection is too general to be relevant because it is based on the idea that patients or research subjects must have full understanding of issues. This ideal level of understanding is not necessary because understanding

\begin{footnotes}
\footnote{Beauchamp, \textit{Principles} 88.}
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\footnote{Beauchamp, \textit{Principles} 88.}
\footnote{Beauchamp, \textit{Biomedical} 89.}
\footnote{Beauchamp, \textit{Principles} 89.}
\end{footnotes}
essential information about the medical intervention clinicians propose is a sufficient standard of understanding. Agents are never fully informed, voluntary, or autonomous but “it does not follow that they are never adequately informed, voluntary, or autonomous.”

Another argument is that some patients have very limited knowledge bases, which makes communication about new or unfamiliar procedures extremely difficult, particularly if new information includes new concepts or cognitive constructs. Proper understanding of scientific goals and procedures is particularly difficult and distorted. Nevertheless, patients can often acquire adequate understanding and make decisions if professionals can communicate new and specialized information by drawing analogies between this information and ordinary circumstances in patients’ lives. Likewise, professionals can express risks in qualitative as well as quantitative terms or probabilities. They can simultaneously help patients give meaning to the probabilities by comparing the probabilities with more common risks and experiences such as driving a car or using power tools.

Although the above strategies are helpful, the job of enabling a patient to understand and appreciate the risks and benefits of medical intervention is still formidable. For instance, patients often underestimate the level of postoperative pain even though they understand that some pain accompanies surgical procedures. Additionally, some very ill patients lose the ability to judge clearly between the threat of pain and the benefits of surgery and overwhelmingly choose surgery, while they greatly devalue risks. Consequently, in some ways these patients have a good understanding of facts regarding procedures that include pain, but they have an inadequate understanding of risks.

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122 Beauchamp, Principles 89.
123 Beauchamp, Principles 89.
124 Beauchamp, Principles 89.
125 Beauchamp, Principles 90.
126 Beauchamp, Principles 90.
Problems of Information Processing

One of the problems of information processing that require more research is information overload because it can preclude adequate understanding.\textsuperscript{127} Information overload becomes amplified if new terms are used or if information is not organized in a meaningful way. Contributing to this problem is patients’ reliance on selective perception, making it difficult to figure out when words have a "special meaning for them, when preconceptions distort their processing of the information, and when other biases intrude."\textsuperscript{128}

Another difficulty regarding information processing is that an inadequate level of understanding regarding risk disclosures compromises autonomous choice. Risk disclosures often lead to distortion of information and encourage "inferential errors and disproportionate fears of risks."\textsuperscript{129} Consequently, the manner in which health professionals communicate the negative and positive aspects of information to their patients is extremely important. If patients are to make an autonomous choice regarding a medical intervention, they must acquire adequate level of understanding. Certain ways of framing information, however, reduce understanding thus compromising autonomous choice. Some ways of framing information can be misleading to the extent that both health professionals and patients misinterpret the content of information. If, for instance, clinicians presented information in terms of survival or death, the choice of procedure to curtail the outcomes is markedly different. In one study, radiologists, outpatients with chronic health problems, and graduate business students made a hypothetical choice between two therapies for lung cancer, radiation therapy, and surgery. When presenters framed information about risk in terms of probability of survival, 25% in all three groups chose radiation over surgery. When presenters framed the outcome of intervention in terms of immediate death from surgical intervention, all three groups chose radiation 42%.\textsuperscript{130}

\textsuperscript{127} Beauchamp, \textit{Principles} 90.
\textsuperscript{128} Beauchamp, \textit{Principles} 90.
\textsuperscript{129} Beauchamp, \textit{Principles} 90.
\textsuperscript{130} Beauchamp, \textit{Principles} 90.
Problems of Nonacceptance and False Belief

A problem of nonacceptance and false belief refers to a breakdown in decision making caused by person’s inability to "accept information as true or untainted, even if he or she adequately comprehends the information."\textsuperscript{131} Examples of a false belief are: (1) Patients' false beliefs that their doctor will not fill out insurance forms unless they agree to interventions their doctor suggested. (2) Patients who are capable of consent and are sufficiently informed, might agree to partake in nontherapeutic research because they falsely believe that it is therapeutic. (3) Seriously ill patients might refuse to make a decision about treatment because they falsely believe that they are not ill. This situation is particularly problematic because the physician might recognize that the patients hold false beliefs, inform the patient about it and show evidence of patients mistaken beliefs, yet patients might still believe that information his physician truthfully disclosed, is false.\textsuperscript{132}

Other issues like inconclusive evidence and a lack of agreement about what constitutes the truth and falsity of beliefs, complicate the problems of nonacceptance and false belief.\textsuperscript{133} Given that the uncertainties and probabilities beset many beliefs we should judge truth claims by the available evidence. This also is problematic because evidence is subject to various interpretations. Additionally, different standards of evidence may exist, and collecting of evidence has to occur within some framework that specifies what counts as evidence. An agreement for the criteria that define the justifiability of beliefs must exist for an "adequate basis for determining whether a given belief compromises understanding or simply involves an essentially contestable proposition." This claim is not a skeptical denial of the possibility of knowledge. Rather, it is a warning that "the evidence for thinking that a belief is false may be rationally contestable."\textsuperscript{134}

\begin{flushleft}
\textsuperscript{131} Beauchamp, \textit{Principles} 91. \\
\textsuperscript{132} Beauchamp, \textit{Principles} 91. \\
\textsuperscript{133} Beauchamp, \textit{Principles} 91. \\
\textsuperscript{134} Beauchamp, \textit{Principles} 91. 
\end{flushleft}
The problem of waivers

In biomedical ethics, waivers refer to people's voluntary relinquishing of the right to an informed consent and the release of the physician from the obligation to procure informed consent. By waving the right to informed consent, agents (patients) delegate decision making to others (physicians), or agents ask that others do not inform them about either their condition, or risks of interventions. In such cases, patients decide to forgo informed decision making.\textsuperscript{135}

Some support exists for wavers in the legal system as well as in ethics, possibly because a substantial number of patients seems disinterested in the type of interventions they might need, the risks, and the information to help them make decisions.\textsuperscript{136} Some courts have ruled that when patients request waivers of informed consent, physicians do not need to disclose risks associated with medical interventions. In biomedical ethics, some researchers maintain that individuals can always waive their rights, including the right to informed consent. Different studies show that up to 60\% of patients want to know almost nothing about particular interventions or about the accompanying risks. Additionally, a high percentage of patients would consent without knowledge of risk, and only a minor percentage utilizes the information supplied in making their decisions.\textsuperscript{137}

Although we have a discretionary power of exercising our rights in the context of consent, it is dangerous to allow waivers as a general practice in clinical settings because too many patients trust their physicians too much. In research and therapeutic settings, this inordinate trust "makes patients vulnerable to those who have a conflict of interest or abbreviate or omit consent procedures for convenience, already a serious problem in health care."\textsuperscript{138}

No likely general solution regarding the problems with waivers is likely to appear because each case of waiver requires separate consideration, although a sufficient procedural response is possible.\textsuperscript{139} For instance, we could develop rules for disallowing waivers except

\textsuperscript{135} Beauchamp, \textit{Principles} 92.
\textsuperscript{136} Beauchamp, \textit{Principles} 92.
\textsuperscript{137} Beauchamp, \textit{Principles} 92-3.
\textsuperscript{138} Beauchamp, \textit{Principles} 93.
\textsuperscript{139} Beauchamp, \textit{Principles} 93.
when committees such as hospital ethics committees or institutional review committees approve them. The committees' decision to allow or disallow waivers would be based on protection of patients’ best interest in each specific case. This procedural tactic would virtually eliminate problems with waivers. Still, inflexible rules would violate autonomy and fail to help individuals dismiss their responsibilities in institutional environments. To insure protection for patients and to flexibility in reflection and decision making, close monitoring of this process is necessary.¹⁴⁰

Voluntariness and Forms of Influence

Although some researchers (Feinberg) have analyzed voluntariness in the scope of the presence of adequate knowledge, and the absence of psychological and external constraints,¹⁴¹ voluntariness in the context of this paper pertains to individuals’ actions that are free of controlling or coercive influence of others.¹⁴² This is a narrow view of voluntariness intended to differentiate it from a broader concept that would make it synonymous with autonomy. Certain conditions such as psychiatric disorders, debilitating disease, and drug addiction can also reduce or void voluntariness.¹⁴³ For the purpose of this paper, however, the focus is on control by other individuals.

It is important to mention that controlling others is necessarily an influence. All influences, however, are not controlling.¹⁴⁴ In a medical environment, physicians’ control their patients when they are threatening to abandon them if they do not agree to undergo certain medical procedures such as cardiac catheterization. Physicians influence, but do not control, patients when they persuade initially reluctant patients to undergo certain procedures. Additionally, while individuals resist some influences, they welcome others. In a broad sense, influence includes various interactions, all of which can have a profound effect on individuals. Such interactions include "acts of love, threats, education, lies, manipulative suggestions, and

¹⁴⁰ Beauchamp, Principles 93.
¹⁴² Beauchamp, Principles 94.
¹⁴³ Beauchamp, Principles 94.
¹⁴⁴ Beauchamp, Principles 94.
emotional appeals." The literature on informed consent mentions three categories of influence: coercion, persuasion, and manipulation.

**Coercion**

Coercion refers to one person's intentional and successful use of “credible and severe threat of harm or force to control another.” Coercion is incompatible with informed consent because it robs others of autonomous choice. Three essential features define coercion: (1) “the agent of influence must intend to influence another person by using a serious threat,” (2) the threat must be credible, and (3) the threat has to be irresistible. A common type of coercion is the threat of force that some police, courts, and hospitals use in acts of involuntary committal for psychiatric treatment. For the threat to be credible, both sides have to believe that the person making a threat has the power to carry it out, or has to successfully deceive a person being threatened into believing so. For instance, a prison physician who tells an inmate that he must be sedated may need to have prison guards present in order to make the threat credible. Situations where no one has issued a threat, yet the person feels threatened, do not constitute coercion because coercion happens only if there is a believable and intended threat that substitutes for a person’s self-governance. Coercion renders even intentional and well-informed conduct nonautonomous.

**Persuasion**

Persuasion is a form of influence that relies on appeal to reason. In other words, persuasion is the intentional and successful effort to convince others, by appealing to reason, to

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145 Beauchamp, Principles 94.
146 Beauchamp, Principles 94.
147 Faden, History 339.
148 Beauchamp, Principles 94.
voluntarily accept as their own, the intentions, values, beliefs, attitudes, or actions that another person advocates.\textsuperscript{149} Persuasion is always an open form of interpersonal influence because persuaders openly discuss reasons for adopting their recommendations. Any choices that people make or any acts they perform as a result of persuasion are not only non-controlled but also autonomous provided that other conditions of autonomous action such as proper disclosure and adequate understanding, are satisfied.\textsuperscript{150}

In this discussion, persuasion is distinguishable from influence by appeal to emotion. In the medical field it is difficult to differentiate between cognitive and emotional responses and also to decide which response is likely to occur. The problem arises when disclosures or techniques that might "rationally persuade" one person, overwhelm another because they might experience the level of fear or panic that short circuits reasoning ability. The primary aim is to avoid overwhelming a person with alarming information, especially if that person is psychologically defenseless.\textsuperscript{151}

Manipulation

\textit{Manipulation} refers to several types of influence that include all intentional and successful influence of others by non-coercively modifying the actual available alternatives or by non-persuasively changing other people's' perceptions of those alternatives.\textsuperscript{152} Manipulators use one of these two means to alter other people’s choices or perceptions of those choices. The most common form of manipulation in the medical field is informational manipulation, i.e., a purposeful handling of information intended to non-persuasively change other people's’ understanding of a particular situation, thus influencing them to act according to wishes of the agent of influence such as a physician. Examples of informational manipulation are deception that includes lying, withholding information, and misleading exaggeration meant to lead a person

\textsuperscript{149} Faden, \textit{History} 261.
\textsuperscript{150} Faden, \textit{History} 261.
\textsuperscript{151} Beauchamp, \textit{Principles} 95.
\textsuperscript{152} Faden, \textit{History} 261.
to believe in false facts.\textsuperscript{153} Although informational manipulation does not deplete the realm of manipulation, it is incongruent with autonomous decision making and is a major problem for informed consent.\textsuperscript{154}

Some problems that affect understanding recur as problems of informational manipulation. One such instance is clinicians’ use of therapeutic privilege to withhold information to manipulate patients to consent to a medically advisable intervention. Also, the manner in which medical professionals present information such as the tone of voice, forceful gestures, and positive (this therapy is effective most of the time) rather than negative (this therapy fails in 35\% of the cases) presentation of information, might alter patients’ “perception and response, and thereby affect understanding and voluntariness.”\textsuperscript{155}

The threat of control by manipulation in medical care is easily inflatable beyond its actual importance because we normally make decisions in a context of rivaling influences such as "personal desires, familial constraints, legal obligations, and institutional pressures."\textsuperscript{156} These influences are not necessarily controlling to a great degree. Still, to insure that patients or research subjects make an autonomous choice, it is necessary to establish a point at which autonomous choice becomes imperiled. At the same time we must recognize that in many situations the line between controlling and non-controlling influences is not sharp.\textsuperscript{157}

In summary, the autonomy model presented above is conceptual not normative. Faden and Beauchamp provide the most sophisticated analysis of informed consent to originate from new medical ethics, which considers patient autonomy as its basis for good medical care.\textsuperscript{158} The strengths include the definition of “informed consent” (respect for person's autonomy), which focuses on what appears to be the most important in determining whether patients have given informed consent. Another strength is the concern for patients' understanding of medical intervention that clinicians recommend and its consequences, as well patients' knowledge of existence and the consequences of any alternative treatments. Faden's and Beauchamp's concern

\textsuperscript{153} Beauchamp, Principles 95.
\textsuperscript{154} Faden, History 261.
\textsuperscript{155} Beauchamp, Principles 95.
\textsuperscript{156} Beauchamp, Principles 95.
\textsuperscript{157} Beauchamp, Principles 95.
\textsuperscript{158} Brody, Power 86.
for patients' precise understanding of what they want is a strength. They warn of possible confusion of patients in the sense that they might think they are getting one thing but actually getting something else. Also present is a concern for undue influence from others or from internal forces such as fear, depression, addiction, or metabolic imbalances. Patients' view of the process of decision making, whether they see it as active participants or as just a conversation or simply a legal formality, is also a concern. The additional strength of Faden's and Beauchamp's analysis is the differentiation between full and substantial autonomy, and between the autonomy of the action and autonomy of the person. Associating informed consent with autonomous action may help identify it as only one element of the physician-patient relationship. The overall focus of this relationship is the autonomy of the person, while informed consent has a more narrow focus on the individuals' autonomy of actions and decisions.\(^\text{159}\)

The objections to Faden's and Beauchamp's analysis of informed consent are mainly to their predominantly theoretical strategy, which fails to provide an operational model for clinicians to follow.\(^\text{160}\) It also leads them to ignore the complexities of power relationships in medical practice, namely the authority or the power of physicians in physician-patient relationships.\(^\text{161}\) I will address this point in a later chapter. Faden and Beauchamp themselves make a general disclaimer about *A History and Theory of Informed Consent*, claiming that their aim is not to define “the proper role of informed consent in medical care and research.”\(^\text{162}\) They also claim that they do not supply “an analysis of the desirability of participation by patients of subjects in decisionmaking, nor (that they) identify the conditions under which health care professionals and research investigators should obtain informed consent.”\(^\text{163}\) Finally, they claim that they discuss “the nature of informed consent, its conditions, and the ends it serves, but not whether and when informed consent obligations should be imposed.”\(^\text{164}\) Although Faden and

\(^{159}\) Brody, *Power* 86.

\(^{160}\) Brody, *Power* 87; Wear, *Consent* 86.

\(^{161}\) Brody, *Power* 87.

\(^{162}\) Faden, *History* vii.

\(^{163}\) Faden, *History* vii.

\(^{164}\) Faden, *History* viii.
Beauchamp do not offer an operational model of informed consent, their theoretical framework presents a standard by which to evaluate any operational model.\textsuperscript{165}

In this chapter I have discussed the legal and the philosophical theories of informed consent, with latter being based on the principle of respect for autonomy. I have also discussed the principle of beneficence on which physicians have been historically relying in medical care. Although both the autonomy and the legal models dominate the discussion of informed consent, they have received a jaundiced reception in the health care field, where its application is at most routine. In practice, there are many obstacles to informed consent other than those mentioned, which will be the subject of a later chapter. I will first provide the historical and scientific background for hormone replacement therapy (HRT) that I will analyze later, to determine how well clinicians apply informed consent in practice.

\textsuperscript{165} Wear, Consent 89.
Historical and Scientific Background of Human Hormones

Liberal democracies, including that of the United States, grew out of the need to respect peoples' rights and their freedoms to promote their self-development. Many political and international documents encourage equality, life, and liberty for all, but implementing respect for them in practice has been difficult because they require change of attitudes and values. Informed consent, with the principle of respect for autonomy as its basis, also requires re-orientation of attitudes and values of those in the position of authority and those who seek their assistance. Physicians are sworn to uphold the best interest of the patients, a model that relied on the principle of beneficence alone, and are also supposed to respect patients' autonomy. The need to respect patients' rights is necessary because the quest for cures, and the search for new drugs can lead to the wrong kind of medical enthusiasm, i.e., the kind that is sometimes misguided and that may cause harm to those whom they are supposed—first and foremost—to treat.

Moreover, other interests can be harmful rather than therapeutic. Drug makers tirelessly promote their products to both physicians and patients, which sometimes creates an artificial need for drugs to treat conditions that often do not, or might not, require medical intervention, e.g., menopause.

America's fascination with youth and beauty in the last part of the 20th century found a partner in the field of medicine. To help women maintain youthful appearances by preventing normal effects of aging, medicine offered hormones. Moreover, in the 1960s the medical profession declared menopause, a natural event in every woman's life, a disease, and hormone prescription and use became a panacea for all disturbances connected with menopause.

Except for a short period in the 1970s, when numerous studies confirmed that estrogen intake caused an up to fourfold increase in development of uterine cancer, clinicians have been prescribing hormone replacement therapies (HRT) to menopausal women to prevent a variety of
health conditions such as heart disease, osteoporosis, depression, Alzheimer's, hot flashes, and thinning of vaginal tissue.\textsuperscript{1} Since its introduction in 1949 the drug of choice for those conditions has been Premarin (a synthetic form of hormone estrogen). Clinicians have been prescribing Premarin routinely “in a one-size-fits-all manner–the same dose for every woman, regardless of her size or medical history.”\textsuperscript{2} To prevent uterine cancers, clinicians have also been prescribing Provera (a synthetic form of hormone progesterone) for 10-12 days of every month.\textsuperscript{3}

In addition to the risk of uterine cancer, hormone replacement therapy confronted another serious problem in the middle of 1990s.\textsuperscript{4} Multiple studies, including the Nurses' Health Study, showed an indisputable link between estrogen and breast cancer.\textsuperscript{5} This connection is plausible because estrogen is “well known to stimulate the growth of estrogen sensitive tissue, like that in the breast and uterus.”\textsuperscript{6} The cardiovascular benefits, however, appeared so convincing that clinicians persuaded many women to set aside their fear of breast cancer and continue using Premarin.\textsuperscript{7}

Doubts about hormone replacement, however, resurfaced when at the end of the year 2000 several large prospective studies\textsuperscript{8} disputed its heart protection benefits. The large Heart and Estrogen/Progestin Replacement Study (HERS) of women who already had a heart disease, hormone replacement utilizing Premarin and Provera, “not only did not decrease their risk for subsequent heart attack, it actually increased that risk significantly in the first year of use, after which the risk leveled off.”\textsuperscript{9} Additionally, initial results from the Women's Health Initiative, a National Institutes of Health (NIH) study of over 100,000 of women on Premarin (and often Provera), showed that replacement hormones did not decrease the statistical risk of heart attack.
or other heart problems in healthy women. Other clinical trials also failed to confirm hormones-heart-benefit link. While many experts still believe that estrogen has a cardiovascular benefit, clinicians cannot assume that this is true for everyone.\textsuperscript{10} Medicine's focus on cardiovascular benefit of estrogen is important because “Coronary heart disease is the single leading cause of death in women and a significant cause of disability. Menopause adversely affects several risk factors for coronary heart disease (such as good and bad cholesterol), suggesting that hormones influence the risk of coronary heart disease in postmenopausal women.”\textsuperscript{11}

A comprehensive new report casts more doubt on longstanding claims that hormone replacement can prevent heart disease or other ailments such as Alzheimer's, severe depression, urinary incontinence, and osteoporosis.\textsuperscript{12} The report claims that while hormone therapy is the best way to relieve menopausal symptoms like night sweats and hot flashes, scientific evidence to support its use for other problems is lacking.\textsuperscript{13} The \textit{International Position Paper on Women's Health and Menopause}, a joint venture of the National Institutes of Health and the private Giovanni Lorenzini Medical Science Foundation of Italy,\textsuperscript{14} reviews existing studies and has engaged twenty-eight doctors and scientists from the United States, Italy, Sweden, Switzerland and Australia. The significance of the report is in its authors' decision to emphasize “evidence-based medicine,” i.e., treatments tested in randomized controlled trials that assign patients on random basis either a placebo or a treatment. Such treatments represent the gold standard in medical research. This paper describes “Women's health and menopause (as) a rapidly expanding field of medical practice and scientific investigation. It is a field of great social importance and impact, nationally and globally in developed as well as developing countries.”\textsuperscript{15} Furthermore, the stated purpose of this “international and multidisciplinary paper is to enhance the composite

\begin{itemize}
  \item Northrup, \textit{Wisdom} 137.
  \item Mosca, "Role" 2263.
  \item National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 1-34.
  \item All pertinent information is from an advanced copy of chapter13 of this paper, titled “Best Clinical Practices.”
\end{itemize}
health of menopausal and postmenopausal women on a global basis, and to make recommendations regarding needs for future research. The International Position Paper on Women’s Health and Menopause might, therefore, provide more reliable guidelines that could stop routine prescription of hormone therapy which places women at great health risks without the necessary scientific evidence of its benefits. Additional reports from the Women's Health Initiative, such as the one published in JAMA on July 17, 2002, might dramatically change the current routine prescription of HRT for prevention of chronic diseases such as heart disease.

Some clinicians like Deborah Grady, a professor of epidemiology and medicine at the University of California of San Francisco, have already changed their approach to prescribing hormonal therapy to all postmenopausal women as a preventive measure except those at high risk of breast cancer. They prescribe hormonal therapy for symptoms for which it is the best treatment. In a dramatic reversal, Grady, who was a lead author of the 1992 guidelines on hormone replacement for the American College of Physicians and who thought at the time that clinicians should prescribe “preventive hormone therapy to most menopausal women, except those at high risk for breast cancer,” now spends much time “trying to figure out how to help women taper off estrogen.”

Although, many clinically significant questions regarding menopause are still to be answered, women who seek advice about menopause now have more information and also have more options for a healthy life in their postmenopausal years. Additionally, “New trial results and new medications may further change recommendations for the assessment and management of the postmenopausal woman.”

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15 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 4.
16 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 4.
17 Grady was a lead author of the 1992 guidelines on hormone replacement for the American College of Physicians. At the time Grady thought that clinicians should prescribe “preventive hormone therapy to most menopausal women, except those at high risk for breast cancer” and included that view into the guidelines. Denise Grady, "Scientists Question Hormone Therapies for Menopause Ills," The New York Times [New York] Apr. 18, 2002, Health.
18 Grady, "Scientists."
19 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 7.
Definition and Functions of Hormones

Hormones are chemical messengers. More specifically, hormones are our body’s liquid communication system: they circulate throughout the body, either in the cardiovascular or in the lymphatic system, targeting specific cells with certain messages. They carry chemical messages from more than a dozen endocrine glands (glands that secrete hormones directly into the bloodstream or lymphatic system) and tissues to cells throughout the body where they activate their regulatory effect.\(^{20}\)

We have much to learn about the complex functioning of the endocrine system, including the functioning of hormones because we have only a general understanding of its many actions. Continuing research ought to provide more detailed knowledge of all the individual processes.\(^{21}\)

There are, however, some things we do know about hormones. For instance, we know of 50 different hormones in the human body. We also know that even small amounts of hormones such as estrogen, adrenalin, or insulin, can have powerful effects on organisms. Hormones regulate an assortment of physiological activities, among them metabolism, growth, reproduction, and homeostasis (maintenance of constant internal environment such as body temperature and electrolyte balance). Although they vary in their structure, action, and response, hormones control a mixture of biological processes including heart rate, muscle growth, hunger, and the menstrual cycle.\(^{22}\)

Major endocrine glands include the pituitary gland (the so called master gland, the size of a pea, located at the base of the brain just above the roof of the mouth in line with the bridge of the nose) the thyroid gland, the parathyroid gland (in the neck), the adrenal glands, the pancreas (in the abdomen), and the sex organs or gonads.\(^{23}\)

Given their structure hormones fall into two main groups: amino acids and steroids. Most nonsteroidal hormones consist of chains of amino acids (the building blocks of protein), either short chains (polypeptides) or long chains (proteins). The hormones of the adrenal medulla,

however, are made of amino acid derivatives called amines. The thyroid hormones are composed of a single amino acid combined with atoms of iodine. Steroid hormones, on the other hand are lipid compounds made from cholesterol.24

Once hormones locate a particular target cell, they bind to it with specific protein receptors inside the cell (steroid hormones and the hormones of the thyroid) or on its coating (polypeptide, protein, and amine hormones) in order to change the cell's activities. The protein receptors read the hormone's message(s) and execute the instructions either by shaping gene operation (by instructing them to make new proteins) or by altering the cell’s existing proteins. These activities produce an assortment of quick reactions and long-term effects.25 Too much or too little of any hormone leads to a physiological disruption. For instance, high estrogen levels adversely affect cell membranes, which leads to the inflow of water and sodium into cells. This causes intracellular water retention and a loss of potassium and magnesium and often results in high blood pressure in women.26 Excessive levels of sodium or of any other mineral have an adverse, lowering effect on all other minerals, in the case of high estrogen in particular, potassium and magnesium.27

Hormones have different targets. Although some hormones can bond with matching receptors in a variety of cells, others aim at only one or a few tissues. Estrogen can regulate functions by bonding to particular receptors in breast, uterine, and bone cells. The same cells (in breast, uterine, and bone) also act as target cells (receptors) for various other regulatory molecules or hormones. For instance, the same breast, uterine, and bone cells that receive estrogen, also contain receptors for progesterone, testosterone, glucocorticoid (an adrenal hormone), vitamin D, and vitamin A.28

Once hormones have initiated the necessary action, the body eliminates them from the system. The target tissues destroy the leftover hormones or the liver breaks them down into
water-soluble compounds. The body’s excretory system then disposes the remaining water-soluble compounds.29

Amino Acids

Major endocrine glands that produce amino acid-based hormones are the anterior and posterior pituitary glands, thyroid gland, parathyroid gland, adrenal medulla gland, and the pancreas. The anterior pituitary gland produces six different hormones: thyrotrophin (THS), the adrenocorticotropic (ACTH) hormone, the follicle-stimulating hormone (FSH), the luteinizing hormone (LH), the lactogenic hormone (LTH) or prolactin, and the growth hormone (GH or somatotropin. The thyrotrophin (THS) stimulates the thyroid gland and the adrenocorticotropic (ACTH) hormone stimulates the adrenal cortex. The two gonadotrophic hormones, the follicle-stimulating hormone (FSH), the luteinizing hormone (LH) stimulate the gonads: the follicle-stimulating hormone (FSH) regulates egg and sperm functions and the luteinizing hormone (LH) regulate sex hormones production. The lactogenic hormone (LTH) or prolactin is involved in milk production and the growth hormone (GH) or somatotropin is involved in many functions regarding growth. The growth hormone and prolactin work directly on the body tissues.

The other four hormones control the actions of other endocrine glands. The posterior pituitary acts as a storage region for two hormones that the hypothalamus manufactures: (1) the antidiuretic hormone (ADH or vasopressin) acts on the kidneys to regulate proper water balance in the body and (2) oxytocin regulates uterine contraction. The hypothalamus is an organ that serves as an essential link between the brain, the nervous system, and the endocrine system. It has two functions: (1) it produces the hormones that the posterior pituitary releases, and (2) it controls the anterior pituitary gland by releasing hormones. The thyroid produces thyroxin, which increases the body's metabolic rate (cellular respiration). It also produces calcitonin which regulates the plasma level of calcium. The parathyroid produces parathormone (PTH), which regulates the plasma level of calcium and phosphorus. The adrenal medulla produces adrenalin

29 Clark, "Endocrine" 191.
(norepinephrine), a hormone involved in the fight-or-flight responses to stress. The pancreas produces insulin (lowers blood sugar) and glucagon (raises blood sugar).  

Steroid Hormones

The major glands involved in the production of steroid hormones are the adrenal cortex, the ovaries, and the testes. The adrenal cortex produces glycocorticoids (cortisol), mineralocorticoids (aldosterone) and sex hormones. Glycocorticoids regulate the production of glucose from nonglucose substances. Mineralocorticoids regulate sodium retention and potassium excretion by the kidneys. Sex hormones regulate the development of sex characteristics. The ovaries produce various sex hormones, estrogen, progesterone, and testosterone. For instance, the follicles (sacs that encase eggs) produce estrogens, which regulate the development of female characteristics during puberty (breast development, pigmentation of the nipples and genitals, and underarm and pubic hair growth). Estrogen is also responsible for the cyclic growth of the endometrium (the inner lining of the uterus), which takes place early in the menstrual cycle. The corpus luteum (tissue that grows inside the follicle once the egg is released) produces progesterone, which also regulates growth of the endometrium to prepare it for implantation of a fertilized egg and provides support during pregnancy. Additionally, the ovaries produce progesterone in the later half of the cycle and in large quantities during pregnancy. The third sex hormone that ovaries produce, testosterone, is the source of energy and sexual drive in women as in men. Finally, the testes produce androgens (testosterone and its derivatives) that regulate the functioning of the male sex organs and the development of secondary male characteristics (hair growth).

Both women and men produce estrogen, progesterone, and testosterone, but the end results of the actions of those hormones are quite distinct in the two genders. Women and men

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31 Estrogen is a name most often used in medical literature for three major estrogens--estradiol, estrone, and estriol--with estradiol being the predominant one.
produce different amounts of each hormone. Estrogen and progesterone are predominant in females, and testosterone is predominant in males.  

If our bodies fail to produce the required hormonal levels, we may experience medical conditions requiring therapy. For instance, physicians administer corticosteroids and their synthetic parallels, such as prednisone and dexamethasone, to control rheumatism and other inflammatory ailments. Physicians sometimes administer anabolic steroids (defined as “any of a class of steroid hormones, esp. testosterone, that promote growth of muscle tissue”) to postoperative and geriatric patients to encourage muscle development and tissue regrowth. Athletes have used anabolic steroids in the form of synthetic testosterone to speed up muscular development and to increase strength. Anabolic steroids, however, can have harmful effects, especially in young people who have not fully developed physically. Continuous and long term use of anabolic steroids may result in heart disease, immune deficiencies, liver damage, sexual and reproductive disorders, stunted growth in teenagers and young adults, and aggressive, violent behavior.

Similarly, physicians prescribe hormone therapy to menopausal women to ease discomfort and prevent serious conditions associated with menopause. Since the 1960s, the medical profession adopted a view that menopause is a hormone or estrogen deficiency disease. Declaring menopause a disease opened doors to the “medicalization” of an event that every woman experiences, which begets the following question. If menopause is an event that every woman experiences, why is it a disease? As we will see later, in the last decade, some medical professionals, organizations, and women activists have promoted a new definition of menopause.

**Menopause and Hormone Replacement Therapy (HRT)**

Some current writings on menopause define it as “a change” in a woman’s life; however, this does not say much about what kind of change menopause involves. The term “change” refers

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33 Clark, "Endocrine" 190.
35 “Steroid.”
to only a physical change somehow leading to mental, physical, and sexual decline, while on the contrary, decline does not happen.\textsuperscript{36} A better way to define “menopause” is that it is a complex event in a woman’s life, one that the effects of changing hormone levels cannot easily explain.\textsuperscript{37} This definition is viable because it reflects the current state of understanding of an important and unique event in each woman’s life. There are two important reasons for the plausibility of this new definition. First, menopause is not a disease but a normal event.\textsuperscript{38} It is a biological occurrence, involving the permanent discontinuation of the menstrual cycle. This further involves a variation and decline of ovarian hormones including estrogen, progesterone, and androgen. This decrease in the ovarian production of hormones (specifically estrogen) may result in short-term, unpleasant effects such as hot flashes, insomnia, vaginal dryness, mood swings, and irregular menstrual cycles that negatively affect the quality of life during perimenopause (the transition time that starts immediately before the natural menopause). For many years clinicians thought that hormone (especially estrogen) decline also increased the risk of osteoporosis and coronary heart disease in the postmenopausal years.\textsuperscript{39}

The second reason for the plausibility of the new definition is that menopause is more than a biological, i.e., physical, event. It is also a psychosocial passage. All women go through menopause but their subjective experiences differ. Some feel a sense of freedom at the prospect of the end of fertility and concerns about contraception and menstrual cycles. It is a link to a phase of life when they feel better about themselves in a sense of being “more confident, empowered, involved, and energized then in their younger years.”\textsuperscript{40} For others, menopause may contribute to serious health problems, aggravated by a combination of changing hormone levels, the effects of aging, and the stresses associated with midlife. In general, however, menopause is

\textsuperscript{37} North American Menopause Society, Menopause Guidebook (Cleveland: North American Menopause Society, 2001) inside cover, 3; National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 4.
\textsuperscript{38} National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 4; North American Menopause Society, Menopause Guidebook 3.
\textsuperscript{40} North American Menopause Society, "Basic."
an opportunity to improve the quality of life.\textsuperscript{41} Acknowledging these findings, the North American Menopause Society (NAMS) and the \textit{International Position Paper on Women’s Health and Menopause} guidelines encourage clinicians to use an individualized approach to the health problems associated with menopause.\textsuperscript{42} No treatment fits every woman and each choice has a benefit/risk feature characteristic to each woman.\textsuperscript{43} In other words, clinicians' recommendations need to be specific to each woman and her background because “There are country-specific and cultural variations in menopausal symptoms, the frequency of different post-menopausal diseases, clinical practice, health care resources, and affordable interventions.”\textsuperscript{44}

The transition time that leads to natural menopause is perimenopause. It starts immediately before natural menopause and can last six or more years ending one year after menopause. The usual signs of perimenopause are hot flashes, vaginal dryness, irregular menstrual periods, difficulty sleeping, and mood swings. The cause for those changes is a shift in ovarian production of hormones (estrogen, progesterone, and testosterone) and the hormones that regulate them.\textsuperscript{45} The anterior pituitary gland produces the follicle-stimulating hormones (FSH) and the luteinizing hormone (LH), both of which regulate ovarian functions, including sex hormone production.

We may understand perimenopause better if we think of it as puberty in reverse.\textsuperscript{46} Barring abnormalities, every woman is born with two ovaries. They contain all the eggs she will have throughout her lifetime. Eggs remain idle until the start of the menstrual cycle. With the onset of puberty, the hormone levels start to fluctuate wildly and eventually settle into an

\textsuperscript{41} North American Menopause Society, "Basic."; National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 6.
\textsuperscript{42} NAMS describes itself as “North America’s leading nonprofit organization dedicated to promoting understanding of menopause, and thereby improving the health of women as they approach menopause and beyond.” Its membership is multidisciplinary, consisting of “2000 leaders in the field, including clinical and basic science experts from medicine, nursing, sociology, psychology, nutrition, anthropology, epidemiology, and education,” which allows NAMS to be uniquely qualified to provide accurate and unbiased information. Some recognize NAMS as the premier source of information on all facets of menopause to both healthcare providers and the public.
\textsuperscript{43} North American Menopause Society, "Basic."; National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 6.
\textsuperscript{44} National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 6.
\textsuperscript{45} North American Menopause Society, \textit{Menopause Guidebook} 3.
equilibrium once a woman reaches biological maturity. Weight gain, bloating, and mood swings are common among adolescent girls, and physicians assume that high estrogen is the cause. When perimenopausal women experience the same symptoms in addition to hot flashes (not characteristic of puberty), clinicians assume it is because estrogen levels are too low. Big hormonal shifts are common to both stages of life, puberty, and perimenopause. Symptoms of those hormonal shifts eventually disappear when the body reaches a new balance point, either maturity after puberty, or natural menopause after perimenopause.\textsuperscript{47}

Natural menopause describes a spontaneous event, permanent cessation of the menstrual cycle without any medical intervention. It is only one day in a woman’s life. The majority of women in the Western world go through natural menopause between the ages of 40 and 58, with the average age being 51. Some women undergo natural menopause in their thirties and some in their sixties. Genetics and cigarette smoking are the only proven factors that affect age at menopause. Women usually experience menopause at about the same age as their mothers and sisters. Smokers, including former smokers, may reach it a year or two earlier than nonsmokers.\textsuperscript{48}

Menopause can also be induced or premature. Induced menopause is an instantaneous event resulting from surgical removal of both ovaries. This is surgical menopause. It stops menstrual bleeding and makes a woman infertile. Induced menopause can also happen as a result of ovarian damage from other medical treatments such as pelvic radiation and cancer chemotherapy. A hysterectomy without removal of the ovaries does not induce menopause because ovaries continue to produce hormones; the menstrual bleeding stops and natural menopause will occur because the ovaries gradually produce less estrogen.\textsuperscript{49}

There are important differences between natural and induced menopause. First, premenopausal women who go through induced menopause (caused by surgical removal of ovaries and thus loss of hormones) do not experience perimenopause but rather face an abrupt loss of ovarian hormones, including estrogen. Consequently, their menopause-related

\textsuperscript{46} Love, Book 4.
\textsuperscript{47} Love, Book 4.
\textsuperscript{48} North American Menopause Society, Menopause Guidebook 3.
\textsuperscript{49} North American Menopause Society, Menopause Guidebook 3-4.
disturbances, such as hot flashes, are more intense. They may also be at the greater risk of osteoporosis and, possibly, heart disease because they live more years without the protective effects of estrogen. Another important difference is that the emotional effect of induced menopause may be greater. Women often have to struggle with the condition or disease that led to the medical intervention (e.g., chemotherapy or pelvic radiation) and also with the side effects of treatment. For instance, pelvic radiation results in hot flashes and acute vaginal dryness and irritation. Finally, women who undergo induced menopause have a greater need for treatment to control intense symptoms and, potentially, to decrease the risk of some disease later in life; however, for younger women who use hormones long-term, risk reduction benefits may not be desirable. Knowledge in this area is limited because all the studies focused on postmenopausal women. Also, not much is known about the safety of using hormones for many years, and often hormones are not an option because medical conditions may preclude them and women and their doctors may have to choose alternative treatments.50

Premature menopause can be natural or induced, and women reach it before the age of forty. Genetic inheritance, autoimmune processes, or medical interventions such as chemotherapy or pelvic radiation can cause premature menopause. Women who undergo premature menopause have an increased risk of osteoporosis and heart disease for the remainder of their lives. Premature menopause signifies the end of normal childbearing and, consequently, can be a cause of psychological distress. Grieving the loss of fertility and subsequent loss of the children they could have had, is common among many younger women. Also, some women associate fecundity with their idea of sexual desirability and femininity. Consequently, the psychological effect of premature menopause is as significant as the physical effect and physicians need to treat both.51

Menopause is, therefore, a complex event that requires careful evaluation for each individual woman who needs more than hormone prescription, yet that is not what was happening in medical practice until now. Although organizations such as NAMS, encouraged physicians to use an individualized approach when designing hormone treatments for women,

some clinicians claim that millions of women are currently on hormonal drug therapy to prevent diseases and conditions that they may or may not contract. By taking those drugs they might be exposing themselves to the risk of such serious diseases as breast and endometrial cancer.\textsuperscript{52}

How did hormonal therapy gain prominence as \textit{the} treatment for menopausal problems despite the obvious ambivalence women have about it?

Hormone therapy has been called a product in search of a market. Most research on menopause is designed to demonstrate the desirability of medicalized interventions. Although the use of hormones to help women cope with common signs of menopause, such as hot flashes, has been known since 1937, hormone treatment was popularized for a mass market in the 1960’s. It was promoted not simply as a palliative for the discomforts of menopause but also as a panacea for “psychological problems” supposedly related to the change of life. Such claims were unproven but were treated as common knowledge. These assertions promoted a stereotyped view of postmenopausal older women as asexual, neurotic and unattractive. As a result, exogenous estrogen was approved for prescription use without adequate testing and soon became one of the five top-selling prescription drugs.\textsuperscript{53}

These claims, (1) that most research on menopause is designed to show the need for medicalized interventions; (2) that hormone treatment was promoted/approved for prescription as a cure all for “psychological problems” as well as for physical discomforts of menopause without proper testing; and (3) that those actions lead to a stereotypical view of postmenopausal women as neurotic, asexual and unattractive, are plausible if we look at other evidence.

In his immensely successful book, \textit{Feminine Forever} (1966), Robert Wilson declared that menopause is “a serious, painful, and often crippling disease.”\textsuperscript{54} He saw the elimination of menopause as perhaps “the most technical advance by which women may equip themselves for

\textsuperscript{52} Love, \textit{Book} xvi.
\textsuperscript{53} Paula B. Doress-Worters in a foreword of Sandra Coney’s book, \textit{The Menopause Industry: How the Medical Establishment Exploits Women}.
an enduringly feminine role in modern life. Wilson’s perception was that women would not feel “fully feminine” throughout their life span without hormone therapy to keep them looking youthful and vibrant. He further contended that large segments of the medical profession failed to understand that need. He suggested that medical doctors needed to treat this “disease” with hormones to preserve women’s femininity and vitality.

The effect of Wilson’s book was such that it “set off a mania for long-term estrogen therapy for every woman.” Although studies in the 1960s failed to document the proclaimed benefits and the safety of hormones, the estrogen obsession did not stop. Estrogen appeared to be the fountain of youth, promising to slow ravages of time, and both women and their doctors embraced it enthusiastically. Wilson’s enthusiasm for keeping women looking young and feminine, by having them use estrogen, blinded him to its considerable risks. To gain its full benefits, women were supposed to take estrogen not only at menopause but for years or decades afterward to prevent heart disease and osteoporosis. Observational studies, however, showed that a prolonged use of this drug leads to serious side effects and, as we have already seen, increased risks of malignant illnesses.

Wilson’s book had a far-reaching impact. Thirty-five years after the publication of *Feminine Forever*, physicians routinely prescribe hormones to premenopausal and postmenopausal women. The prescription of synthetic hormone regimens such as estrogen alone, or a combination of estrogen and either progestin or micronized natural progesterone (which some call progestogen), was a routine practice because medical professionals assumed that those treatments serve as safe, necessary, and effective methods of preventing or managing health problems associated with menopause.

Not surprisingly, until recently there was a near-consensus regarding estrogen therapy for menopausal and postmenopausal women. Physicians had two words for these women: “take it.”

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55 Wilson, Feminine Forever 30.
56 Wilson, Feminine Forever 25.
57 Love, *Book* 133.
60 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 20.
61 Progestogen is a term that some writers use for a combination of natural progesterone and its synthetic form, progestin.
Recent studies, however, suggest a more intricate connection between “health, sickness, and hormones.” Some specialists argued that we simply do not know enough about the benefits and risks of hormone replacement therapy (HRT) to prescribe it so widely. For instance, there were more than forty studies in medical literature regarding HRT and its effects on the cardiovascular system, the most noteworthy being the Nurses’ Health Study. The preponderance of evidence indicated a 50% reduction in heart disease for women who took HRT compared to those who had not. The problem with these studies is that they have been limited, even though hundreds of women participated in them, because they have all been observational studies. As such they cannot resolve questions about the risks and benefits of HRT. This happens because researchers can only ask questions about women's habits. They cannot interfere with what they normally do.

Another problem with these studies is that they focused on white middle-class women residing in the United States and Western Europe. Consequently, their results may not be applicable to other women. The most that observational studies can do was provide researchers with clues. The randomized, placebo-controlled, double-blind clinical trials provide the proof.

Results from recent clinical trials focusing on HRT differ from those that observational studies produced. Additional results from large clinical trials to be released in five years may further change the medical establishment's “thinking about the optimal management for the menopausal woman.” I will discuss the studies regarding HRT prescriptions in the next section. But first let us take a closer look at the types of hormone treatments doctors prescribe.

The types of hormones physicians prescribed to correct certain bodily functions are usually synthetic. Some physicians promote natural hormones claiming that they have lesser side effects, if any at all. Both hormones are made in the laboratory but the determining factor for

62 Sasha Nemecek, “Hold the Hormones?” Scientific American 277.3 (September 1997): 38-41.
64 National Institutes of Health, “Therapy” 1.
65 Love, Book 65.
66 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best” 5.
67 National Institutes of Health, “Therapy” 5; National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best” 5.
68 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best” 5.
classifying hormones as natural or synthetic is their molecular structure. Natural hormones are chemically identical or bioidentical to the hormone molecules our bodies produce. The molecular structure distinction is important because some people could misuse the term natural to claim that something is natural when it is not. For instance, the makers of Premarin could claim that their product is natural since its composition is 48% estrone, an estrogen hormone that is natural to humans; however, 52% of it consists of several horse estrogens that are foreign to humans. In other words, they are not bioidentical with human hormones although they are natural horse’s hormones, and come from a natural product (from estrogens extracted from urine of pregnant mares).

Synthetic hormones, on the other hand, have a molecular structure that is similar to, but not identical to the hormones our bodies produce. This can mean that they act differently in the human body and produce considerably dissimilar effects from the effect of our bodies’ own hormones. A better name for synthetic hormones may be “similar” or not “bioidentical” because they are not native to human metabolism and are generally much more powerful and more toxic than natural hormones. Synthetic or similar estrogens, for example, can cause metabolic changes in the liver, which can lead to an increased number of such side effects as fluid retention, high blood pressure, and blood clots. Furthermore, because our bodies’ natural enzymes cannot easily break down synthetic hormones, they tend to accumulate in the body. If this is the case, the pertinent question is, why produce synthetic forms of drugs if bioidentical versions cause less harm and might offer the same benefits of their more toxic synthetic counterparts? The answer is economics.

Bioidentical hormones are not patentable so there is no motive for drug companies to conduct expensive research and development needed to produce new drugs containing them. Drug companies change the molecular structure of a hormone so that they can patent it. This new hormone has the effect of the natural hormone; however, any change to the three-dimensional structure of the hormone changes its effects on the cell in the way we cannot completely

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69 Balch, Prescription 385; Northrup, Wisdom 138.
71 Northrup, Wisdom 139.
72 Balch, Prescription 385.
understand. Drug manufacturers can also patent unique delivery systems and have utilized such systems in patches such as Climara, Estraderm, and Vivelle. They contain bioidentical estradiol, the most potent form of estrogen, and are profitable for its manufacturers. For the purposes of this paper I will use word natural or bioidentical to mean hormones that have the same molecular structure as those that our bodies produce. I will use word synthetic to mean hormones that have a molecular structure that is similar to our own hormones.

Empirical Basis for Prescribing HRT

A great number of studies showing new and unexpected benefits of estrogen in the 1960s stimulated medical exuberance for HRT treatment. In the 1970s a dramatic increase in endometrial cancer, cancer of the lining of the uterus, related to estrogen treatment lessened that enthusiasm until researches discovered that adding progestin to the estrogen mix protected the uterus from cancer. From then on routine prescription of HRT took hold. Not all women, however, shared their physicians’ excitement about HRT.

More than half of the women who do fill their HRT prescriptions quit taking the drugs within a year. Other data show that by the end of one year, only about half of the women who received the prescription for hormone therapy use hormones and that they do not like to use them for long periods. Most women who begin HRT therapy discontinue it by the end of the first or second year. Among the first time users of hormone therapy, 20% stopped using it within nine months; 10% have used it intermittently (whenever they remembered), and 20-30% never filled their prescription because they were not completely convinced of its benefits or safety.

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73 Northrup, Wisdom 141.
74 Northrup, Wisdom 141.
77 North American Menopause Society, "Continuance" 69-76.
Additional drug data showed that 100,000 women in the United States stop using HRT every month. Some claim that only 30% of the women who receive prescriptions from their physicians for HRT actually filled them. The main reasons for discontinuance included negative side effects such as weight gain, unscheduled uterine bleeding, mood changes, breast tenderness and bloating. Other reasons were lack of knowledge about why they were taking HRT and misinformation about its effects. Finally, clinicians' failure to listen and discuss women's concerns may explain why so many women did not fill their HRT prescriptions.

Not surprisingly, much of the medical literature was about the need to develop clearer guidelines about who should be taking estrogen and for how long. To fulfill this need the National Institutes of Health (NIH) has recruited more than 164,500 women of diverse socioeconomic and ethnic backgrounds to participate in the Women's Health Initiative (WHI), “a $628 million, 15-year project that is one of the most definitive, far-reaching clinical trials of women's health ever undertaken in the United States.” The NIH established the WHI in 1991 and plan to complete it in 2005. The study explores “how diet, hormone therapy, and calcium and vitamin D might prevent heart disease, breast and colorectal cancer, and osteoporosis. These chronic diseases are the major causes of death, disability, and frailty in older women.” The general goal of WHI is to identify ways to reduce coronary heart disease, breast and colorectal cancer, and osteoporosis among menopausal women through prevention/intervention strategies and risk factor identification. Many risk factors, defined as habits or characteristics of some people that makes them more likely to develop a disease, are controllable. The goal of the HRT component of WHI is to study cardiovascular disease, cancer, and osteoporosis among postmenopausal women by conducting nationwide randomized clinical trials compare hormonal therapy with a placebo. NIH designed this study is to provide women and their physicians with greatly needed additional evaluation of risks, as well as benefits, of hormone therapy. The WHI

79 North American Menopause Society, "Continuance" 69-76.
80 Love, Book xvi.
81 For instance, high expectations that treatment will immediately reduce hot flashes, sleep disturbances or relieve mental distress North American Menopause Society, "Continuance" 69-76.
82 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 8.
83 National Institutes of Health, "Therapy."
84 National Institutes of Health, "Therapy."
85 National Institutes of Health, "Therapy."
study design will avoid major criticism of the Nurses’ Health Study, namely that it only observed the habits of the select segment of the population, namely nurses, who are ordinarily healthier than the general population.\textsuperscript{86} The difference between these studies is that the WHI is a clinical trial type of study, a prospective randomized double-blind controlled study. It is the least flawed and consequently the most reliable.\textsuperscript{87}

The Nurses’ Health Study in Boston, Massachusetts, is a cohort or follow-up type of observational study where researchers simply observe, without interfering, what people normally do. This study began in 1976 and researchers have carefully followed the group of 121,700 nurses. The nurses fill out questioners every two years. The researchers periodically analyze various diseases or risk factors in this group. Given that the number of women in this group is very large, data that researchers obtain are powerful. The study, however, has limitations. The researchers cannot control women’s behavior in the sense that they cannot decide who takes hormones or who has a mammogram. They can only ask women questions about their study related health activities. Consequently, the study might include some women at risk for breast cancer who are not taking hormones or who have more frequent mammograms. These variables skew the results.\textsuperscript{88}

Until more long-term studies are completed such as the WHI study, the consensus regarding the use of HRT regimen, according to the NIH, has been the following: the short-term use of HRT to treat symptoms of menopause for the length of their duration, usually from several months to two years, benefits the majority of women with minimal or no risk. The long-term use of HRT has a questionable benefit, and women need to consider their risks for osteoporosis and cardiovascular disease before starting HRT regimens. Women have to evaluate the potential benefits for those diseases against the potential risk of breast, endometrial and ovarian cancer. Additionally, according to NIH, the contraindications for estrogen hormonal therapies are unexplained vaginal bleeding, chronically impaired liver functions, active liver disease, and blood clotting.\textsuperscript{89}

\textsuperscript{86} Nemecek, "Hold the Hormones?" 38-41.
\textsuperscript{87} Love, Book 67.
\textsuperscript{88} Love, Book 65.
\textsuperscript{89} National Institutes of Health, "Therapy" 5.
Women who were concerned about the risks of estrogen could choose from the variety of nonhormonal drugs to fight osteoporosis and heart disease. Clinicians like JoAnn E. Manson, one of the researches on the Nurses Health Study and main investigator of the WHI at Harvard, suggested that women who were concerned about heart disease could prevent it by paying attention to diet, exercising, not smoking, and controlling blood pressure. Francine Grodstein, one of the investigators in the Nurses’ Health Study, agreed. She suggested that “lifestyle changes ‘only have benefits’ for preventing heart disease, osteoporosis, and possibly breast cancer.” Grodstein claimed that “estrogen is one of many options, and women are recognizing that they have other choices.”

NAMS' Gallup survey of menopausal women conducted in 1997 and 1998 confirmed Grodstein's claim. Women may or may not have been using hormone therapy, but they viewed menopause as a positive experience and an opportunity to make the changes necessary to maintain or begin a health oriented life. The International Position Paper on Women's Health and Menopause issued similar recommendations regarding estrogen use.

Let us now take a closer look at the claims that hormone regimens served as safe and effective methods of hormone replacement therapy. Evaluating positive and negative effects of hormones will be helpful here.

Positive Effects of HRT

Estrogen, its proponents claimed, can preclude or retard the effects of aging, menopausal problems, heart disease, osteoporosis, mental deterioration, colon cancer, and aging skin. Consequently, in the middle of 1990s estrogen use was higher then ever. Gynecologists

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90 Francis Grodstein, M.D., co-author of the article published in the New England Journal of Medicine (NEJM) on the significant increase of risk of breast cancer among women who used estrogen for menopausal problems. Grodstein has also authored or co-authored numerous other medical articles.
91 Nemecek, "Hold the Hormones?" 38-41.
recognized that there were risks associated with estrogen therapy. They, however, tended to accentuate the benefits. For instance, William Andrews, M.D., previous president of the American College of Obstetrics and Gynecology, claimed that eight times as many women died of heart attacks as of breast cancer. To address concerns about cancer physicians claimed that reducing the dosages used in HRT diminished risks of cancer. They also claimed that adding synthetic progesterone (progestin) to the estrogen prescription can virtually eliminate the risk of uterine cancer.

The oldest and most common use of HRT was to relieve hot flashes, nights sweats, vaginal dryness, and other symptoms that usually occur around menopause when ovaries produce declining amounts of estrogen. Other claims about benefits of HRT were about more serious health problems. First, HRT could reduce the risk of heart disease. Several studies, including the famous Nurses’ Health Study that followed 120,700 nurses for more than 10 years, established that postmenopausal women on estrogen have about 50% less incidence of heart disease than those who do not take hormones. Also, HRT appeared to improve a woman’s ratio of beneficial cholesterol (HDL) to harmful cholesterol (LDL) and also to maintain the flexibility of the blood vessels, reducing the risk of blockage.

Second, HRT, namely estrogen therapy, was supposedly the most effective way of preventing osteoporosis that makes older women susceptible to bone fractures. Studies have shown that estrogen lessened the risk of hip fractures up to 50% if treatment began at menopause. New evidence suggested that this was true even if women started using estrogen at age 70 or older. Third, several small trials indicated that estrogen improved memory for postmenopausal women. Also, a tantalizing 1993 study established that HRT enhanced the mental operation of women with mild to moderate symptoms of Alzheimer’s disease. Fourth, a large study, completed in April 1995, found that estrogen users had a 29% reduced risk of dying from colon cancer than nonusers. For women on estrogen more than 10 years, the risk was 55%.

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94 Wallis, "The Estrogen Dilemma" 48.  
95 Wallis, "The Estrogen Dilemma" 48.  
96 Wallis, "The Estrogen Dilemma" 46-53.
lower. Finally, HRT seemed to help maintain skin elasticity because it helped maintain collagen level that keeps the skin appearing moist and plump.97

Given all the above benefits, doctors were, perhaps unsurprisingly, handing out estrogen prescriptions with “almost gleeful enthusiasm.” This is evident from Food and Drug Administration data which show that estrogen prescriptions in the United States more than doubled between 1982 and 1992.98 And while gynecologists admit that there were risks to HRT therapy, they believed that the benefits outweighed them.

Negative Effects of HRT

Several negative effects accompanied the use of hormone replacement therapy. First, hormone therapy, especially without the use of progestin (the synthetic form of natural progesterone), increases the risk of cancer of the uterus. Second, hormone therapy possibly increased the risk of breast cancer; long-term use could pose the greatest risk. With The New England Journal of Medicine report issued on June 15, 1995, and more recent reports, hope faded that progestin would provide estrogen users protection against breast cancer, as it did in uterine cancer. In reality, it appeared that the combined hormones may place women at higher risk for breast cancer than estrogen alone.99 Third, an alarming report issued in May 1995 suggested that the long-term use of estrogen increased the risk of fatal ovarian cancer. A recent JAMA report dated March 21, 2001, confirmed that women who took estrogen for 10 years after menopause were two times as likely to die of ovarian cancer as those who did not.100 Fourth, hormone replacement could have unpleasant side effects, such as bloating or irritability. Finally, hormone therapy could be dangerous to women already at risk of blood clots.101 The latest information is that hormone replacement therapy increased the risk of heart disease in women who already have

97 Wallis, "The Estrogen Dilemma" 46-53.
a heart disease by 50% in the first year of treatment and showed no benefit from four years of hormone treatment. Additionally, another study, a part of Women's Health Initiative, found that women who at the beginning of the study did not have heart disease had a slight increase in heart attacks, strokes, and blood clots in the lungs after three years of use of hormone treatment.102

Despite these serious negative effects of hormone replacement, millions of women received prescriptions for them from their physicians. New guidelines may change the way clinicians prescribe hormone therapy. Besides the medical profession's view of menopause as a disease, other factors may have contributed to the place of hormone therapy as a preferred treatment for menopausal women.

Profits and Menopause

From an economic standpoint, menopause represents a gold mine for hormone drug manufacturers. In 1997 some estimates show that about 30 million women in the United States were postmenopausal and approximately 10-11 million were on hormone replacement therapy or HRT.103 Most HRT users (7.5-9 million) are on Premarin, a brand name for conjugated estrogens made from the urine of pregnant horses. It was the most widely-prescribed medicine in the United States in 1996.104 If strong and rapidly growing sales indicate a trend, Premarin will continue to hold the primary position as the most often-prescribed hormonal drug. Premarin sales were $865 million in 1996, up 57% from 1992.105 Worldwide sales were more than 1 billion, up 60% since 1992.106 Hormone replacement medication sales reached $1.7 billion in 2000 and about two thirds of it was in Premarin.107 In 2001 American women spent $2.75 billion on

101 Northrup, Wisdom 145-50.
102 Grady, "Scientists."
105 Ingersoll, "Generics" B6.
106 Ingersoll, "Generics" B6.
Premarin, “making it the third most commonly prescribed drug in the United States last year, with more than 45 million prescriptions dispensed.”\(^{108}\) In 2000, the estimate for the number of women over 50 years old in the United States is 41.75 million and about 31.2 million are over 55 (compared with 28.7 million in 1990).\(^{109}\) The number of women over 55 in the United States is estimated to be 45.9 million in 2020. The projected number of Canadian women age 50 and older in 2000 was 4 million or 15% of the Canadian population. On the global scale there are over 470 million 50 or older and 30% live to age 80.\(^{110}\)

The above figures are significant because the average age of *natural (spontaneous) menopause (not premature)* for women in the Western world is about 51 years. Life expectancy of a woman is predicted at 79.7 years. Currently, a woman who lives to age 54 can expect to live 84.3 years. About two thirds of the total United States population will live to age 85 or more, and most women spend one third to one half of their lives in post menopause. In the year 2000 the rough estimate of the number of the women in United States reaching menopause is 1,328,000 natural and 481,000 surgical menopause, totaling 1,809,000 plus or over 4,900 per day.\(^{111}\) The National Institutes of Health issued a news report in 1997 stating that about 75% of all women experience some adverse symptoms surrounding menopause, possibly because of the loss of hormone estrogen and its beneficial effects.\(^{112}\)

This fact represents a huge market for manufacturers of hormone products, notably for Wyeth,\(^{113}\) whose drug Premarin is, according to several reports, the world’s biggest selling estrogen product.\(^{114}\) The drug companies' incentive to promote and market HRT for short-term and, especially, long-term use in order to create profits seems to be beyond doubt. The goals of drug companies, however, often do not serve those women whose need for hormone replacement was questionable. Clinicians often follow drug companies' recommendations and, without regard

\(^{108}\) Grady, "Scientists."


\(^{110}\) North American Menopause Society, "Statistical."

\(^{111}\) North American Menopause Society, "Statistical."

\(^{112}\) National Institutes of Health, "Therapy" 5.

\(^{113}\) Formerly the American Home Products Corporation

for actual individual need, prescribe those drugs to all postmenopausal women as a preventive measure. Drug companies often funded the studies that afterwards issued guidelines for physicians. By treating menopause as disease, the medical profession may have violated the rights of women who relied on their physicians' recommendations to treat the symptoms with synthetic hormones. Approaching menopause as a disease, may have had a deleterious effect on health of millions of women who took these hormones. Menopause is a natural stage in every woman's life; declaring that menopause is a disease, whatever the motivation, was a mistake. Routine prescription, without solid research to support it, a consequence of the zeal and profit motives of drug companies, was another mistake. Those errors violated women's rights, especially the right to informed consent. Most medical practitioners seem to have followed the guidelines of their peers, drug companies, and professional associations regarding hormone therapy prescription and treatment. In doing so they adhered to the professional standard of information disclosure about the risks and benefits of hormonal therapy. By using a relaxed standard of evidence and medical judgment, the profession showed deficient respect for patients' autonomy and it may have caused needless fear and harm to unknown number of women.

In the next chapter I will address the general problems and the limits of informed consent in practice. I will also analyze the routine prescription of HRT regimens to menopausal women in terms of the tenets of informed consent.

Chapter 5

The Problems and the Limits of Informed Consent in Practice

Legal theorists and most bioethicists agree that informed consent of competent patients is ethically necessary, which implies that they have sufficiently explained the nature of informed consent. Some object to this notion, arguing that law and ethics achieved neither closure nor adequate explanation of informed consent.¹ Although ethical necessity is obvious to proponents of informed consent, those who have to provide it in practice, such as practicing clinicians, are at most halfhearted about it. Moreover, even those clinicians who are committed to informed consent are unclear about how to use it at bedside. Many clinicians question the need for it in the therapeutic setting. They also question its underlying assumptions such as that "the most competent patients are ready, willing and able to ‘participate in medical decision making,’ as the proponents of informed consent claim."² Consequently, regardless of lawyers’ and bioethicists’ position that the right to informed consent is beyond doubt, clinicians remain not only unconvinced but, more critically, uncommitted to it. Additionally, a substantial number of clinicians view the idea of informed consent as a myth.³

Informed Consent and the Physician-Patient Relationship

Clinicians' skepticism about informed consent is troubling given that informed consent is the most profound and far-reaching issue in medical ethics in the last three decades. Its purpose is to give power to patients who have traditionally not spoken and have been powerless in the

¹ Wear, Consent 2.
² Wear, Consent 2.
³ Wear, Consent 2.
light of medical proficiency and authority. Informed consent places obligations on health care providers to supply information to patients so that they can form their own views and make decisions concerning the nature of their health care. Informed consent also gives power to patients to implement their decisions, a power or right to reject medical treatment. Consequently, some view informed consent as the cutting edge of the patient-autonomy movement. The proponents of the “autonomy-based medical ethics” advocate a general restructuring of the model of every interaction between patients and physicians. Some ethicists claim that a “cogent and clinically effective tool for respecting and enhancing patient autonomy” is not available. Consequently, physicians view patients' refusal of medical treatment with suspicion and are uncommitted to providing effective services, which makes respect for patient autonomy an empty notion and the improvements are lacking. Under these circumstances, patients' autonomy is simply a formality.

Some proponents of the respect for autonomy play the trump card that offers a reductionistic view of autonomy, i.e., that we must be free to choose or that we must have freedom from interference. This definition is based on the idea that we live in a free society and wish to have certain freedoms for ourselves and others. According to this view, all people are competent, able and free to manage their own lives and affairs in most areas of their life. Aside from few exceptions, “our freedom ensures that we can pursue our lives in terms of our own values, beliefs, and experiences, regardless of how clear or cloudy these are to us, and without concern as to whether others concur with our agenda, or see us as making foolish, stupid, or tragic choices.” Also, our rights such as the right to control our lives and the right to be left alone protect us from external intrusions and interference. This view suggests that our competence necessarily has a low threshold level, which everyone can easily reach. The law suggests that we should assume that all adults are competent and that those who question competence of others carry the burden of proof, which can only be severe mental incapacity or

4 Katz, Silent.
5 Wear, Consent 3.
6 Wear, Consent 39. This is a view of the principle of respect for autonomy that Beauchamp and Childress identified as a negative obligation.
7 Wear, Consent 39.
dysfunction. This view of autonomy is narrow and impoverished, and it makes autonomy the absolute principle. The respect for autonomy, as we saw earlier, is one among other principles of morality.

One of the main threats to autonomy, which makes informed consent in health care a necessity, is people's illness, or “wounded humanity,” as some call it. An onset of illness (e.g., cancer) may threaten their very existence. Other basic accompanying factors of illness, such as fear, stress, and confusion, and also “the effects of the pathology (e.g., discomfort and the distraction attendant upon it), and the treatment (e.g., drugs),” cause a childlike regression. Chronic illness in particular, causes loss of personal control, resulting mainly from pathology and requires as much therapeutic response as profuse bleeding. In these situations informed consent could play a crucial role “in addressing such regression and the functional loss of freedom it entails.” Consequently, patients may want reassurance rather than “the decision making authority.” Informed consent would remind them that risks are involved and that someone will have to make decisions. Physicians may feel a need to refuse the beneficence-seeking conduct from their patients because they may want to prevent the childlike regression that patients might be experiencing, or because the choice in question is so significant that only the patients can address it. Informed consent, then, can help restore the sense of freedom and self-determination that illness so often diminishes. An equally important role of informed consent may be to protect patients from their “own inclinations in a vulnerable and exhausting situation.”

A deep division between the proponents and opponents of informed consent is at least partly responsible for the ineffective application of informed consent in a therapeutic setting. Physician Jay Katz, a proponent of informed consent, describes interactions between doctors and patients as the “silent world” that challenges some of the most basic beliefs of free society. He claims that freedom and personal control of one's life are not possible in a field where others

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8 Wear, Consent 40.
10 Wear, Consent 42.
11 Wear, Consent 42.
12 Wear, Consent 42.
systematically hold knowledge and power. Opponents of informed consent argue that patient-autonomy movement has made inroads among the healthy and educated but that ill people still seek physicians' expertise and reassurance, not knowledge and power. The sick, they claim, still want physicians to cure their ills and reassure them, not to educate them and force them to make decisions about health matters about which they know very little.

Both the proponents and opponents make valid points about informed consent, e.g., the preservation of values and the ineffectiveness of the doctrine in practice respectively. Although the proponents of informed consent have proposed a doctrine that is frequently too theoretical and unconcerned with effective practical application they have nevertheless provided a solid basis for the need for informed consent, i.e., the loss of too many values. Its opponents are sometimes too harsh and go too far, but their criticisms that “the doctrine of informed consent (is) unrealistic, ineffective, and in effect, unintelligible are often forceful and cogent, and merit a detailed reply.” Assuming the premise that there is a solid foundation for informed consent, while concuring that law and ethics have not adequately developed the doctrine to make it acceptable in practice, it is difficult to see how informed consent would be a myth. To combat clinicians’ skepticism and to make informed consent workable in practice, some ethicists call for "a cogent, clinically realistic model of informed consent." Some physicians, e.g., Howard Brody, proposed such model, a “transparency model.” This model avoids content-filled informed consent in favor of physicians' making clear to the patients the reasons for the treatments they recommend. In such presentation physicians might mention a number of risks, and possibly the alternative treatments, not for the wider purpose of the informed consent, but to clarify the significant factors in physicians' decision making process. Brody believes that the advantages of his model are substantial. First, physicians are to arrange only “the typical patient-management thought process” and convey it to patients in a language they can understand. Second, the

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13 Katz, Silent 3.
14 Wear, Consent 3.
15 Wear, Consent 3.
16 Wear, Consent 3.
17 Wear, Consent 4.
18 Wear, Consent 2-4.
transparency model of informed consent has specific standards regarding what is involved and when the process is sufficiently completed. Third, the transparency model helps physicians avoid hyper-informing the patients about the proposed medical treatment or about their medical condition. Instead they offer a specific communication of the essential components and pertinent issues.\textsuperscript{20} There are several drawbacks of this model but some think that physicians can easily implement the missing aspects into the model, e.g., mentioning the risks that physicians view as routine and inconsequential.\textsuperscript{21}

Another problem with clinical medicine has been that physicians and patients are moral strangers who often do not share the same values and beliefs and do not understand each others' moral views.\textsuperscript{22} Although the past image of physicians depicts them as wise and beneficent, worthy of their patients' trust, respect and adoration, this image has given way to a quite different, jaundiced vision. First, given that medicine, as well as society, have a pluralistic character, people hold fundamentally different views about the notion of good life and how to go about pursuing it and sustaining it. Second, physicians and patients are not likely to understand each others' moral views because patients are essentially strangers in “a strange land,” and because they are not aware of “the special expectations and agendas of (their) caregivers.”\textsuperscript{23} On the other hand, physicians are caught up in what some call “the evolved and idiosyncratic cult of medicine, a cult that remains largely isolated and unresponsive to the culture around it, and gives very little status to the patient's perspective within clinical decision making.”\textsuperscript{24} In this context physicians' old thinking that “M.D.” means “make decisions” is still present in medicine. Such an ingrained attitude is not likely to allow for understanding of, or the congruency with, patients' values and beliefs because it basically maintains the paternalistic view that people dislike.\textsuperscript{25} Consequently, “a deep core of distrust has developed regarding the intentions and capabilities of the medical profession.”\textsuperscript{26}

\begin{itemize}
\item \textsuperscript{20} Brody, "Transparency" 5-9.
\item \textsuperscript{21} Wear, Consent 118.
\item \textsuperscript{23} Engelhardt, Foundations 256; Wear, Consent 36.
\item \textsuperscript{24} Robert M. Veatch, "Medical Ethics: Professional of Universal," Harvard Theological Review 65 (1972): 531-59.
\item \textsuperscript{25} Wear, Consent 36.
\item \textsuperscript{26} Wear, Consent 36.
\end{itemize}
To what extent this view dominates among proponents of patient autonomy is unclear, although it is present in the writings of well-known thinkers such as Robert Burt, H. Tristram Engelhardt, Jay Katz, and Robert Veatch. Because Katz and Engelhardt are also physicians, their claims and those of students of medical ethics add additional credibility to the charge that “a deep level of distrust has developed regarding the intention and capabilities of the medical profession.”

Early concerns about patient autonomy had a negative basis in the sense that the medical profession posed “profound threats to both patient freedom and well-being.”

Biomedical research provided a strong basis for such concern starting with the trial of Nazi doctors and continuing with medical community's own concern that biomedical research community became too ardent about in its dealings with research volunteers. The medical community provided research subjects with little or no informed consent about risky and often non-therapeutic interventions. Additionally, biomedical research often focused on the most vulnerable and the least free segments of society such as institutionalized patients in prisons, mental hospitals, the developmentally disabled and the old.

Biomedical research posed a special problem for the medical profession because researchers abandoned the traditional governing principle of physicians' primary responsibility “to the protection and promotion of patients' best interests, regardless of the impact of doing so on other considerations, such as the advancement of medical knowledge.” Given that the goal of medical research is to benefit the current patient-subject but also future patients, those physicians brought conflicting interests and agendas to the physician-patient relationship. In some instances, the emphasis shifted too far away from research subjects, notably in the Tuskegee and Willowbrook experiments where, respectively, clinicians purposely did not treat 400 southern black men with syphilis, and also purposely infected developmentally disabled patients with hepatitis, so that they could study the natural progression of the disease. Although protests against this kind of research originated from different fields, the medical profession itself seemed to acknowledge the dangers and inappropriateness of such conduct, and a directive

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27 Wear, Consent 36.
28 Wear, Consent 30.
29 Wear, Consent 31.
30 Wear, Consent 31.
for informed consent in the research environment developed gradually. Institutional review
toards also became a reality at the same time. These adjustments, however, did not stop growth
of residual distrust that physicians might use patients as experimental subjects.31

Extraordinary, life-threatening cases also created a feeling of distrust in physicians and
thus influenced the development of the patient-autonomy movement.32 Those cases are set in big,
urban hospitals and focus on conflicts between patients and physicians in extraordinary life-
threatening situations. Some examples include cases of patients with severe burns or spinal-cord
injuries whom clinicians sedated or ignored because they refused aggressive treatment that
would save lives but which the patients did not consider worth living.

Other cases include competent patients whose lives physicians prolong in “inhumane”
ways, particularly in intensive care, rather than let them “die with dignity.” Such cases are well
documented in the movies “Please Let Me Die” depicting severely burned Donald Cowart, and
in “Whose Life is it Anyway” with Richard Dreyfus playing a quadriplegic. Those cases provide
fuel for moral indignation. Both patients are competent and articulate and demand an end to their
awful and hopeless situations. Physicians appear aloof and arrogant, refusing to honor wishes of
their patients by drugging them, denying their competence, and handling them as ignorant,
 hysterical children.33

In addition to insights regarding medical experiments and extraordinary cases, there is a
routine mistrust in social institutions and in the ability of the sciences to produce adequate moral
sensitivity and insight to keep up with the rapid expansion of knowledge and technical
capability, placing the interest and freedom of citizens at risk.34 Although this vision of distrust
of medical field has a factual base, it is important to mention that many clinicians embrace the
idea of patient autonomy. Still, the assembly-line character of modern medicine does not bode
well for improving physician-patient relationship. Hospital care and treatment are divided among
loosely coordinated teams and shifts with no one person directly in charge of the individual
patient care. When someone is in charge, it is often an overworked resident providing a variety

31 Wear, Consent 31.
32 Wear, Consent 31.
33 Wear, Consent 32.
34 Wear, Consent 36.
of services, or it is a tightly scheduled community physician who checks on his patients in a
grueling daily run from hospital to clinic to private office. Another situation is that many hospital
patients do not have personal physicians and resident physicians treat them without knowing
anything about their background. These physicians often hesitate to initiate personal
relationships or to inquire about patients' fears, needs, and wishes because they will not have the
chance to pursue these to any meaningful level.\textsuperscript{35}

Because resident physicians' workweek is sometimes 120 hours, in shifts 36 hours long, it
is unlikely that they have the resources for anything more than to provide minimal care to
patients.\textsuperscript{36} The Accreditation Council for Graduate Medical Education will impose strict new
rules limiting resident physicians weekly hours to 80 because of the mounting evidence that 120
work weeks are detrimental to young resident physicians and to their patients. Medical residency
lasts three to eight years and the medical profession has viewed long hours as just one more
component of new physicians' education. The intense schedule is supposed to prepare physicians
for their careers, which often necessitate that they make decisions when they are exhausted. This
practice has attracted the attention of the United States Congress, which is pressing for
legislation mandating shorter hours for medical residents. In March 2002, the University of
Washington released the results of the largest survey of medical residents, which found that 75%
of residents “felt burned out and about one-third believed that they occasionally delivered
substandard care because of exhaustion.”\textsuperscript{37} Other studies showed that residents have increased
rates of depression, car accidents, and obstetric complications. Another study showed “that a
resident who stayed up for 24 straight hours had the motor skills of someone with a blood
alcohol content of .10, well above the legal limit for driving.”\textsuperscript{38} Teaching hospitals where
residents receive their training often serve more poor and minority patients, which raises
questions about the quality of care they receive.\textsuperscript{39}

\textsuperscript{35} Wear, Consent 37.
\textsuperscript{36} Ceci Connolly, "Shorter Hours Mandated for Young Doctors," \textit{Washington Post} [Washington] June 13,
\textsuperscript{37} Connolly, "Doctors" A01.
\textsuperscript{38} Connolly, "Doctors" A01.
\textsuperscript{39} Connolly, "Doctors" A01.
Similarly, because of the time constraints and stresses that lead to burnout and the nature of health care, private physicians do not address the psychosocial needs of their patients. The arrival of managed care in the early 1990s has dramatically decreased the number of Americans receiving optimal health care. Optimal care means that people have a well-trained primary care physician of choice who provides continuous primary and preventive care. They also have access to specialists and hospitals they chose or that their primary care physician recommends, and they have “a ready access to all available diagnostic and therapeutic procedures, including newer medicines that may be very expensive.” It is true that “Some Americans still have access to this optimal type of health care with minimal out-of-pocket expense,” but most do not. Escalating costs of this fee-for-service model of health care motivated employers and employees to look for less expensive alternatives such as managed care, which initially stopped the escalation of health care cost. It did so by reducing the portion of the health insurance premium that goes for health care. The rest of the premium pays for administrative costs and creates profits for the managed care organization. Managed care organizations reduced payments to physicians, hospitals and other health care providers, reduced services by limiting patients' access to specialists as well as to expensive tests, treatments, and medicines. Although this reduction of costs lessened the rate of increase in health care premiums, which benefitted those who pay premiums, it did not lead to a decrease in premiums. Managed care organizations kept the profits to benefit stockholders and rewarded their executives with increased salaries and bonuses. For instance, U.S. Healthcare chief, Leonard Abramson, was to receive a $1 billion dollar bonus in 1996, after Aetna Life and Casualty Company merged with U.S. Healthcare. After the merger, Abramson role was to be that of a consultant to Aetna for five years with compensation of $10 million per year. In contrast, the number of uninsured Americans has grown to 43 million in the same years and “millions

40 Wear, Consent 39.
42 Dalen, "Health Care" 2573.
43 Dalen, "Health Care" 2573.
44 Dalen, "Health Care" 2574.
more are underinsured,” which suggests that insurance companies may not be using profits to increase coverage or to reduce the number of uninsured.  

Some physicians argue that managed or for-profit care has had a deleterious effect on both patients and physicians and the nature of physician-patient relationship. For patients, managed care seriously jeopardizes continuity of care. Because the quality of care is difficult to judge, consumers base the choice of managed care entirely on price. Consequently, employers and employees often switch to the lowest-cost plan, which means that patients go through a succession of primary care physicians. An additional effect is that contract terms change and physicians may drop certain plans, or the plan may drop them if it deems their practice patterns expensive. Moreover, primary care physicians' ability to refer patients to specialist or hospital depends on the plan's contract with specific specialists or hospitals. Finally, patients' access to diagnostic and therapeutic services as well as to some expensive medicines, is limited because the plan, not the patients' physicians may determine the need.

Physicians, on the other hand, are in the middle because they must do what is best for the patients without transgressing the managed care plan. Certain plans limit physicians' income when they prescribe expensive treatments and medicines. Also, physicians have lost the ability to direct their patients' care because the managed care plan approves every medical decision, prospectively and retrospectively. Continuous decreases in income force physicians to see an increased number of patients to maintain their income, leading to a decrease in time they can spend with any single patient. Less time with patients greatly increases the probability of mistakes in diagnosis and treatment. Consequently, both physicians' and patients' satisfaction also decreases.

Some argue that significant improvements have occurred in the patient-physician relationship. As Katz, however, counters, there are two main problems with this argument: (1) a meaningful cooperation between patients and physicians is unlikely to happen until physicians learn to treat patients as adults rather than children; until they learn how to differentiate between their ideas of what is the best treatment from those of their patients; and also until they learn

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46 Dalen, "Health Care" 2574-5.
47 Dalen, "Health Care" 2574.
“how to acknowledge to their patients (and often to themselves as well) their ignorance about
diagnosis, treatment, and prognosis.” (2) Medical educators have not prepared future physicians
for the responsibilities of involving the patients in the decision making. Katz claims that
physicians’ education in technical competence is remarkably high; their competence in shared
decision making is not. Medical educators, therefore need to be aware that learning how to talk
with patients is as difficult as “learning about diseases, their patho-physiology, diagnosis, and
treatment.” And as Franz Kafka commented, “to prescribe pills is easy but to reach an
understanding with people is very hard.”

To those who claim that physicians lack time to attend to psychosocial need of patients,
Katz says that time cost is not serious an impediment or the real reason. The high cost of
surgical intervention, for instance, provides surgeons with adequate compensation for taking the
time to make sure that patients understand them and the treatment they are recommending. The
real problem is the unfamiliarity with how to talk to patients, unwillingness to talk,
“embarrassment about admitting ignorance and uncertainty, and loss of income.” If time costs
prove relevant, then physicians must recognize that those costs undermine disclosure and
consent. Physicians then must try to identify those procedures that have high risk of morbidities
and mortalities, for which full disclosure becomes crucial to honor good patient care.

Some primary care physicians claim that although every physician's time is limited,
physicians can still address patients' psychosocial needs, as well as medical conditions, when
trust is an integral part of their relationship. Observation of highly experienced physicians
shows that they do not follow standard interviewing skills. They focus chiefly on patients'
complaints or symptoms and at times interrupt them to ask specific questions early in the
interviews. At certain times these physicians recognized clues, such as emotion in patients' tone
of voice, or posture, which suggest a concern that patients might want to express. Physicians then

48 Dalen, "Health Care" 2575.
49 Katz, Silent xi.
50 Katz, Silent xi.
51 Katz, Silent xi.
52 Katz, Silent xii.
53 Katz, Silent xii.
54 William T. Branch, "Is the Therapeutic Nature of the Patient-Physician Relationship Being Undermined,"
use basic interviewing skills by asking simple, open-ended questions, such as, “What is going on?” with gentleness and softness that encourages patients to talk. After the second follow-up question, patients usually express their concerns and physicians listen intently for several minutes. These brief but quick changes of pace in the interviews with patients help physicians establish their relationships with patients by dealing with their psychological and social concerns. Although most of the patient-physician routine interactions lasted a few minutes, some were 30-40 minutes long. The flexibility in the amount of time physicians spend with patients is a key factor in addressing their psychosocial as well as their physiological needs. There is a threat to this flexible element of physicians' practice and thus to the trust element of the patient-physician relationship, however, because there is push for physicians to meet industry standards by seeing a set number of patients a day. 55

To cultivate trusting relationships with their patients, physicians must address their psychosocial as well as their physical problems because they are inextricably intertwined. 56 Until recently, physicians had an inherent advantage because patients usually expected that they can trust their physicians. Trust, however, develops through a series of interactions where parties demonstrate “trustworthiness” to each other. To gain their patients' trust, physicians must show they care (as demonstrated above), that they have integrity (by keeping promises), and that they are willing to serve as patients' advocates and advisors. Patients need a physician they can trust when they need to make important decisions. If they become seriously ill, they may have to make a choice between surgical or medical therapy, whether to follow specialists' advice or seek a second opinion, or make other decisions that may seriously change their lives. To trust their physicians' advice, patients must believe that their physician is reliable, understanding, and honest. 57

Given the above challenges, clinical medicine now appears to be practiced mainly between strangers who often do not share the same values, with little time to share them, thus putting in jeopardy the therapeutic nature of the patient-physician relationship. Patient autonomy and informed consent are thus not only antidotes to skeptical, busy, physicians, but some

55 Branch, "Therapeutic" 2258.
56 Branch, "Therapeutic" 2258.
ethicists see them as “absolute necessities because no one can speak for patient except the patient.”\(^{58}\) The above and additional problems are apparent in the decades long practice of routine prescription of hormone replacement therapies to menopausal women.

**Informed Consent and HRT Regimens**

Routine prescription of hormone regimens for menopausal problems has been problematic in many ways, but some are most troublesome: (1) physicians' recommendations were not appropriate, (2) clinicians' enthusiasm for technology prevailed over consideration for serious risks, (3) clinicians treated menopause problems as ordinary medical problems that did not require patients' consent, and (4) clinicians relied on the prevailing medical judgment, not the prevailing factual evidence to justify the practice. I will explore these problems in the context of the larger problems of implementation of the three principles of informed consent: disclosure, understanding and voluntariness.

**Insufficient Disclosure**

In relation to the criterion of disclosure, I argue that while routinely prescribing HRT to menopausal women, physicians provided insufficient disclosure because physicians minimized serious risks regarding HRT use such as increased risk of endometrial and breast cancer. The medical community guidelines, such as those of the American College of Physicians and the attitude of the clinicians regarding hormone therapy, has been that every woman should take hormones to prevent serious diseases such as osteoporosis and heart disease. Clinicians recommended hormone therapy without relying on any substantive factual evidence from long-term studies utilizing randomized clinical trials to gather such evidence. Instead they relied on observational studies, which are not dependable in providing the proof that something works.

\(^{57}\) Branch, "Therapeutic" 2258.
Because the purpose of disclosure is to insure that patients have sufficient information for making decisions regarding medical treatment, clinicians' failure to disclose the lack of certain substantive factual evidence was not justified. In other words, because no solid factual evidence exists for the claim that HRT regimens would prevent certain diseases, physicians' recommendation to patients to use those regimens for such purposes, was inappropriate. It appears that physicians used the professional practice standard of disclosure, which allows the medical community to determine the standard of disclosure, and proposes that the proper role of the physician is to act in the best interest of the patient. Under this standard, the medical community determines what type of information, as well as the quantity of information, clinicians should disclose to the patient. The professional standard of disclosure, along with the reasonable person standard, is sufficient to start conversations with patients but it fails to address their individual needs or their level of understanding about a medical treatment or procedure.

In order to help patients gain an adequate level of understanding about their health condition, physicians need to open a dialogue with patients and help them feel powerful. According to Brody, physicians can reach this goal “neither by reflexively disclosing nor by reflexively withholding any particular sort of information.” They most effectively help patients by asking them to participate and talk, by carefully listening for the clues that patients provide as the conversation develops. The most helpful action is to assist patients to position the new information “in the context of the patient's life experience and life story in the most meaningful, encouraging, and health-promoting way.”

In the case of routine prescription of hormonal therapies, clinicians erred in failing to disclose the lack of good evidence to support their opinion that women should use hormone therapies to prevent diseases they may or may not get. By failing to disclose this critical information, clinicians' undermined patients' autonomous choice and failed to fulfill their positive obligation to involve their patients, to disclose information, to explore and ensure their understanding and free choice, and to encourage proper decision making. Women have a right to all the relevant information about medical treatment because they are the ones who will suffer or

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58 Wear, Consent 37.
59 Brody, Power 136.
benefit from the consequences of treatment and, therefore, the ones who should make decisions for or against a medical regimen. If physicians presented HRT as one of the treatments for their menopause related symptoms such as insomnia, night sweating, and hot flashes, women might have chosen an alternative treatment to HRT. For instance, they might have chosen to adopt healthier life habits by avoiding alcohol beverages, reducing caffeine intake, or avoiding spicy food and beverages, all effective in reducing hot flushes and night sweats. To prevent osteoporosis women could have chosen one of the nonhormonal drugs, raloxifene, or they might have chosen no treatment at all. Physicians, therefore, needed to utilize the moral rule of veracity or truthfulness when disclosing relevant information to their patients rather then to rely on their medical opinions or to simply follow along the recommended guidelines.

The moral rule of veracity, along with other rules, such as privacy, confidentiality, and fidelity, apply to medical professionals or researchers and their patients or research subjects. Some of the rules denote only one principle, e.g., respect for autonomy, while others denote more than one. The traditional code of ethics and current literature show considerable uncertainties and vagueness about “the nature and status of norms and virtues of veracity.” There has been disagreement whether veracity is “an absolute and independent obligation, or a special application of some higher principle.” Some philosophers think that veracity is an independent principle, as important as the principles of beneficence, nonmaleficence, and justice. The best way to understand obligations of veracity is to view them as specifications of several principles. Conscientiously following these specifications is crucial for strong physician-patient relationship.

The code of medical ethics, however, “traditionally ignored obligations and virtues of veracity.” Neither the Hippocratic Oath nor the Declaration of Geneva of the World Medical Association recommends veracity. The Principles of Medical Ethics of the American Medical

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60 Brody, Power 136.
61 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 9.
62 Beauchamp, Principles 284.
65 Beauchamp, Principles 284.
66 Beauchamp, Principles 283.
Association (AMA) never mentioned an obligation of virtue of veracity until 1980, thus allowing physicians “unrestricted discretion about what to divulge to patients.”67 In the 1980 revision of its principles, the AMA recommends, without explanation, that physicians “deal honestly with patients and colleagues.”68 This traditional indifference to veracity in medical ethics is peculiar because, “virtues of candor, honesty, and truthfulness are among the most widely praised character traits of health professionals and researchers in contemporary biomedical ethics.”69

In the medical profession veracity pertains to “comprehensive, accurate, and objective transmission of information, as well as to the way the professional fosters the patient's or subject's understanding.”70 Three arguments justify the obligations for veracity. First, the obligation of veracity relies on the idea of respect for others. The respect for autonomy provides the primary foundation for justification for the rules of consent and disclosure. The obligation of veracity holds even when consent is not at issue because it utilizes the principle of respect for others. Second, the obligation of truthfulness is closely connected to obligations of promise keeping and fidelity.71 In our communications with others, we implicitly promise to tell the truth and to avoid deceiving them. In a therapeutic setting, “the patient or subject enters into a contract or covenant that includes a right to the truth regarding diagnosis, prognosis, procedures, and the like, just as the professional gains a right to truthful disclosure from patients and subjects.”72 Finally, “relationships between health care professionals and their patients and between researchers and their subjects ultimately depend on trust, and adherence to rules of veracity is essential to foster trust.”73 In the case of menopause therapy clinicians did not utilize the principle of veracity because they provided insufficient disclosure of information regarding the risks of hormone therapy. They failed to disclose the lack of solid evidence that HRT prevents

67 Beauchamp, Principles 283.
69 Beauchamp, Principles 283.
70 Beauchamp, Principles 284.
72 Beauchamp, Principles 284.
73 Beauchamp, Principles 284.
certain diseases and that its use exposed them to the risk of other potentially more harmful diseases.

Some might object that the argument (that while routinely prescribing HRT, physicians provided insufficient disclosure of risks of HRT), that women needed HRT whether or not physicians gave full disclosure of information. In other words, clinicians might have reasoned that it was better to help women who required immediate relief from severe (menopausal) discomfort (insomnia, night sweating, hot flashes) and to prevent heart disease and osteoporosis than to focus on a small probability that they may get cancer. Because physicians assumed that the benefits outweighed the risks, they believe that their conduct was justifiable. Again, for women the cardiovascular disease is a more common cause of sickness and mortality in most of the world than osteoporosis and cancer combined. This is especially important because some risk factors for heart disease are nonmodifiable. Those risks are age, the presence of heart disease or other evidence of atherosclerotic arterial disease, a family history of premature heart disease. The risk for heart disease, for instance, increases about threefold for every 10-year increase in age.\(^\text{74}\)

Although the risk of heart disease is significant, the objection is flawed that it was better to relieve severe symptoms of menopause and prevent the long term risk of heart disease and osteoporosis by relying on hormone therapy. First, health professionals cannot decide for patients to trade possible immediate relief over a serious risk later. This sort of action relies on the notion that physicians know what is in the best interest of the patient. This is a fallacy because physicians and patients are basically moral strangers who do not share the same beliefs and values. The level of risk tolerance, therefore, is for patients to decide. Ideally, “The patient-physician relationship is founded on trust and confidence; and the physician is therefore necessarily a trustee for the patient's medical welfare.”\(^\text{75}\) This is a model of fidelity that depends more on values of trust and loyalty.\(^\text{76}\)

Since the nature of medicine and medical practice have changed, physicians and patients often do not have an opportunity to develop a relationship of trust and loyalty. Consequently, it is important that physicians play the role of a guide and help patients make decisions that may

\(^{74}\) National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 15.

\(^{75}\) Beauchamp, Principles 312.
seriously affect the quality of their life later. Second, because some of the risks for heart disease, for instance, are modifiable through exercise, not smoking, proper nutrition, and weight control, women might choose to use those measures to prevent heart disease. Physicians, therefore, needed to disclose that their standard recommendations to women to take HRT for preventative purposes, are not based on any solid evidence. They could have counseled women about alternative treatments. Because the latest evidence shows that hormonal treatment, for instance, not only did not help prevent heart attacks and strokes, but rather increased their risk, the medical profession was not justified in issuing recommendations without informing patients about the lack of reliable evidence for it.

Inadequate Understanding

In relation to the criterion of understanding, I argue that physicians often did not address many concerns women are likely to have about menopause as a normal yet complex event in every woman's life and about effectively evaluating the long-term risks and benefits of HRT. Because the medical profession has viewed menopause as a disease and has treated it as such for at least three decades, clinicians provided insufficient guidance to patients concerning menopause. Most often clinicians simply provided a prescription for a drug that was meant to keep women looking young, beautiful, feminine, and wrinkle free. Physicians were thus apparently trying not only to stop the occurrence of any fluctuation in hormones that accompany menopause, but also to stop the aging process. The short term effects of hormone fluctuation, however, do not necessarily require treatment. The severity, duration, and the extent to which they interfere with woman's life are determinants of the need for intervention. For instance, hot flushes that are not troublesome do not require treatment. Physiological symptoms, however, do not define menopause because menopause is a psychosocial passage that every woman experiences differently. An individual approach is necessary to address the specific needs of

76 Beauchamp, Principles 312.
77 Grady, "Scientists."
78 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 8.
women. Some of the things that clinicians need to be sensitive to when addressing women's needs are: their (1) beliefs and attitudes about menopause, including their medical and nonmedical therapy preferences, concerns, and coping style, (2) “sociocultural and ethnic background that may affect (women's) concerns and choices,” (3) employment situation, job satisfaction, and stress, (4) other life stressors, especially personal relationships, (5) “overall quality of life,” (6) “current use of nonprescription herbal, nutriceutical (a nutritional supplement designed for a specific clinical purpose), or phytoestrogen remedies.”

If clinicians do not discuss menopause related issues such as these and listen to women's concerns, they may not comply with physicians' recommended treatment, e.g., they may not fill their HRT prescriptions.

To properly address women's concerns, physicians must also evaluate both nonmodifiable and modifiable risk factors in evaluating and determining treatment for a more serious menopause related problems such as cancer. Nonmodifiable risks include family history of cancer, age, previous history of cancer, precursors to cancer, and reproductive factors such as the age of the onset of menarche and menopause. Modifiable risk factors include estrogen treatment, overweight, nutrition, physical activity, cigarette smoking, alcohol, radiation, and certain mammograms. This is particularly important because of the increased risk of cancers in postmenopausal women, especially breast and endometrial cancers, is connected to “the effects of age and accumulated lifetime exposure to carcinogens.”

Critics might object that while it is true that some women want more general information about menopause, many women simply want their physicians’ recommendation regarding HRT use because they lack time, background, and the ability to understand all the available information, and are simply willing to trust their doctors. There is a substantial evidence that clinicians' perspective on informed consent and patient autonomy is predominantly that patients want physicians to fix and reassure them, not to educate them, and that patients are incapable of

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79 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 8.
80 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 8.
81 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 21.
82 National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 21.
comprehending, evaluating, and making decisions about their medical condition and outlook. The clinicians' argument is that most patients seek medical assistance because they want physicians’ expertise in identifying and resolving problems that patients want solved. In other words, they want physicians to solve their health problems, and sometimes they want their reassurance.

Physicians also tend to believe that patients do not come to see clinicians so that they educate them about their health conditions because patients often fail to listen to whatever information physicians provide and because patients often fail see themselves as “decision makers regarding matters about which they have no expertise and of which they are often very ignorant.” Furthermore, the argument goes, patients are wise about this because “they often have as many misconceptions about their problems as they do insights.” Patients often see the basics of physicians' recommendation as an abstract of a much more complex, developing, and uncertain situation. Finally, assuming that patients have an interest in, and are capable of, understanding their medical condition and prospects, there is very little time for them to internalize and reflect on such matters, at least in the sense that would make informed consent anything more than a formality. For those clinicians, informed consent is a myth that conceals “a much simpler reality—that of the patient who chooses whether or not to trust in his physician's judgment.” These physicians view informed consent as a concept without substance because they believe that patients they see every day in their practice confirm such a view. Whatever informed consent offers, those physicians do not believe that patients spontaneously seek it. This is important because it reflects patients' lack of desire to exercise their autonomy and consequently make informed choices regarding their health matters.

While it is true that many women simply want their physicians’ recommendation regarding HRT use, the clinicians must realize that they have a duty to educate their patients about menopause and issues regarding its treatment, regardless of women’s desires to rely on their health professionals’ recommendation. In other words, clinicians have a duty to encourage

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83 Wear, Consent 50.
84 Wear, Consent 50.
85 Wear, Consent 50.
86 Wear, Consent 50.
patients' understanding and autonomy in a meaningful way. Failure to do so would violate women’s right to know relevant facts or risks that may result from certain treatments. Simply issuing professional recommendations, without discussing the accompanying risks, suggests that physicians do not show respect for patient autonomy. In other words, physicians serve their patients better and respect them as autonomous beings if they educate them about their health options and encourage them to make educated decisions.

Admittedly, patients may have difficulties processing information about risks. Risk disclosures often lead subjects (professionals and patients) to distort information and promote inferential errors and disproportionate fears of risks. In other words, “Some ways of information framing are so misleading that both health professionals and their patients regularly distort the content.”88 For example, clinicians can present the same information about risky alternatives as “a gain or an opportunity for a patient or as constituting a loss or a reduction of opportunity.”89 If physicians use the second approach, it is likely that patients will experience more fear and distress about their medical treatment. In the case of hormone therapies, clinicians minimized the risks. This might have reduced women's fears about risks of cancer, but that so many women failed to fill their prescriptions and half of those who did quit taking the hormones within the year suggests women's uneasiness about hormones that physicians could have addressed. Consequently, physicians need to look for the ways to overcome their skepticism about patients' ability to understand medical information and about the value of informed consent.

One of the ways that clinicians could overcome their scepticism about informed consent is to view it as a basic medical management tool.90 As such a tool, informed consent can enhance freedom in two important ways. Because illness threatens freedom, it requires, sometimes primarily, “the special expression and exercise” of freedom in the sense that clinicians need to stimulate self-determination in their patients to treat their illness effectively. Without patients' compliance and cooperation, medical intervention cannot be completely successful, and in some situations its success depends on such intervention. In these situations, informed consent serves

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87 Wear, Consent 50.
88 Beauchamp, Principles 90.
89 Beauchamp, Principles 90.
90 Wear, Consent 43.
as the most significant and effective intervention to encourage compliance and cooperation, especially in the people with chronic illnesses and people who take their bodies and health for granted. It is easy to prescribe medicines for a health condition such as hypertension. Only clinicians with special interest in their patients’ well-being can motivate patients to exercise self-determination. It is especially difficult for patients to practice self-determination with certain health condition such as borderline hypertension, which requires that they take medicine that will make them feel chronically worse, and to do some self-monitoring to control the condition.  

Another way to enhance freedom in health care by using informed consent as a medical management tool is to reflect on the positive aspects of freedom, beyond the minimal sense such as freedom from noninterference. We value autonomy because it allows us to evaluate our choices “in terms of our own personal values, beliefs, and life experiences.” Clinical medicine is a field that requires assessment of a variety of choices. Every clinical decision relies on value judgments concerning risks and benefits and the cost of choosing one treatment over others or choosing not to have a treatment. In considering these choices, informed consent may serve as mechanism for physicians to help patients identify and assess choices regarding medical treatment in terms of their own values, beliefs, and life experiences. Medical management thus needs to include clarification of values and negotiation. The role of informed consent is, at least in part, to emphasize and enhance freedom.  

Some clinicians might object that besides the limited time they have to spend with each patient in order to attain their more encompassing consent, such consent is often unnecessary because medical treatment does not require evaluation of patients' basic values and beliefs, and the choice is simple. If, for instance, a person with pneumonia comes to see a physician, the treatment of choice is antibiotic ampicillin, for which not much reflection is needed. The most a physician needs to do in this case is to encourage the patient to take the prescribed medicine, and to take all of it without stopping even as she begins to feel better. In other words, chronic illnesses aside, which along with extraordinary cases and research experiments, represent the

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91 Wear, Consent 43.
92 Wear, Consent 44.
93 Wear, Consent 44.
minority of medical cases, informed consent is unnecessary and unjustified in common medical treatment.\footnote{Wear, Consent 44.}

It might be true that in the case of a prescription of an antibiotic for pneumonia, and in much of medicine where physicians are comfortable with their recommendations and patients willingly consent, counseling and values clarification are not necessary, but it is wrong to assume homogeneity of needs and tasks in clinical decision making.\footnote{Wear, Consent 45.} This view considers only the limited or negative notion of autonomy or “freedom from interference” and fails to consider what informed consent can achieve. In cases of continuing chronic conditions or patients whose disease has spread, many “substantial value choices arise.” In such situations patients may need time, reflection, and counseling. Moreover, physicians may need to help patients establish certain views, rather than just identify them. It is unrealistic to expect patients to have adequately developed views about unexpected or extraordinary situations. The “freedom from interference” view does not consider such situations. Instead, it focuses on protecting patients from those who might be the only source of insight and support. Under this view clinicians are supposed to use informed consent for all clinical situations without considering the variety of needs and situations in clinical medicine. Also, by failing to recognize “the diminishments and vulnerabilities often attendant upon illness, the 'freedom from interference' view fails to recognize two corollary realities: (1) that patients often need help and encouragement toward accomplishing further reflection and insight and (2) that sometimes they are essentially incapable of doing so.”\footnote{Wear, Consent 45.}

The final point here is that besides clarification and negotiation, other essential needs, crucial to autonomy and self-determination, emerge in some clinical situations. For instance, unfolding chronic illnesses require patients to make decisions that go beyond the scope of just treatment decisions. Those illnesses often affect their lives in inescapable and profound ways that they must learn to value their new way of life to which they have to adapt. Thus affected patients need clinicians to assist them to anticipate further developments in their medical care so that they can adjust their activities, ambitions, and plans. They need to interpret for themselves what it
means to live with a handicap or a continuous threat to life. In other words, patients have to “make judgments about what kind of person (they) have become now that (they) are chronically ill or seriously threatened.”\textsuperscript{97} In such situations physicians are an essential resource and informed consent needs to be a necessary component of it.\textsuperscript{98}

Clinicians' conscientious and forceful pursuit of patients' understanding and autonomy is crucial if informed consent is to be effective in pursuing certain values beside those directly related to patients' decision making.\textsuperscript{99} This is especially important in developing physician-patient relationship beyond the stage of moral strangers and in establishing physicians as guides and advocates within “the otherwise threatening medical assembly line.”\textsuperscript{100} In this regard, some writers insist on \textit{the therapeutic model} of the physician-patient relationship. This model suggests that physicians must be flexible and adapt to whatever the patients' needs are in the sense of responding to whatever model serves patients the best, which may include paternalism, beneficence, patient autonomy, or mutual decision making.\textsuperscript{101} In most cases, however, physicians “must also accommodate the patient's deepest concerns, confidences, fears, and dependencies in the relationship.”\textsuperscript{102} This inequality is inherent in the traditional physician-patient relationship. It places a great ethical weight on the physicians' professionalism, because patients depend on physicians to satisfy so many of their needs. A basic ethic of this model specifies that, especially for the sickest patients, physicians need to nurture patient autonomy and be ethically committed to this goal. This also recognizes the essential therapeutic nature of the patient-physician relationship.\textsuperscript{103}

Other goals that informed consent might serve include clinical goals, such as helping patients get a sense of the source of their health problems and what they can do about them, and

\begin{thebibliography}{99}
\bibitem{96} Wear, \textit{Consent} 45.
\bibitem{97} Wear, \textit{Consent} 46.
\bibitem{98} Wear, \textit{Consent} 46.
\bibitem{99} Wear, \textit{Consent} 73.
\bibitem{100} Wear, \textit{Consent} 73.
\bibitem{102} Branch, “Therapeutic” 2259.
\end{thebibliography}
enhancing the possibility of successful intervention “by generating knowledgeable, committed, even optimistic patients, which in turn can be rewarding in terms of patient compliance, cooperation, and self-monitoring.” The pursuit of informed consent might help to achieve many other clinical goals. Such pursuit of “the restoration or protection of patient autonomy may, at times, need to occupy a center stage and be preparatory and foundational to all other goals.” For instance, enhancing functions to extend life is useless unless a patient values it or takes advantage of it.

Sometimes the main goal will relate to other goals that are strictly in the domain of the patient such as “active participation in rehabilitation, major modifications and acceptance of a lifestyle imbedded in chronic illness, or the performance of the 'last things' to the extent that terminal illness threatens” life. Informed consent, if extended beyond the legal protocol and if connected with referrals to “self-help groups, community assistance, and counseling services,” can make a substantial difference in patients' lives.

Informational Manipulation

In relation to the criterion of voluntariness, I argue that routine prescription of HRT to menopausal women failed to meet the voluntariness standard of free informed consent because health professionals’ often well-intentioned bias toward HRT influences patients’ perceptions and responses regarding its use. Clinicians' bias toward prescribing hormone therapies resulted in informational manipulation, a major problem for informed consent. In the case of HRT, clinicians were biased toward HRT use and had advised their patients to use it for all transitory symptoms. Physicians also prescribed HRT to prevent a variety of other conditions such as heart disease, osteoporosis, Alzheimer's, severe depression, and urinary incontinence, even though there was no solid evidence preventive evidence for such a regimen. Clinicians either relied on

103 Branch, "Therapeutic" 2259.
104 Wear, Consent 74.
105 Wear, Consent 74.
106 Wear, Consent 75.
107 Wear, Consent 75.
their medical judgments in making recommendations to their patients or they may have followed the guidelines of professional medical associations such as the American College of Physicians, which issued guidelines on hormone replacement in 1992. In either case, if physicians did not disclose the facts about the nature of evidence, they have excluded their patients from making an informed decision. They have not respected their patients' autonomy. And to the extent that autonomy is essential to being a person in the highest degree, physicians have in these cases diminished the inherent value of their patients. In this case it is probable that clinicians used the traditional medical approach that allows them to decide what constitutes patients' best interests.

Another instance of informational manipulation of menopausal women is that physicians have presented the information about hormone therapy as positive rather than negative in the sense that it influenced women's perception of the therapy and possibly their response. First, if women suffer from insomnia, night sweats, and hot flashes for a while, which may have caused exhaustion and interfered with their normal activities, women may want a quick relief to get a needed rest and resume normal activities. For those particular symptoms, HRT therapy is safe and effective because those symptoms are temporary and medical opinion is that the short-term hormone therapy is safe. Current attitudes of some physicians regarding hot flashes, for instance, is that they disappear after three to six months even without treatment, although in some instances they may last four to five years. Second, standard medical practice is a necessary but insufficient means to address specific needs of some patients, and physicians need to look for ways to meet such needs. For more serious conditions, however, such as heart disease and osteoporosis, until recently only the results of observational studies were available, which did not justify routine prescription of hormone therapies for preventive purposes. Physicians should have used an individualized approach, similar to the one that the *International Position Paper on Women’s Health and Menopause* recommends—“tailored to the specific needs and concerns of each woman and designed to provide an optimal quality of life.”

Clinicians’ might object that their well-intentioned biases toward HRT did not breach the voluntariness standard of free informed consent because clinicians' biases are non-controlling types of influences, and women are thus free to refuse their recommendations. Although some

\[^{108}\text{National Heart Lung and Blood Institute (NHLBI) and National Institutes of Health (NIH), "Best" 7.}\]
patients know their rights, are informed, are comfortable around authority figures, and are at ease asking questions, clinicians can have a controlling influence over many and probably the majority of patients because they appear authoritative, unapproachable, and are more knowledgeable about patients' health. As Katz, however, points out, when lacking basic information about their conditions and alternative treatments, patients are unable to raise questions they want to ask, and often cannot even formulate them. They thus might appear confused, ignorant, embarrassed, and tongue-tied. Physicians, and often patients themselves, view this conduct as confirmation of patients' incapacity to understand their medical condition or the necessary and alternative treatments to correct it. If physicians assume and foster patients' incapacity for understanding medical information, their assumption becomes self-fulfilling.\footnote{Katz, \textit{Silent x}.}

Because patients often approach physicians with the awe, deference, and fear, their ability to question their physicians or to refuse treatment is limited.\footnote{Katz, \textit{Silent x}.} They surrender their right to ask probing questions because they are afraid of offending physicians and feel guilty because they believe they are imposing on physicians' time. As Katz points out, even highly educated people, including renowned non-medical university professors, have difficulty questioning their physicians' recommendations. Although patients' concerns might be distorted, they nevertheless guide their interactions with physicians.\footnote{Katz, \textit{Silent x}.}

To alter patients' distorted views, physicians need to vigorously oppose these views to avoid self-fulfilling ways in which they will affect the physician-patient relationship.\footnote{Katz, \textit{Silent x-xi}.} In other words, if physicians want their patients to develop more positive views of them, they need to help patients develop more favorable view of them. To do so physicians must show willingness to take the time to discuss the available options with patients to insure that patients' compliance reflects their own wishes. Without patients' participation in decision making process, it is uncertain whether physicians' conduct compelled their compliance, which patients were unequipped to oppose. Compelled compliance can result in patients' disappointment, which may lead them to leave their physicians or to file malpractice suits. Also, while it is true that some
patients want physicians to make decisions for them, physicians cannot find out whether they are unwilling or unable to partake in the decision making “until they radically change their perceptions of patients, assist patients in altering their perceptions of their doctors, and learn to speak with patients in new and unaccustomed ways.”

In the HRT case, informational manipulation is a factor because the medical community, as we have seen, defined “menopause” as a disease. This definition suggested that menopause requires medical intervention. Given that some patients view physicians as authority figures it would have been difficult for women to question their views about menopause, unless they had a physician with whom they developed a therapeutic relationship. One of the disturbing trends in health care, however, is that the patients who need their physicians' therapeutic powers are elderly or poor. The Medical Outcomes Study, however, shows a troubling tendency toward diminishing health in those vulnerable groups who were enrolled in a health maintenance organizations rather than in private practice.

Furthermore, patients in indemnity plans trust their physicians more than those in managed care plans. Some studies also suggest that patients are more satisfied with the care they receive in private practice. In HRT case, the majority of the studies were observational. Women who choose treatment are healthier and have better health habits than those who do not. Currently, there is no information on the habits or needs of poor women regarding hormone therapies. Even for the women who have good health care, however, if physicians simply handed out prescription for HRT to women who were approaching menopause or any of the subsequent stages for any symptoms or conditions, they were displaying their bias toward HRT. Alternative and better treatments are available for prevention of serious diseases. For instance, although hormones can help lower LDL or the undesirable kind of cholesterol, and raise HDL, the beneficial kind of cholesterol, other, statin drugs are a treatment of choice for cholesterol imbalance. Moreover, the practice of simply evaluating symptoms and prescribing medicines amounts to impersonal transaction that denies the essential nature of the therapeutic patient-
physician relationship, which consists of “taking care of the whole patient.” This is necessary because patients suffer from psychological and socially related problems as they do from physiological ones, which require a “biopsychosocial” approach. Given that menopause is a psychosocial passage, as well as a biological one, this approach to treating menopause related problems and conditions is preferable.

In sum, physicians' skepticism about the existence and the need for informed consent, lack of clear guidelines about its implementation, patient apathy, the assembly line nature of medical care, and the medical field's tendency to define physiological conditions as diseases that require drug treatment, prevent proper implementation of informed consent. Although the right to informed consent is an important concept that many physicians respect, promote, and use in practice, it is limited in the sense that it is not a substitute for a therapeutic patient-physician relationship based on trust. In a trusting type of relationship, physicians use a variety of models to serve their patients including autonomy, beneficence, paternalism, and shared decision making, while staying committed to the goal that they continuously need to nurture patients' autonomy. In the case of HRT, physicians simply followed professional community guidelines and their professional judgment in routinely prescribing hormone therapies to menopausal women to prevent serious diseases, without giving much consideration to the specific needs of patients. Conversing with women about their needs could have helped them select proper treatment or no treatment for their menopause related symptoms and thus fostered compliance with physicians' recommended treatment. As Katz points out, a younger generation of scientifically trained physicians may wish to experiment with new ways of interacting with patients to find out whether the practice of medicine can be more rewarding to both patients and physicians. Moreover, “In this age of depersonalizing medical science and acrimonious

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117 Branch, "Therapeutic" 2257.
118 Branch, "Therapeutic" 2257. For further discussion of this approach see G. Engel, “The Need for a New Medical Model: A Challenge for Biomedicine,” Science 196. (1977): 129-136; M. Balint, The Doctor, His Patient,
malpractice litigation, the need for such interaction is even more compelling; for physicians must learn whether a radically different dialogue with patients will restore confidence in the humanity of a great profession."\textsuperscript{119}

\textsuperscript{119} Katz, \textit{Silent} xii.
Conclusion and Epilogue

In the preceding chapters I have tried to show the basis and the need for the right to informed consent, which some define as respect for people's autonomy because autonomy justifies informed consent. The concept of Informed consent gained prominence in biomedical field following abuses in biomedical research. Since the 1970s there has been an effort to incorporate informed consent into medical practice. Although some clinicians accept the idea of patient autonomy and, by default, the idea of informed consent, the effort to incorporate it into medical practice has met resistance. Those who embrace the idea of patient autonomy are not clear how to implement it in everyday practice. They claim that conceptual models are too complex and do not consider the problems of implementation in practice. Those who oppose the idea of patient autonomy claim that patients come to see physicians for help and reassurance, not to make decisions. Some ethicists classify these physicians as paternalistic or simply as physicians who operate on the model of beneficence that permits them to decide what is in the best interest of the patient. Other barriers to informed consent are the assembly line nature of current medical care with its attendant constraints on a physician's time, burnout and superiority. Yet, whatever the problems with respect for patient autonomy in practice might be, given that society's strong emphasis on freedom, it is not likely that anyone would be willing to give up the right to informed consent. The legal model of informed consent falls short of respecting the principle on which it is based, the people's right to self-determination, and clinicians and institutions often use it as a tool for legal protection, not as a tool for respecting people as autonomous beings.
Consequences and Future Trends

Current emphasis seems to be to convince skeptical clinicians that genuine consent can be effectively implemented in practice, and also to stimulate their patients to engage actively in the responsibility for their health. The emphasis assumes that patient cooperation is crucial in successful medical treatment.

Some ethicists suggest that a cogent, clinically workable model of informed consent is needed. Howard Brody offers an operational model, which he calls a “transparency model,” for which Stephen Wear supplied the philosophical/conceptual model with needed clinical support/articulation/specification.” There is not much reliable information on whether anyone is implementing the model and if so, how well it is working. Others offer practical models as well. Ethicists in medical schools teach resident physicians about the importance of informed consent and introduce them to the concepts behind it. The real change thus might happen over time as each new generation of physicians familiarizes itself with the idea of respect for people's autonomy and implement it in a meaningful way into their practice. Other factors might influence clinicians to do the same. The benefits of change might be respect for peoples' humanity or dignity, which supports the ultimate goal of the medical field, good medical care.

Epilogue

One of the strong and venerable traditions in Western philosophy describes human beings--insofar as they are uniquely human--as beings who possess reason and will. If this tradition is viable and is one that we should take seriously, whether we accept it fully or not, then we also take seriously that functioning human beings deliberate carefully and, as autonomous, make their own reasoned choices. To be autonomous is, after all, is to be a being who can decide and choose for oneself.

1 Stephen Wear <wear@acsu.buffalo.edu>, "Wear's Book on Informed Consent," 2002 (Apr. 25, 2002).
Prominent philosophers, such as Rene Descartes (1596-1650), Kant (1724-1804), and Ralph Waldo Emerson (1803-1882), advanced the idea of freedom and choice. In his Fourth Meditation Descartes claims that he, as the thing that thinks, has two basic capacities, understanding and willing or choosing. He thus implies that human minds, and by the Sixth Meditation, human beings have an ability to reason and make free choices based on their informed understanding.\(^2\) Descartes claims that the human intellect is finite, while the will is far less limited. And while the job of human intellect is to come to beliefs based on “clear and distinct perception,” the job of the will is to make a choice whether to affirm or deny these beliefs. When human beings make choices before they have a “clear and distinct perception” of the problem, they frequently make mistakes because the will is more extensive than the intellect. Given the limitations of the intellect, human beings can avoid making mistakes if they wait until they have a clear understanding of relevant facts about the problem they are trying to solve.

Being truly and completely free means that human beings can never be indifferent.\(^3\) At times, however, they appear indifferent, in the sense that reason does not move them in one direction or another. In this instances, human beings, according to Descartes, are the least free. In such situations they lack knowledge. If they were always clear about what is good and true, there would be no need to make choices.

Kant also argued that humans are free or autonomous beings. He claimed that “freedom is the source of all value—that it is intrinsically valuable, and that other valuable things must not only be compatible with freedom but actually derive their value from the value of freedom.”\(^4\)

Freedom is, on the one hand, that faculty which gives unlimited usefulness to all the other faculties. It is the highest order of life, which serves as the foundation of all perfections and is their necessary condition. All animals have the faculty of using their necessary condition. All animals have the faculty of using their powers according to will. But this will is not free. It is necessitated through the incitement of *stimuli*, and the actions of animals involve a *bruta necessitas*. If the will of all

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\(^3\) Descartes, *Meditations* 37.

beings were so bound to sensuous impulse, the world would possess no value. The inherent value of the world, the *summum bonum*, is freedom in accordance with a will that is not necessitated to action. Freedom is thus the inner value of the world.\(^5\)

Kant thus claims that human beings are unlike other animals in the sense that they have a will, which is beyond the influence of mere inclinations, and that this fact about them serves as the ultimate source of value in this world.\(^6\) As we have seen earlier, human will is self-legislating and a quality that makes humans autonomous beings, which enables human beings to be self-governing agents. Kant demonstrated that they alone, unless there are other free and rational beings about which we are ignorant, can legislate universal moral law by using their own reason and wills, which places them under moral law and permits them to accept moral law.\(^7\)

Emerson also has much to say about human autonomy and self-reliance. He claimed that to be human is to be a nonconformist, to explore things such as goodness for ourselves because “Nothing is at last sacred but the integrity of [y]our own mind”\(^8\). Moreover, he suggested that the only law that is sacred is the one that respects our nature.\(^9\) In other words, we should maintain who we are and speak the truth as we see it in large societies, in institutions, and in the presence of others regardless of their position.\(^10\)

What is true for philosophers and essayists is not often doctrine for non-philosophical human beings. It is unfortunate, therefore, that patients--especially women who simply accept prescriptions for HRT--often fail to act as autonomous agents, either because they fail to take an active part in their own conditions and therapy or because physicians, whose medical authority they fear to question, inhibit their autonomy. If Kant is right that human beings are capable of legislating universal moral law, then they ought to be able to make reasoned decisions that affect their own lives. One of the reasons for patients' passive and inhibited conduct could be the

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\(^6\) Guyer, *Kant* 130.

\(^7\) Kant's categorical imperative as a principle of autonomy is this: “Always choose in such a way that in the same volition the maxims of choice are at the same time present as universal law.” Kant, *Grounding* 44, Ak. 440.


\(^9\) Emerson, "Self-Reliance" 141-42.

\(^10\) Emerson, "Self-Reliance" 142.
inability to think independently. Kant, for instance, thinks that people can become independent thinkers if they rely on their own understanding, provided they outgrow their self-imposed immaturity, which he defines as "the lack of resolve and courage to use understanding, without guidance from another."\textsuperscript{11} Timidity and laziness, according to Kant, are reasons for people’s immaturity, even after they reach their physical maturity. This conduct makes it possible for others to make decisions for them.\textsuperscript{12} For instance, patients are being lazy if they simply ask physicians to determine what medical treatment they need and blindly follow their advice. In this case, patients are not using their own reasoning faculties to evaluate physicians' advice and decide what is best for them. While this is not true in all cases, it happens often.

Of course, those in positions of authority, such as physicians and pastors, might be happy to keep their position of power by warning those who seek their help of dangers and difficulties of thinking independently. To think independently need not be so difficult nor dangerous as it seems because people would learn from their mistakes. Errors, however, frighten people and stop them from making independent decisions again. Immaturity thus almost becomes a part of human nature, and people might even become “fond of this state and for the time being is actually incapable of using (their) own understanding, for no one has ever allowed (them) to attempt it.”\textsuperscript{13} Rather than exercising their natural ability to reason, Kant argues, people conform to rules and formulas, which can permanently keep them in the state of immaturity, thereby limiting their freedom to think independently. A few people succeed in finding this freedom by cultivating their minds.\textsuperscript{14}

Despite the hurdles to overcoming immaturity, Kant thinks that enlightenment is inevitable because, even in the most rigid society or situations, some will successfully overcome their supposed limitations and always think for themselves. Those few independent thinkers will spread “the spirit of a rational appreciation for both their own worth and for each person’s calling to think for himself.”\textsuperscript{15} As the solution to enlightenment, Kant offers the freedom of public

\begin{itemize}
\item \textsuperscript{11} Kant, "Enlightenment" 41, Ak. 35.
\item \textsuperscript{12} Kant, "Enlightenment" 41, Ak. 35.
\item \textsuperscript{13} Kant, "Enlightenment" 41, Ak. 35.
\item \textsuperscript{14} Kant, "Enlightenment" 41, Ak. 35.
\item \textsuperscript{15} Kant, "Enlightenment" 42, Ak.36.
\end{itemize}
discourse. In a liberal democracy such as the United States, this freedom ought to help encourage people to exercise their autonomy and their rights.

If, then, to be genuinely and actively human is (a) to reason well and (b) to choose under the guidance of reason, the patients who fail to do either (a) or (b) or both (a) and (b) are in some real sense subjugating capacities that make them human. This is unacceptable because, as Locke points out, to enslave anyone is immoral and to allow oneself to be enslaved is both immoral and unreasonable. Patients might take a lesson from Locke: “The natural liberty of people is to be free from any superior power on earth, and not to be under the will or legislative authority of man, but to have only the law of nature for his rule.” Locke is talking about freedom under government, not about free and informed patients, but the more general foundations of his Second Treatise of Government are the need for self-assertion and protection of basic rights. For him, as for Descartes, Kant, Emerson, and many others, alienating one's rights or timidly allowing others to disregard them is to sacrifice the autonomy that is inseparable to a life worth protecting, and living.

The point of this thesis, then, is (among other things) that people should behave autonomously and should be no less autonomous in medical contexts than in any other context. A corollary to this position and this thesis is that patients who behave non-autonomously also fail to make informed choices or are imposed upon to such a degree that they fear to make them. In this situation, patients seem to forget that finding out what they must do to take care of their health should be the prevailing concern in their interaction with physicians.

Another helpful approach to overcoming fear in dealing with others and maintaining our freedom might be to think, as Emerson suggests, as those whom we admire, e.g., like Moses, Plato and Milton. The problem is, as Emerson points out, that we dismiss our thoughts without notice, simply because they are ours.
Earlier in this thesis I spoke about the development of trust in physician-patient relationship, emphasizing that physicians ought to conduct themselves in a trustworthy manner. Patients could emphasize their right to informed consent. Both factors are equally important to insure that patients exercise their autonomy and make informed choices. Without trust in themselves and their own thought processes, when making choices in medical treatment or in any other context, true freedom is not possible.
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