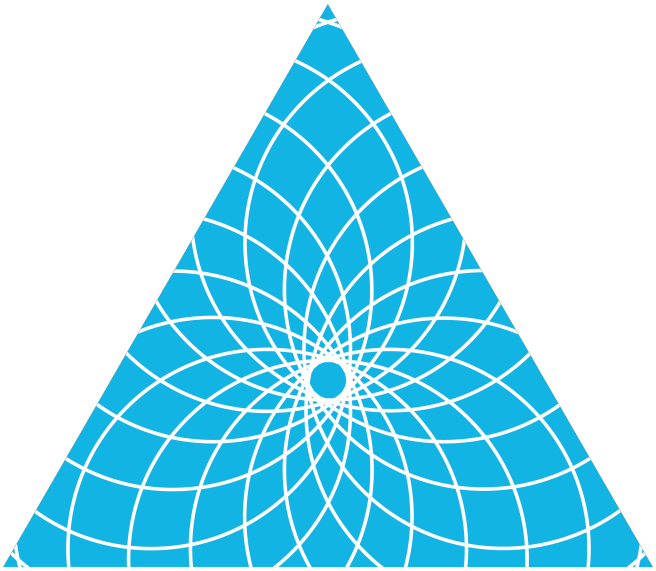

A · R · H · P

EMPOWERING HUMAN RESOURCEFULNESS

BIOETHICS, INFORMATION AND CHOICE:

Individual Autonomy, Patient Driven Healing and the Informed Health Consumer

Association for Reorganizational Healing Practice

www.reorganizational.org

April 2016

The Association for Reorganizational Healing Practice (ARHP) is a professional association dedicated to advancing human resourcefulness through applications that impact health and personal development. ARHP practitioners seek to elevate client baseline health and life experiences and inspire constructive choices for a richer life.

The choices we make reflect our level of health and development, and serve as an avenue to personal improvement. Empowering one's resourcefulness, by necessity, involves active conscious participation in one's health care options, and making conscious choices for oneself and one's family. These conscious choices may or may not reflect current conventional opinions or approaches.

ARHP practitioners, and others who support expanding human resourcefulness, and raising the standard of health beyond the return to a "prior minimal state", recognize that returning someone to the state they were in just before the occurrence of a symptom, diagnosis or a disease, is often simply not enough. These practitioners are a voice united both for more effective health and quality of life and for a better economic disease and health care model. The unique ways individuals experience their bodies, symptoms, diagnosis, and their understanding of how participating in the process can impact the outcome of their challenge influences the way a disease or symptoms are addressed.

Daily choices reflecting high personal standards for health promotion and well being impact upon and often become predictors of increasing optimal health and decreased morbidity. Ultimately, knowledge of desirable outcomes are needed to help individuals to establish a higher order functional state. This is associated with an increased awareness of the ways they participate in initiating, creating, transforming or resolving health and disease challenges. Healing into a more energy efficient life involves the individual transcending less desirable states.

At the core of individual empowerment to improve ones' health and life options, for themselves and for those to whom they are guardians, are the principles of individual consent to a method of treatment or prevention. Included within, or at, this juncture is the health care provider's philosophy and that as well of the patient. Ultimately what happens at this juncture

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impacts the patient's personal belief as to the appropriateness of the intervention for the health and life of that individual and their minor children.

It has been demonstrated that personal belief and perspective on one's health and choices is a powerful determinant of outcome. In order to give truly personal consent, one must have unfettered information and respect for the individual's autonomy in making a choice.

The commonly used biomedical definition of health as an absence of symptoms and disease is no longer adequate. The consumer is better served when the health approach includes the social science definition, in addition to the biomedical convention. In the social science model one's personal resources and resourcefulness, belief and perceived ability to navigate life are included in the assessment and outcomes. These psychosocial factors are powerful determinants of health, wellness, quality of life and desired larger outcomes for individuals, families and societies.

Creating information strategies that assist practitioners and clients to navigate and reorganize their living, thinking and experiences while also achieving a better, more adaptive, state of health than they were in just before the "diagnosis" of "disease, is the essence of Reorganizational Healing and Living. This is necessary to go beyond continuing the cascade of new symptoms/conditions/diseases and "side effects" and a minimalistic, and often-outdated set of outcomes. Diagnosis and treatment models that strip the disease or symptom from the life of the patient are often driving much of our "broken" system that directs individuals, families and society into frustration, further illness and even bankruptcy.

The ARHP approach relies on informed choice to clarify for each individual the difference between treatment of disease, symptoms and an overall healthy state. Since most disease (even cancer) is now coming to be seen as lifestyle and environmentally shaped, treatment that includes reorganization of lifestyle and of one's personal environment is essential. This may have as much, or more, to do with improving an individual's overall health or survival than the treatment of disease itself.

Individuals need to be informed about approaches that include ways to optimize function and health, that may differ from the proposed procedure or treatment under consideration. Providing such information is necessary for assisting clients to make their own personal choices and to choose care consistent with their values. This naturally impacts responsible living, individual health, well-being and the experience of personal autonomy.

To make the best choices for oneself and one's family, a body of information from which to make one's decisions is necessary. This information must be broad and free from professional

and/or commercial interest and other bias, or the client is to be advised of the conflict of interest.

Informed Consent, recognized as being at the center of responsible, ethical, and dignified health care and social agreements, can only be achieved if individuals have sufficient information to make informed choices, and the freedom to choose from both established and less conventional approaches. For consent to be meaningful the information available to consumers must include options, and consumers must be free to make choices. Thus, Informed Choice is a necessary component of Informed Consent.

It is in this spirit that this document has been prepared for the ARHP by Jim Turner of Swankin and Turner in Washington, DC. Mr. Turner is a respected, talented, and prolific legal counsel on consumer rights, responsible consumption and their relationship to responsible regulatory agencies. As a strategic and legal advisor to this community of practitioners and clients who seek such an integrated and reorganized healthy life for the past twenty years, Mr. Turner has provided essential and practical policy and regulatory guidance. With this history it was natural for ARHP to call on him to prepare a policy document that could begin an expanded social dialogue on Informed Consent and Choice.

This penetrating policy "white" paper is designed to begin the conversation and prompt responsible action to put into practice informed choice and consent for modern times. When broadly considered and applied, it will help liberate individuals and societies, save an immense amount of time and finances now spent on legal issues and legislation, and describe a vibrant baseline of personal and social interaction that will support a more dignified and vital society.

The principles of consent and choice have been recognized by organizations such as the United Nations (the Universal Declaration of Human Rights), the American Medical Association, the European Medical Association, the Nuremberg Code, and many others outlined in the paper as crucial to human health and dignity. It is essential for effective health outcomes for all practitioners to recognize that Informed Choice is a fundamental component of every exercise of Informed Consent.

In addition to enlivening and energizing the flow of information within health care relationships, the principles of Informed Choice can also be applied productively in a variety of professional fields, including education, law, and politics. As the information resources of society grow, each individual's ability to make informed choices in every aspect of their lives becomes more achievable.

ARHP would like to see the broadest possible group of organizations step up to support recognition of the right to Informed Choice.

Please read and redistribute this document if you represent a professional association in health, social outreach, education. If you are part of legal, political, or other group, that values human dignity, personal choice, and the integral nature of personal decision-making in one's life we desire to find you and for us to ban together to create a new reality for current and future well-being of the healthcare system and individuals. We encourage you to write letters and engage in social media in a way that shows support for our organization's position in this domain. Please feel free to use it in your professional or personal area of interest.

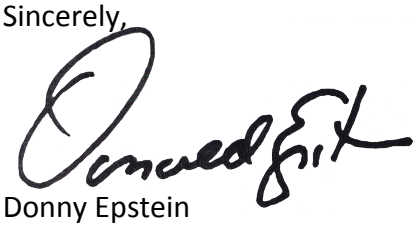
We would love to place your association or group's name or logo in support of this ARHP Informed Choice "policy paper" for display on our website. The ARHP will be providing educational support and dissemination of information for this vital topic for individuals and groups. We seek to begin new dialogues, collaborations and new initiatives that can offer significant and constructive advances in the health, educational, legal, and political arenas.

Informed Choice and Informed Consent, along with the integrity of one's personal beliefs and personal and family dignity, are central issues for today's modern, technology and information driven world. Today, in the name of "security", the rights of the individual are often sacrificed for what are questionably claimed to be the rights of the group.

Please join your voice with ours to advance the principles that personal choice and the freedom of the individual to responsibly participate in their health, life, and personal development decisions, free of incrimination, will ultimately lead to healthier and happier individuals, and in turn to a healthier and happier society.

Thank you for sharing this passionate subject with us.

Sincerely,



Donny Epstein
President
Association for Reorganizational Healing Practice

BIOETHICS, INFORMATION AND CHOICE: Individual Autonomy, Patient Driven Healing and the Informed Health Consumer

I. Introduction: Essentials for Informed Consent/Choice

"The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice." This statement, from The American Medical Association's Code of Medical Ethics Opinion 8.08 - Informed Consent[1], sets forth the widely accepted legal, ethical and practical form of Informed Consent/Choice addressed in this paper.

Informed Consent means consent to treatment by a patient, or to participation in an experiment by a subject, after achieving an understanding of the risks and benefits.[2] It should also include risks and benefits of alternatives including no treatment. This information enables real choice. Consent by both patients and subjects relies on the principles discussed in this paper.

After this Introduction, Part II of this paper sets out practitioner responsibilities for obtaining consent and how to meet them; Part III examines the legal and ethical rules governing consent; Part IV describes three current consent news items—the eugenics legacy, research, and mandatory vaccination; Part V concludes with how informed health choice promotes wellness and wellbeing.

Patient choice is an inseparable component of informed consent. The current patient (client/practice member) consent and choice system arose in the 20th Century in reaction to widespread knowledge of involuntary medical treatments such as Nazi medical experimentation,[3] research like the Tuskegee syphilis experiments,[4] and eugenics programs in the U.S. and worldwide.[5]

Recognizing individual autonomy and dignity as universal human rights leads to patient and research subject choice. Bothe reqire informed choice. The post-World War II Western consensus on individual autonomy is manifested in Informed Consent laws and practices. Informed Consent policies recognize that consent requires knowledge of treatment alternatives, including no treatment, and a treatment's risks and benefits.

This paper gives health practitioners guidance for applying informed consent/choice procedures and why they should do it. It sets out how legislation, treaties, and international, national, local, and regional declarations establish informed health choice as a universal human right. It

presents that right as rooted in individual autonomy, patient driven healing, and informed consumers.[6]

The treatment of an individual patient/client by a specific practitioner addresses, in detail, very specific individually focused facts of context treatment and outcome. It is about the individual. Research focused informed consent is about the study and each participant must be informed that they are not in a therapeutic, healing situation—that their interests and otherwise are secondary to purposed of the research.

II. Informed Consent: Formation of and how Practitioners can Comply with the Rules

Practitioner responsibilities for obtaining informed consent from patients and clients for proposed treatments, and procedures for meeting those responsibilities, rest on a solidly established foundation of law and practice. The right of patients to choose or refuse medical treatment has been contained for centuries within English and American common law. The legal obligation of clinicians to obtain consent before treating patients was established by several landmark decisions in the U.S. in the 20th century.

The rules governing consent by research subjects, developed in the context that created the Universal Declaration of Human Rights, and fleshed out by a number of international laws and agreements, recognizes "the inherent dignity" and the "equal and unalienable rights of all members of the human family."[7] The concept of patient rights developed from those concepts of fundamental human dignity and equality,

Core Compliance…Basic Forms

The full text of The American Medical Association's Code of Medical Ethics Opinion 8.08 - Informed Consent captures the flavor of inherent dignity, equality and unalienable rights belonging to all members of the human family as follows:

> The patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice. The patient should make his or her own determination about treatment. The physician's obligation is to present the medical facts accurately to the patient or to the individual responsible for the patient's care and to make recommendations for management in accordance with good medical practice. The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice. Informed consent is a basic policy in both ethics and law that physicians must honor, unless the patient is

> unconscious or otherwise incapable of consenting and harm from failure to treat is imminent. In special circumstances, it may be appropriate to postpone disclosure of information, (see Opinion E-8.122, "Withholding Information from Patients").
>
> Physicians should sensitively and respectfully disclose all relevant medical information to patients. The quantity and specificity of this information should be tailored to meet the preferences and needs of individual patients. Physicians need not communicate all information at one time, but should assess the amount of information that patients are capable of receiving at a given time and present the remainder when appropriate. (I, II, V, VIII)[8]

A health care practitioner adopting and implementing an informed consent/choice policy providing all that is required in this AMA ethics opinion establishes a solid basis for meeting all ethical and legal obligations for ensuring that each patient receives the information necessary to evaluate risks, benefits and choices for treatment of their known condition.[9]

Sample Informed Consent Forms

Each practice needs to lay out its information policies in forms and procedures necessary to ensure that patients have the full opportunity to effectively participate in their personal care. This requires each practice to establish a written policy for ensuring that it meets its information responsibility to its clients/patients and forms to implement that policy. The components of such a policy are set out in the next section. The forms are described in the next two paragraphs.

Sample forms for obtaining patient's informed consent and informed choice are included with this paper at Appendix One A through C.[10] Sample forms for obtaining patients' informed consent for clinical trials are provided in Appendix Two A through D. These templates give a sense of the breadth and depth of the client/patient's right to informed consent and choice.

The fundamental informed consent dialogue set out in the following section spells out in greater detail the nature of the client/patient's information rights. Appendix Three sets out principles of informed consent and choice for inclusion in a practitioner's practice policy manual and or posting in practitioners' offices.

Beyond Forms…Fundamental Dialogue

A healthcare practice needs more than the right forms to implement a sound informed consent/choice policy. In North America and Europe there are four distinct models of the

patient-physician relationship: 1. paternalistic; 2. informative; 3. interpretive; and 4. deliberative. Each model gives the physician different obligations, and all require practitioner/client/patient dialogue.[11]

The paternalistic model assumes that the physician knows best what to decide in the best interest of the patient, rather than needing to provide comprehensive information and decision-making power to the patient. The informative model, in contrast, sees the patient as a consumer best able to know his or her best interest, and thus views the doctor as principally a provider of information.

In the interpretive model, the physician helps patients explore their values, and select the treatment that best fits those values. In the deliberative model, the physician helps patients explore health-related values, and choose their treatment based on those values. Each model, but especially the deliberative model, requires practitioner-client/patient dialogue.

Reorganizational Healing as practiced by ARHP[12] members assumes that health and wellbeing requires more than treatment of disease and symptoms. Such practitioners need to inform clients of the difference between treatment of disease and systems and an overall healthy state.

Currently much if not most disease, even cancer, is seen as significantly influenced, if not caused, by lifestyle and environmental factors. Informed choice requires sharing this context with patient/clients and suggests a combined "deliberative/interpretive" model as the best approach.

Western medicine has developed from the paternalistic model. The Hippocratic rules required that physicians act in the patient's interests according to the physician's judgment, and to "do no harm." U.S. (and European) jurisprudence, in contrast, bases its information rules in liberty and justice, leading to development of the doctrine of informed consent and informed choice.

Each model requires deliberative interaction between physician and client. This means that a practitioner-client dialogue about a proposed intervention or treatment's nature, consequences, harms, benefits, risks, and alternatives must occur.[13] A complete informed consent process combines the interpretive and deliberative models and consists of the following seven elements.

The process begins with (1) discussing the patient's role in the decision-making process followed by (2) describing the clinical issue and suggested treatment. Next (3) the alternatives to the suggested treatment (including the option of no treatment) and (4) risks and benefits of

the suggested treatment (and comparing them to the risks and benefits of alternatives) get discussed.

The practitioner (5) presents uncertainties and answers inquiries about them, (6) assesses the client/patient's understanding of provided information and (7) elicits the client/patient's preference (including no treatment).[14] Concluding a discussion that includes these seven important aspects creates informed client/patient consent and informed choice.

For a reasonable person to make a decision, sufficient detail must be provided.[15] All risks of serious complications, even if rare, as well as less serious but common risks must be discussed.[16] This consent process may occur in one or several encounters.[17] A sound informed consent/choice practice policy includes both the proper forms and proper dialogue. Law creates the context.

State Legislation

In the United States the individual states regulate health practices. They do this primarily through health practice acts and regulations which establish profession-governing State Boards. These include state Medical and Chiropractic Practice Acts as well as licensing acts for Dentistry, Acupuncture, Massage Therapy, and other specific health modalities.

State courts in the various states interpreting these licensing and practice acts define the legal meaning and rules of legal practice, including informed choice based on informed consent. Health modalities may be practiced only by qualified individuals who satisfy specific educational and licensing requirements for their respective professions and comply with their Board's rules.

State Practice Acts set up state medical and chiropractic boards. These acts do not apply to dentists, nurses, podiatrists, psychologists, etc. Many state licensing rules, such as those for dentistry and acupuncture, establish boards for these disciplines. All boards, subject to court review, define and enforce their state's rules including those for informed consent/choice.

In 2015 the United States Supreme Court significantly altered the operating context of State Boards in a case overturning the North Carolina Dental Board's effort to ban teeth whitening by less expensive non-dentists. Attorney General Kamala Harris of California explains the case as follows:

> The North Carolina Board of Dental Examiners…[administers] a licensing system for dentists. A majority of the members of the board are themselves practicing dentists. ...Following complaints by dentists that non-dentists were performing teeth-whitening services for low prices, the dental board…issued cease and

> desist letters to dozens of teeth-whitening outfits…The effect on the teeth-whitening market in North Carolina was dramatic, and the Federal Trade Commission took action.
>
> In defense to antitrust charges, the dental board argues that, as a state agency, it was immune from liability under the federal anti-trust laws. The Supreme Court rejected that argument, holding that a state board on which a controlling number of decision-makers are active market participants must show that it is subject to "active supervision" in order to claim immunity.[18]

Since most professional regulatory boards, whether set up under practice acts or licensing legislation, consist of a majority of members from the regulated profession, this Supreme Court decision heralds major change in the form and behavior of regulating boards across the country. Oklahoma's Attorney General, E. Scott Pruitt, summarized the new context for boards:

> The Office of the Attorney General is concerned that many State boards and commissions present the risk of appearance of protecting private monetary interests rather than advancing sound public policy because they are controlled by active market participants, and this risk leaves the boards and commissions open to antitrust liability.[19]

While regulation of informed consent is a minor part of a regulatory board's work, it is likely that all the undertakings of state regulatory boards including consent and choice will be affected by the major review that boards should receive to ensure that they protect consumers and not merely the economic interest of the profession they regulate.

The U.S History of Informed Consent Formed Through Case Law

Over the last century, state courts have recognized and expanded informed consent.[20] For centuries before that, English and American common law recognized the right of patients to consent to or refuse medical treatment in the form of "physician does no harm" rules. The early law, however, largely viewed consent in a doctor-knows-best framework.

Beginning in the twentieth century, U.S. courts expanded clinicians' informed consent duties. A 1914 New York case upheld a patient's right to give or withhold consent. In finding for a woman whose doctor removed a tumor, although she had consented only to examination under anesthesia, the court said "… every human being of adult years and sound mind shall have the right to determine what shall be done with his own body..." [21]

In 1957, the California Court of Appeals established the doctrine of Informed Consent, holding that clinicians must disclose to a patient "all the facts which mutually affect his rights and interests --" including all known dangers of a procedure plus all information necessary for a patient to consent to treatment.[22]

In a 1960 Kansas case, a court found for a patient who suffered severely disabling burns as a result of cobalt irradiation for breast cancer in spite of having been told that the treatment posed no risks. In this case the court held the medical profession responsible for a standard of risk disclosure that a reasonable practitioner would be expected to provide a patient. [23]

In 1972, the California Court of Appeals expanded Informed Consent, saying that "The scope of the physician's communication to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision."[24] Also in 1972, the DC Circuit Court of Appeals expanded the scope of physician's disclosure duty further, requiring that patients be told: [25]

> 1. The condition being treated; 2. The nature and character of the proposed treatment or surgical procedure; 3. The anticipated results; 4. The recognized possible alternative forms of treatment; and 5. The recognized serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, as well as the recognized possible alternative forms of treatment, including non-treatment.

Cases subsequent to the 1972 DC case additionally required physicians to disclose personal or economic interests that may influence their judgment;[26] all diagnostic tests that may rule out a possible condition;[27] all information that a reasonable patient would find important;[28] and any information that the particular patient would find important.

Fully informed consent may also require disclosure of risks of not seeking treatment. One case held that a physician had a duty to disclose the risk of the inability to detect precancerous cells when the patient declined to undergo a pap smear.[29] One case said a physician could withhold statistical life expectancy data since it did not apply directly to the individual patient.[30]

"As the doctrine of informed consent unfolded with more clarity and became widely implemented in the 1980s, a clear shift from physician authority to patient autonomy took place amidst a public and political movement that emphasized patient access to information, choice, and personal control over medical treatment. This shift was monumental in the evolution from the paternalistic model to the current ethical and legal doctrines of informed consent in healthcare."[31]

This summary of case law on informed consent sets out the parameters of the legal underpinnings of the practitioner's obligation to comply with informed consent/choice policy, rules and laws. How to comply is set out in the first section of part II. The next section gives some sense of how informed consent is opening up access for individual client/patients to less conventional health and wellness modalities currently not subject to practice acts.[32]

Parties interested in informed consent/choice can learn from Minnesota law which, on the cutting edge of practitioner-client/patients' rights, contains a robust protection of informed consent/choice. Minnesota law requires that its health care bill of rights be provided to all patients and posted in all licensed facilities.[33] It acknowledges individual rights in part as follows (full text at Appendix Four):

> Information about treatment in language patients can reasonably understand including the likely medical or major psychological results of the treatment and its alternatives. It requires the right to participate in the planning of their health care, to discuss treatment and alternatives with caregivers, and the opportunity to request participation in formal care conferences. Right to refuse care. Written, informed consent must be obtained prior to Experimental research.

Additionally, Chapter 146A, Complementary and Alternative Health Care Practices, requires that unlicensed practitioners post a bill of rights in their office and provide one to the client. Also the client must sign a written acknowledgement of receipt of the bill of rights before the practitioner may provide services to the client.[34] The Complementary and Alternative Health Care Client Bill of Rights requires in part that the following be provided to the client (full text at Appendix Five):

> Practitioner's name, title, address, and phone. Degrees, training, experience, or other qualifications and a disclaimer reading in part THIS STATEMENT OF CREDENTIALS IS FOR INFORMATION PURPOSES ONLY. Supervisor's, if any, contact information; notice of complaint rights to unlicensed health practice office or supervisor. Fees, billing method, insurance companies, and a simple summary of provider's theoretical approach.

The Minnesota Complementary and Alternative Health Care Client Bill of Rights also provides that clients will receive:

> Notice that the client has a right to complete and current information concerning services to be provided; a statement that clients may expect courteous treatment and be free from verbal, physical, or sexual abuse; statement of

confidentiality; access to records; right to choose freely among practitioners; right to refuse services or treatment; assert the client's rights without retaliation.

The Minnesota Natural Health Coalition (MNHC), largely responsible for enactment of the Minnesota law and working to spread the law across the country, says of itself:

> "MNHC educates the public about Minnesota's "Safe Harbor Exemption Law," which was enacted in 2000. The statute, which carries the titles Chapter 146A, is known as the Alternative Health Care Freedom of Access Act. This statute carves out an area of law under which most unlicensed health care practitioners can practice what they do without fear of being prosecuted by the state medical board for "practicing medicine without a license." Upon request, we provide a "practitioner packet" to such practitioners, to explain the law and how to comply with it in order to come under its protections. Unlicensed practitioners may call 651-644-4572 in order to order a practitioner packet.
>
> "The practitioner packet, sent out for a modest fee, includes a copy of the 146A statute, some discussion of how the law works, and a sample "Client Bill of Rights" that serves as a model for the Client Bill of Rights that an unlicensed practitioner must give out to his/her clients in order to be in compliance with the provisions of the statute. With the help of this packet, many unlicensed practitioners will likely be able to learn about Chapter 146A, and how to comply with it, without needing to consult an attorney who specializes in explaining how to comply with this statute."[35]

The Minnesota Alternative Health Care Freedom of Access Act is currently the most advanced state law expanding health choice. It innovated the idea that trained practitioners of complementary, alternative, and integrative health modalities can legally and responsibly practice so long as they provide complete information to their clients and stay within the guidelines of their training. The Minnesota Natural Health Coalition works to spread the principle of that state's law to other states.[36]

A Sound Informed Consent Informed Choice Policy for Your Practice

The AMA Ethics Code underscores the conventional wisdom on informed consent/choice. A practitioner adopting an informed consent/choice policy based on the AMA Code of Ethics most likely complies with relevant informed consent laws and regulations in their jurisdiction. Adding elements of Minnesota's Alternative Health Care Freedom of Access Act (MAHCFAA) strengthens client/patient's access to information and choice.

Minnesota's Act (MAHCFAA) has gone the farthest in legalizing unconventional health practices based on informed consent and informed choice. By combining the AMA informed consent/choice ethics with aspects of the Minnesota law and establishing a practitioner-client/patient dialogue, individual practitioners can develop a sound innovative and legally compliant informed consent and choice policy.

A practitioner following the AMA informed consent/choice ethics guidelines complies with the law. In addition, any practitioner can adopt any of the Minnesota required actions into their own practice. Joining them with the AMA ethics rule on consent/choice creates a strong legal position for the innovative practitioner. Providing client/patients with a robust information dialogue process strongly implements both the legal and practical information rights of client/patients.

States laws control health practices and differ from each other. Each practitioner should consult a legal professional versed in the laws that govern their informed choice obligations to individual patients. These principles apply in the clinical setting,

The development of practices, rules, and laws governing consent and choice by research subjects paralleled those that apply to patients in individual clinical settings. The following section reports legal development affecting research subjects.

III. History and Policy: Legal and Ethical Rules Governing Informed Consent/Choice for research subjects

On October 1, 2010, the US government apologized to the Guatemalan government and people for a 1946-48 study in which American doctors infected many Guatemalan citizens with syphilis and other sexually transmitted diseases without the informed consent of the subjects. At least one died.[37] In his call with Guatemalan President Alvaro Colom, President Barak Obama "reaffirmed the United States' unwavering commitment to ensure that all human medical studies conducted today meet exacting U.S. and international legal and ethical standards,"[38]

One month later, in November 2010, U.S. Centers for Disease Control Director Dr. Thomas R. Frieden, and U.S. National Institutes of Health Director Francis S. Collins wrote of the Guatemala Case in the AMA Journal. [39] After lamenting the ethical failings of this study, the directors set out the safeguards developed in the years since the study. They said:

> **Safeguards**: Over the past 60 years, regulations safeguarding humans participating in research have been enacted. The Nuremberg Code, which articulated the requirement for voluntary consent of research participants, was

> issued in 1947, in response to Nazi human experimentation. The Declaration of Helsinki, the first international set of ethical principles for medical research involving human research participants, was adopted in 1964 by the World Medical Association. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, created following the revelation of the Tuskegee study,[40] issued the landmark Belmont Report on ethical principles and guidelines for research involving humans in 1979. In 1981, these guidelines were embodied in Health and Human Services (HHS) regulations to protect research participants (45 CFR 46). In 1991, Subpart A of these regulations ("The Common Rule") was adopted by an additional 16 federal agencies.[41]

The agreements cited by these two senior U.S. government officials establish an international regimen of information which sets the current standards for the conduct of scientific and medical research. The principles articulated in these agreements track closely the standards for treatment of patients. The following excerpts give a sense of their collective meaning.[42]

The Nuremberg Code[43], issued in 1947, in response to Nazi human experimentation, says:

> 1. The voluntary consent of the human subject is absolutely essential.
>
> This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision. This latter element requires that, before the acceptance of an affirmative decision by the experimental subject, there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person, which may possibly come from his participation in the experiment.

The Declaration of Helsinki, adopted in 1964 by the World Medical Association says:

> 5. Every biomedical research project involving human subjects should be preceded by careful assessment of predictable risks, in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society.

6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, and to minimize the impact of the study on the subject's physical and mental integrity, and on the personality of the subject. …

9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study, and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study, and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.

10. When obtaining informed consent for the research project, the physician should be particularly cautious, if the subject is in a dependent relationship to him or her, or may consent under duress. In that case, the informed consent should be obtained by a physician, who is not engaged in the investigation, and who is completely independent of this official relationship.

The Belmont Report, produced in 1979 by the U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, says:

Part C: Applications…

1. Informed Consent. -- Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension and voluntariness.

Information. Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any

time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc….

The Common Rule

In 1991, 15 U.S. federal agencies, including the Department of Health and Human Services (HHS regulations 45 CFR 46 Subpart A "The Common Rule") adopted the Belmont Report findings to protect research participants saying:

> §46.116 General requirements for informed consent.
>
> Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Together these documents, citied by two top U.S. health officials as a source of ethical medical practice guidance, state the core of the principles defining informed consent and informed choice for medical research. These principles and the documents that contain them exist in a larger context of human rights expressed in statements such as the Universal Declaration of Human Rights and Universal Declaration on Bioethics and Human Rights that recognize these principles for individual clients/patients receiving health treatments as well as research subjects.

Human Rights: Healthcare Informed Choice Included in International Agreements

A growing international consensus holds that all patients have a fundamental right to privacy, to the confidentiality of their medical information, to consent to or to refuse treatment, and to be informed about relevant benefits, risks and alternatives to medical procedures. This growing consensus rests on both U.S. law and International Human Rights agreements.

Medical ethics and human rights work in parallel, with medical ethics taking place within the practitioner-client/patient relationship, and human rights taking place in the socio-political sphere. Human rights impose a duty on the state. Medical ethics impose a duty on individual physicians to comply with ethical standards that parallel human rights principles.

The right of healthcare informed choice is rooted in concepts of fundamental human rights and protection of the individual. Fundamental human rights involving healthcare include the right to the highest attainable standard of health, and civil and political rights such as the right to bodily integrity.[44]

These guarantees have been codified in various international declarations and treaties, including (but not limited to): **The Universal Declaration of Human Rights; World Health Organization Constitution; Universal Declaration on Bioethics and Human Rights; International Covenant on Economic, Social and Cultural Rights (ICESCR); European Convention for the Protection of Human Rights and Fundamental Freedoms; and the World Medical Association Declaration of Lisbon on the Rights of the Patient. The Universal Declaration of Human Rights** recognizes "the inherent dignity" and the "equal and unalienable rights of all members of the human family." It says:

> Article 25. "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care …"

As a result of the human rights atrocities of World War II, the Universal Declaration of Human Rights was adopted by the United Nations General Assembly on December 10, 1948, to guarantee the human dignity and autonomy of every individual.

The Declaration recognizes "the inherent dignity" and "equal and unalienable rights of all members of the human family." The concepts of fundamental human dignity and equality underscore patient rights developed in other international documents created at the time and subsequently.

The Declaration sets the framework for recognition of individual dignity and autonomy, meaning self-determination. Personal autonomy is self-rule free from both controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice.

The concept of patient rights is grounded in the concepts of fundamental human dignity and equality.

World Health Organization Constitution

The World Health Organization Constitution begins by saying "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." It continues:

> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition…
>
> The extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.
>
> Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people…[45]

Universal Declaration on Bioethics and Human Rights unanimously adopted by 191 United Nations Member States of the UN Educational, Scientific and Cultural Organization (UNESCO), October 19, 2005, says:

> Article 6 – Consent
>
> 1. Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
>
> 2. Scientific research should only be carried out with the prior, free, express and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.
>
> 3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or

community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

International Covenant on Economic, Social and Cultural Rights[46] is a treaty that recognizes the right of each individual to the "highest attainable standard of physical and mental health." Specifically, Article 12 of the ICESCR provides:

> Article 12
>
> 1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> > (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
> >
> > (b) The improvement of all aspects of environmental and industrial hygiene;
> >
> > (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
> >
> > (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

Importantly, the Committee on Economic, Social and Cultural Rights, the organization responsible for monitoring compliance with the ICESCR, has found that the right to health includes the right to health-related education and information. Accessibility of health services and facilities impliedly includes the right to seek, receive, and impart health-related information in an accessible format. [47]

European Convention on Human Rights [48]

The European Convention on Human Rights, originally the European Convention for the Protection of Human Rights and Fundamental Freedoms, adopted by the then 10-member (now 48-member) Council of Europe in Rome November 4, 1950 is "a treaty designed to protect human rights, democracy, and rule of law."[49]

The Convention was the first step in implementing the Universal Declaration of Human Rights of 1948, for greater international unity in the equal rights of men and women, and to incorporate the notions of civil liberty.[50] Among its achievements, the Convention created the European Court of Human Rights, which oversees member states' implementation of the Convention.[51]

The Convention became effective on September 3, 1953, and eleven protocols have subsequently been added.[52] The Convention has been codified in the law of some European states.[53] Protocol No. 11 of the Convention, entered into force on Nov. 1, 1998, significantly streamlined the European human rights system.[54]

The Protocol merged two of the enforcement mechanisms under the Convention – the European Commission of Human Rights and the European Court of Human Rights – into a single court, empowering it to hear applications by individual as opposed to merely applications by states.[55] The decisions of the Court are final and binding on the state parties to the Convention.

World Medical Association Declaration of Lisbon on the Rights of the Patient[56]

The World Medical Association (WMA) Declaration of Lisbon on the Rights of the Patient sets out principal rights of the patient, including the right to self-determination and right to information. The preamble to the declaration and the sections on freedom of choice are fully set forth below.

> PREAMBLE
>
> The relationship between physicians, their patients and broader society has undergone significant changes in recent times. While a physician should always act according to his/her conscience, and always in the best interests of the patient, equal effort must be made to guarantee patient autonomy and justice. The following Declaration represents some of the principal rights of the patient that the medical profession endorses and promotes. Physicians and other persons or bodies involved in the provision of health care have a joint responsibility to recognize and uphold these rights. Whenever legislation, government action or any other administration or institution denies patients these rights, physicians should pursue appropriate means to assure or to restore them.
>
> 2. Right to freedom of choice

a. The patient has the right to choose freely and change his/her physician and hospital or health service institution, regardless of whether they are based in the private or public sector.

b. The patient has the right to ask for the opinion of another physician at any stage.

3. Right to self-determination

a. The patient has the right to self-determination, to make free decisions regarding him/her. The physician will inform the patient of the consequences of his/her decisions.

b. A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the information necessary to make his/her decisions. The patient should understand clearly what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent.

Individual autonomy and bioethics

Individual autonomy also lies at the heart of modern American bioethics.[57] Informed consent is the fundamental ethical and legal doctrine that protects the patient's rights of personal autonomy and bodily self-determination. The patient has the right to refuse a treatment and as a research subject to refuse to participate in research or teaching.

A patients' autonomy has instrumental value in medicine. It is also possible that there are cases where patients should be allowed to make their own choices about their treatment even if it is clear for all parties involved that others would be in a better position to make choices that would serve the patients' wellbeing.[58]

Some philosophers maintain that patients' autonomy can be restricted if there is a threat of very severe harm to the patient's wellbeing.[59] Others seem to accept no limits to patients' autonomy when there is no danger of harming others.[60] Ultimately the choice framed by these competing concepts concerns more what is good or bad for patients, not about the value of autonomy.[61]

Informed choice rests on the doctrine of informed consent. Informed choice requires a process of choosing from options based on complete and accurate information and knowledge,

allowing the healthcare consumer to make knowledgeable and reasoned decisions. Individual autonomy underpins informed choice, and informed choice requires informed consent.

Practitioners violate these protections when they fail to provide information regarding treatment options and potential risks and benefits of each procedure.[62] Unless they provide equitable access to safe, quality medical care, ensure patients' privacy, maintain medical confidentiality, and obtain informed consent before employing a medical intervention they fail their duty. [63]

Health information determines the right to the highest attainable standard of health. The right to exchange and impart such information protects access to high standards of health.[64] The right to health depends on, and contributes to, obtaining other human rights, such as the right to food, water, housing, adequate living standards, freedom from discrimination, privacy, participation, benefit from scientific progress and its applications, and access to information.[65]

CONSUMER RIGHT TO BE INFORMED

The movement for consumer rights offers additional support for informed consent and choice in the health marketplace. A 1962 message to the US Congress from President John F. Kennedy set forth a "Consumer Bill of Rights" which has been widely embraced. It specified four consumer rights to ensure effective consumer participation in an efficiently operating economy.[66] The rights are:

1. The right to safety--to be protected against the marketing of goods which are hazardous to health or life.

2. The right to be informed--to be protected against fraudulent, deceitful, or grossly misleading information, advertising, labeling, or other practices, and to be given the facts they need to make an informed choice.

3. The right to choose--to be assured, wherever possible, access to a variety of products and services at competitive prices; and in those industries in which competition is not workable and Government regulation is substituted, an assurance of satisfactory quality and service at fair prices.

4. The right to be heard--to be assured that consumer interests will receive full and sympathetic consideration in the formulation of Government policy, and fair and expeditious treatment in its administrative tribunals.

These four rights, produced in the post-World War II atmosphere that nurtured he International Declaration of Human Rights and the spate of human rights initiatives partially set out above, tracks almost exactly the rights of clients/patients and research subjects protected by courts in the health care arena.

The rights to be informed and to choose, in the Consumer Bill of Rights macroeconomic sense, track the widely recognized right to informed consent and choice in health care. The robust dialogue essential to informed health consent and choice expresses the right to be heard. Health information, choice and dialogue together create the important conditions for health safety.

The Kennedy Consumer Bill of Rights was followed by other expressions of human rights such as the American Hospital Association Patient Bill of Rights, the United Nations Guidelines for Consumer Protection of 1985, the Bill of Rights of the U.S. Advisory Commission on Consumer Protection and Quality in the U.S. Health Care Industry in 1998, and the Patient's Bill of Rights in the Affordable Care Act of 2010.

The American Hospital Association Patient Bill of Rights

Adopted in 1973, The American Hospital Association (AHA) Patient Bill of Rights provided in part the following:[67]

The patient is entitled to considerate and respectful care.

- The patient is entitled to and is encouraged to obtain from physicians and other direct caregivers relevant, current, and understandable information about his or her diagnosis, treatment, and prognosis.

- Except in emergencies when the patient lacks the ability to make decisions and the need for treatment is urgent, the patient is entitled to a chance to discuss and request information related to the specific procedures and/or treatments available, the risks involved, the possible length of recovery, and the medically reasonable alternatives to existing treatments along with their accompanying risks and benefits.

In 2003 AHA replaced its Patient's Bill of Rights with the Patient Care Partnership. AHA said its "plain language brochure informs patients about what they should expect during their hospital stay including their rights and responsibilities." The brochure appears to restate in user friendly language the content of the AHA Patient's Bill of Rights.

United Nations Guidelines for Consumer Protection of 1985

The United Nations Guidelines for Consumer Protection of 1985 set out the principle that governments should provide strong consumer-protection policies, and identified the following key protections:

a) The protection of consumers from hazards to their health and safety;

b) The promotion and protection of the economic interests of consumers;

c) Access of consumers to adequate information to enable them to make informed choices according to individual wishes and needs;

d) Consumer education;

e) Availability of effective consumer redress; and

f) Freedom to form consumer and other relevant groups or organizations and the opportunity of such organizations to present their views in decision-making processes affecting them.

The Guidelines also identify forty-six objectives, which include implementation of policies that inform consumers of foreseeable risks of products, and providing information and education to consumers to enable informed choices.[68]

A Chamber of the European Court of Human Rights (ruled by majority) in 2013 has interpreted the guarantees provided by Article 8 to include "a positive obligation for States … to provide access to essential information enabling individuals to assess risks to their health and lives."[69] In that case, divers claimed damage to their health as a result of diving in the North Sea for oil companies between 1965 and 1990.

The Court, though noting that "authorities had taken a wide range of measures in order to ensure the protection of divers' safety," found that such authorities failed to "provide access to essential information," specifically on "rapid decompression times and on the consequence that this could have on their health and safety," resulting in divers being "unable to fully assess the risks involved and give their informed consent."

Bill of Rights of the U.S. Advisory Commission on Consumer Protection and Quality in the U.S. Health Care Industry in 1998[70]

The U.S. Advisory Commission on Consumer Protection and Quality in the Health Care Industry also adopted a bill of rights and responsibilities in 1998. This bill of rights specifically applies to the insurance plans offered to federal employees; however, the values embodied in it have been adopted by other health insurance plans and facilities, including Medicare and Medicaid.

The bill of rights provides protection in eight key areas. They are, with the information spelled out in total:

- Access to Information. The patient is entitled to accurate and easily understandable information regarding his/her health plan, healthcare professionals, and healthcare facilities. For example, if a patient does not understand English, has a physical or mental disability, etc., he/she is entitled to help to enable him/her to make informed health care decisions.

- Participation in treatment decisions. The patient is entitled to information regarding treatment options, and to participate in his/her healthcare decisions. The patient is entitled to inquire regarding the risks and benefits of any treatment, including no treatment at all. The patient is entitled to refuse any test or treatment, regardless of predicted outcome. The patient is entitled to appoint a representative in an advanced directive.

- Confidentiality (privacy). The patient is entitled to communicate privately with healthcare providers and to confidentiality of health information. The patient is entitled to access to his/her medical records. The patient is entitled to request corrections if any record is incorrect, irrelevant, or incomplete.

The other five areas are: Choice of providers and plans; Access to emergency services; Respect and non-discrimination; Complaints and appeals; and Consumer responsibilities.

Patient's Bill of Rights and the Affordable Care Act of 2010

The Affordable Care Act of 2010 (ACA) incorporates a patient's bill of rights of a slightly different kind. It focuses on insurance availability and fairness more than the actual treatment modalities. It does strengthen all informed consent and choice principles for services paid for by the Affordable Care Act required insurance policies.

In addition the program boasts certain additional rights. The Department of Health and Human Services (DHHS) says "The Affordable Care Act puts consumers back in charge of their health care. Under the law, a new 'Patient's Bill of Rights' gives the American people the stability and flexibility they need to make informed choices about their health."[71]

DHHS lists additional ACA-provided rights including the elimination of denying insurance based on pre-existing conditions; keeping adults younger than 26 years covered under a parent's health plan; ending arbitrary withdrawals of insurance coverage guarantees; appeals of a denial of payment; preventive screening without additional fees or co-pay amount.[72]

The ACA also provides individuals the right to information and to access and an easily comprehensible summary of benefits and coverage.[73] The combination of the clinical right to informed consent and choice with its legal, regulatory and ethical foundation and legal protection of insurance coverage creates opportunities and responsibilities for both clients and practitioners.

Implications of patient centered care

In 1998 the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry summarized the implications of consumer driven healthcare. The following summary provides useful information of consumers and practitioners working together in a consumer driven health care system. The Commission said:

> **Consumers** must take a more active part in treatment decisions. Information can be empowering, but navigating the health care system requires patient effort, from completing advance directives to asking office visit questions. This requires that a consumer understand and give informed consent, and become a full partner in treatment decisions with his or her health care provider.
>
> **Health care providers** also have a central role in ensuring the patient's participation in treatment, including compliance with informed consent. They need strong skills in providing information about the medical and scientific evidence supporting the latest and best available treatments to patients and their families; to strive to overcome cultural, language and communication barriers.
>
> At the same time, they will need to do a better job of listening to their patients and following their decisions, including the decision to forgo treatment or certain types of treatment. Health care providers should assume this responsibility well before a patient reaches a hospital door. To hold the trust of patients, providers will need to disclose financial incentives that may introduce bias into treatment decision making and to avoid such incentives when the balance is tipped against the patient. To be above any potential bias, providers must avoid self-referral arrangements that can cloud their professional judgment. And, finally, health

care providers are and should be the most effective advocates for their patients' rights.

Health care facilities and plans must create and maintain an environment supportive of consumer participation in treatment decisions. In the office practice, this means ensuring adequate visit time for patients and providing support for shared decision making programs when questions about care linger, arise after hours, or require further explanation.

Health plans play a significant role in educating patients on how to get the most out of their visit with a health care provider. They can arrange for translator services for patients and continuing education courses for providers to assure cultural and language competency. By statute, health plans and hospitals have obligations to educate the public about the use of advance directives.

As importantly, once signed advance directives must become part of the patient's health record and move with the patient from care setting to care setting. In establishing provider compensation arrangements, health plans and facilities must avoid unintended, negative consequences of financial incentives by creating and monitoring quality of care and patient satisfaction programs.

The nature of financial incentives ought to be disclosed to patients and providers. In contracting with health care providers, plans and facilities should not restrict the provider's ability to discuss treatment options with the patient and not take reprisal upon the health care provider who serves as patient advocate.[74]

This Presidential Commission summary of patient centered healthcare raises important points that each practitioner and each client/patient can use effectively in establishing and using an informed consent, informed choice policy and program for themselves and their practices. The health and wellness system develops as consumer and practitioner move forward collaboratively.

IV: Informed Consent in the News—insights from current news about America's eugenics legacy, research/treatment rules and mandatory vaccination.

Informed choice grounded in informed consent provides one of the most important protections for individuals against mistaken, ill-conceived, or improperly carried out public health programs and policies. It also guides individuals toward optimum treatment choices. Only informed

people can make informed choices. By withholding information and choice from individuals, public officials and private practitioners both undermine the programs and procedures they wish to advance and harm the individuals kept in ignorance.

Three recent news items underscore the perils of imposed ignorance, government coercion, and the cost of unrestrained professional certainty overriding individual choice. Unchecked certainty can undercut the best interests of individuals and communities. The collective wisdom of a community of informed individuals creates the life blood of democracy. Overriding that wisdom in the name of scientific truth without proper safeguards can create outcomes even its proponents regret.

Each practitioner relying on informed consent and choice helps create an informed citizenry. Informed citizens protect the health of the community from mistaken policies and procedures. Clients/patients involved in the choices made to protect and advance their health build strong, healthy communities. Practitioners and consumers, grounding their relationships in informed consent and choice, contribute to these healthier communities.

The following three items from recent news reports underscore the importance and value of consent and choice in strengthening a community.

American Eugenics Legacy

When officials abandon legal procedures, in the name of scientific certainty, as they did—with horrendous consequences—in Virginia's 1924 to 1974 eugenics program, individual harm and community shame can result. In late 2015, the *Washington Post* wrote, "Virginia adds insult to the injury of eugenics"[75] by not compensating its remaining victims.

The *Post* editorial lauded a North Carolina law, saying that in 2013 the state "blazed a trail toward justice by establishing a $10 million fund to find and compensate surviving victims, all of them now elderly, each of whom would receive about $50,000. State officials estimated at the time that only some 200 victims could be found."[76]

The editorial went on, "the men and boys who underwent castrations or vasectomies, and the women and girls whose fallopian tubes or ovaries were removed, were not aware of … the consequences of procedures carried out without their consent ..."[77] Virginia sterilized 7,325 people, second only to California's 20,000.[78]

The *Post* further said "Former Virginia governor Mark R. Warner (D), now a U.S. senator, took a bold step in 2002 when he became the nation's first governor to apologize formally[79] for the

state's unspeakably cruel, half-century-long program of forced sterilizations…all in the pseudo-scientific cause of enhancing the nation's genetic stock."[80]

In 1927, in *Buck v. Bell*, the U.S. Supreme Court upheld Virginia's eugenics law. Thirty more states then instituted the practice.[81] Justice Oliver Wendell Holmes made two points in upholding the law. First, he cited extensive procedural protections in Virginia's 1924 law. Second, he cited the military draft calling for greater sacrifice than Virginia's eugenics law. On the first point he wrote:

> Carrie Buck…daughter of a feeble minded mother…and the mother of an illegitimate feeble minded child…was eighteen years old at the time of the trial of her case …. An Act of Virginia, approved March 20, 1924, recites that the health of the patient and the welfare of society may be promoted in certain cases by the sterilization of mental defectives, under careful safeguard, …[82]

Buck did not benefit from the safeguards. The entire case was a conspiracy. "Recent scholarship has shown that Carrie Buck's sterilization was based on a false 'diagnosis' and her defense lawyer conspired with the lawyer for the Virginia Colony [hospital] to guarantee that the sterilization law would be upheld in court."[83]

In *Skinner v. Oklahoma* (1942), the Supreme Court blocked Oklahoma from sterilizing criminals and cited the procedural safeguards Holmes relied on. Justice William O. Douglas wrote, "It is argued that due process is lacking because, under this Act, unlike the Act upheld in Buck v. Bell, the defendant is given no opportunity to be heard on the issue as to whether he is the probable potential parent of socially undesirable offspring."[84]

In the *Skinner* case, Chief Justice Stone wrote, "a state may…prevent the transmission by inheritance of his socially injurious tendencies. Buck v. Bell. But, until now, we have not been called upon to say that it may do so without giving him a hearing and opportunity to challenge the existence as to him of the only facts which could justify so drastic a measure."[85]

Justice Douglas wrote for the court that "[S]trict scrutiny of the classification which a State makes in a sterilization law is essential, lest unwittingly, or otherwise, discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws."[86] The *Skinner v. Oklahoma* case made it illegal for some lower class felons to be targeted for sterilization.

The safeguards in the law cited by Justice Holmes made sterilizing Carrie Buck constitutional. Without the "safeguards" it is likely that the court would have overturned the procedure, as it

did in the *Skinner* case. But the "safeguards" were a sham. After 25 years of research, law professor Paul A. Lombardo rendered the final verdict on the case.

In summary, Dr. Lombardo's book on *Buck v. Bell* says, "Carrie Buck's medical records, the honor roll grade book of her daughter, Vivian, private correspondence of the lawyer who was named to represent her, and the only existing photos of all three generations of the Buck family support the conclusion that the Buck case was a fraud, initiated to hide the shame of a poor girl, pregnant after she had been raped."[87]

In 2016 New York Times best selling author Adam Cohen reinforced the outrage in his book Imbeciles: The Supreme Court, American Eugenics, and the Sterilization of Carrie Buck[88] One of America's great miscarriages of justice, the Supreme Court's infamous 1927 *Buck v. Bell* ruling made government sterilization of "undesirable" citizens the law of the land

As Amazon summarizes, in *Imbeciles* Cohen tells the story of one of the darkest moments in the American legal tradition: the Supreme Court's decision to champion eugenic sterilization for the greater good of the country. In 1927, when the nation was caught up in eugenic fervor, the justices allowed Virginia to sterilize Carrie Buck, a perfectly normal young woman, for being an "imbecile."

Not knowing of the outrage and believing in the existence of the safeguards, Holmes then made his second point. Alluding to his service as an officer in the Civil War, he said:

> We have seen more than once that the public welfare may call upon the best citizens for their lives. It would be strange if it could not call upon those who already sap the strength of the State for these lesser sacrifices …It is better for the entire world if, instead of waiting to execute degenerate offspring for crime or to let them starve for their imbecility, society can prevent those who are manifestly unfit from continuing their kind. …The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes.[89] Three generations of imbeciles are enough.

Never overturned, *Buck v. Bell* remains the law. The model act authorizing sterilization that was adapted for the Virginia and California statutes was the basis for Germany's Hereditary Health Law in 1933. In appreciation, Heidelberg University awarded the model law's American author an honorary degree in 1936. After World War II, Nazi lawyers, defending the forcible sterilization of 2 million people, cited this law, pointing out that the U.S. Supreme Court, in *Buck v. Bell*, had declared such laws constitutional.[90]

The American eugenics episode underscores the importance of procedures in ensuring the legality of public programs. Scientific certainty needs the discipline of legal and ethical oversight to contain its enthusiasm. Public health programs and scientific research sometimes lead officials and overconfident researchers to override individual rights for the purpose of advancing what are then considered positive social outcomes.

Among other consequences, the sad story of eugenics led to the 1947 Nuremberg Code's standard that only volunteers could participate in scientific research. In 2010, U.S. officials cited this Code as an important bulwark against exploiting vulnerable individuals.[91] Practitioners and clients engaging in informed choice are key parts of the legal and ethical web that maintains the integrity of health and wellness research and treatment.

Research and Treatment Rules

The eugenics story underscores the essential need for officials to meticulously adhere to the procedural laws and ethics of informed consent and choice. The unfolding news about research and treatment realties and the protection of subjects' and patients' individual autonomy reinforces the lessons of the eugenics program.

Treatment

"Are Good Doctors Bad for Your Health?," a November 21, 2015 New York Times op-ed article by oncologist Ezekiel J. Emanuel, vice provost at the University of Pennsylvania, reported "that patients with acute, life-threatening cardiac conditions did better when the senior cardiologists were out of town."[92]

Dr. Emanuel reported on a JAMA Internal Medicine article, concluding that "High-risk patients with heart failure and cardiac arrest hospitalized in teaching hospitals had lower 30-day mortality when admitted during dates of national cardiology meetings…Mortality decreased by about a third for some patients when those top doctors were away."[93]

The JAMA article said, "High-risk patients with AMI [Acute Myocardial Infarction][94] admitted to teaching hospitals during meetings were less likely to receive PCI [coronary angioplasty][95] without any mortality effect." In an Israeli study, "researchers discontinued almost five drugs per patient for more than 90 percent of the patients. In only 2 percent of cases did the drugs have to be restarted."[96]

Dr. Emanuel also mentioned the use of stents in relation to high-powered cardiologists and antibiotics in the context of the Israeli study. Stents and antibiotics represent two additional

areas of treatment that might benefit from robust informed choice dialogues between patient and doctor. Each is the subject of significant controversy.

Dr. Knut Sroka quotes a 2003 Mayo Clinic USA publication, reported in the American Heart Association's journal Circulation Online, on stable angina, saying, "Balloons and stents do not prevent heart attacks and do not prolong life and stents … do not reduce the frequency of heart attacks or deaths."[97] Informed choice says that at a minimum patients and doctors should discuss the existence of this controversy.

The World Health Organization says, "Antimicrobial resistance threatens the effective prevention and treatment of an ever-increasing range of infections caused by bacteria, parasites, viruses and fungi. It is an increasingly serious threat to global public health that requires action across all government sectors and society."[98] Again, patients need to know about antibiotic resistance.

Dr. Emanuel suggests both policy and personal tactics for these situations. Policies could require doctors to provide patients data "about a procedure, including its rate of success, complications and the like, before every major intervention."[99] For overmedication, mainly in older people, doctors could attempt to discontinue medications at least once a year.

On a personal level, Dr. Emanuel suggests patients ask four simple questions about an intervention. First, what difference will it make? Will results change our treatment approach? Second, will it prolong life, or reduce risk? Third, how likely and severe are the side effects? And fourth, is the hospital a teaching hospital which has lower mortality?[100]

Dr. Emanuel's summary questions frame the empowering informed choice dialogue. Increasingly our culture and its health and wellness components move from professional toward personal decisions. Practitioners decide less and advise more. Informed choice programs, both in treatment and in research, shape and are shaped by these cultural forces.[101]

Research

During the mid-20th century,[102] American public health officials ran the Tuskegee syphilis experiments (1932 to 1972),[103] the Guatemala sexually transmitted disease project (1946 to 1948),[104] the Willowbrook Study that deliberately infected mentally retarded children with hepatitis virus (1963 to 1966),[105] the Brooklyn New York Jewish Chronic Disease Hospital cancer cell injection studies (1963)[106] and many other similar studies that put patients at risk without their knowledge.[107]

The collective weight of this ethically compromised body of work led to the reform of American research laws. While case law established the right to informed consent for medical treatment, Federal Regulations made informed consent a requirement for participation in medical research.[108]

Informed consent to participate in medical research is required by regulations of the U.S. Department of Health and Human Services (HHS),[109] and of the U.S. Food and Drug Administration (FDA).[110] The core principles of these research rules apply as well to the health treatment of individuals.

To insure informed consent medical researchers must be alert to minimizing "coercion" and "undue influence," eliminating the "therapeutic misconception," and avoiding the "double blind placebo problem." U.S. regulations state that "An investigator shall seek such consent…[to] minimize the possibility of coercion or undue influence."[111]

The U.S. Department of Health and Human Services (HHS) says, "*Coercion* occurs when an overt or implicit threat of harm is intentionally presented by one person to another in order to obtain compliance. For example, an investigator might tell a prospective subject that he or she will lose access to needed health services if he or she does not participate in the research."[112] This is coercive.

HHS says "*Undue influence*…occurs through an offer of an excessive or inappropriate reward or other overture in order to obtain compliance. For example, an investigator might promise psychology students extra credit if they participate in the research. If that is the only way a student can earn extra credit, then the investigator is unduly influencing potential subjects."[113] This is undue influence.

The "Therapeutic misconception" occurs when the medical research participant believes that the clinical trial is designed with the individual benefit of participants as its primary objective, potentially failing to understand the investigator's ethical obligations to the scientific goals of the research.[114] The patient believes he or she is the focus of the researcher's efforts when in fact the researcher is focused on conducting the study.

Because clinical research subjects are often also patients, their interests may conflict with the investigator's responsibilities.[115] Patients may think the researcher is treating their condition when the researcher may be actually using the patient to test a new procedure. In order to get informed consent the researcher must be explicit that individual therapy may be less important to them than their research outcomes.

The "double blind placebo problem" occurs when researchers use a double blind placebo controlled–the research "gold standard"—research design to test a new treatment when a recognized treatment already exists. In such a design one group of test subjects gets the new treatment while another gets a placebo or empty treatment. Substitution of an empty placebo for an existing accepted treatment violates medical ethics.

The Declaration of Helsinki[116] expressly precludes the use of a placebo when a proven therapeutic method exists and the absence of therapy poses a risk to the subject.[117] It says:

> 29. The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.[118]

"The Immortal Life of Henrietta Lacks," by Rebecca Skloot, the U.S. National Academy of Science's best scientific book of 2010, raised another informed consent issue. Ms. Lacks died of cancer in 1951 at age 31. Doctors turned samples of her tumor cells into the HeLa cell line, a powerful, lucrative research tool, without informing her or her family. 1n 2013 family members complained about uses of the cell line.

U.S. National Institutes of Health officials acknowledge that they should have contacted the Lacks family before allowing researchers to sequence the HeLa genome. In 2013, the Lacks and the NIH reached an agreement that gave family members a say in future uses of the HeLa cell line. This one time event leaves the larger consent question unanswered.

Eric S. Lander, of the Broad Institute, a Harvard, M.I.T. research center, said that to get the full research value from genome research it will take "hundreds of thousands of patients willing to contribute information from their cancer genomes towards a common good…We are going to need to have ways to have patients feel comfortable doing that. We can't do it without a foundation of respect and trust."[119]

While informed consent research rules apply primarily to research subjects' rights, the principles of respect and trust underlying them reinforce and interact with the treatment rules governing practitioner/patient relationships. Familiarity with the informed consent research rules reinforces practitioner/patient treatment rules. Together the treatment and research consent rules help establish the context for considering mandatory vaccination.

Mandatory Vaccination

A June 30, 2015 *LA Times* headline said "California Gov. Jerry Brown signs new vaccination law, one of nation's toughest." The law[120] required all school children in California to get various vaccines.[121] A picture with the story showed protesters with a sign saying "SB 277 (the new law) is contraindicated to: Nurses and Physicians Code of Ethics." The headline and picture underscore the difficult issue of vaccine consent—how, if at all, can health treatment mandates be reconciled with medical ethics?

States regulate vaccines. However, they do so under the umbrella of a federal law—The National Childhood Vaccine Injury Act of 1986 (NCVIA). This act contains within it the tension of required informed consent about vaccine efficacy and safety affected by the dynamics of mass immunization programs. Specifically the act contains the following information requirements:

§ 300aa–26. Vaccine information

> (a) General rule…the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table.[122] …
>
> (b) Such materials shall be developed or revised—
>
> (2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.
>
> (c) Information requirements. The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—
>
> (1) a concise description of the benefits of the vaccine,
>
> (2) a concise description of the risks associated with the vaccine,
>
> (3) a statement of the availability of the National Vaccine Injury Compensation Program,[123] and
>
> (4) such other relevant information as may be determined by the Secretary.

> (d) Health care provider duties…each health care provider who administers a vaccine set forth in the Vaccine Injury Table [including all of those in California] shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a) of this section,… Such materials shall be provided prior to the administration of such vaccine.…

To be clear, the law requires the Secretary of Health and Human Services to deliver, to any health care provider who intends to administer a vaccine, information about the vaccine, which the provider must in turn deliver to the legal representatives (usually the parents) of any child or other individual vaccine recipient prior to administration of the vaccine.

Healthcare providers can meet their informed consent obligations by giving vaccine recipients copies of Vaccine Information Sheet(s) (VISs) on vaccines they receive.[124] VISs are information sheets produced by the Centers for Disease Control and Prevention (CDC).

Vaccine Information Statements explain both benefits and risks of a vaccine to adult vaccine recipients and the parents or legal representatives of vaccine recipients who are children and adolescents. Federal law requires that VISs be handed out before each dose of certain vaccinations is given.

National Vaccine Safety Net

The law contains other safety measures, in addition to informed consent, as part of a national vaccine safety net. These additional aspects of the law include the Vaccine Injury Table,[125] the National Vaccine Injury Compensation Program[126] and Trust Fund[127] and the Vaccine Adverse Event Reporting System (VAERS).[128]

The Vaccine Injury Table

The U.S. Department of Health and Human Services Health Resources and Services Administration (HSHRS)[129] says the Vaccine Injury Table (Table) lists and explains injuries/conditions that are presumed to be caused by vaccines. The table itself lists the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation is to occur after vaccine administration for purposes of receiving compensation under the National Vaccine Injury Compensation Program.

National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP), located in the HHS, Division of Vaccine Injury Compensation,[130] was established, according to the agency,[131] to ensure an adequate supply of vaccines at stable costs, and establish and maintain an accessible and efficient forum for individuals found to be injured by certain vaccines. The VICP is a no-fault alternative to the traditional tort system for resolving vaccine injury claims that provides compensation to people found to be injured by certain vaccines.[132]

Vaccine Injury Compensation Trust Fund

The Vaccine Injury Compensation Trust Fund provides funding for the National Vaccine Injury Compensation Program to compensate vaccine-related injury or death claims for covered vaccines administered on or after October 1, 1988. The Trust Fund is funded by a $0.75 excise tax on the vaccines recommended by the Centers for Disease Control and Prevention for routine administration to children. The Department of Treasury collects the excise taxes and manages the Fund's investments.[133]

The Vaccine Adverse Event Reporting System

The Vaccine Adverse Event Reporting System (VAERS) is a national vaccine safety surveillance program co-sponsored by the CDC and the FDA. VAERS is a post-marketing safety surveillance program, collecting information about adverse events (possible side effects) that occur after the administration of vaccines licensed for use in the United States. VAERS provides a nationwide vehicle for disseminating vaccine safety-related information to parents and guardians, health care providers, and other constituencies.[134]

Results of the Vaccine Safety Net

The Vaccine Adverse Event Reporting System is based on the law requiring health professionals and vaccine manufacturers to report to the Department of Health and Human Services adverse events that occur after the routine administration of recommended vaccines. It has, HHS says with examples, demonstrated its public health importance.

In one example, HHS says, in 1999 VAERS detected reports for intussusception (a condition leading to intestinal obstruction)[135] in excess of the number that would be expected to occur by chance alone after receiving the RotaShield rotavirus vaccine. Epidemiological studies confirmed an increased risk, and these data contributed to the product's removal from the U.S. market.

In another example, HHS reported that VAERS determined that there may be a potential small increase for Guillain-Barre' syndrome (GBS)[136] risk after receiving the meningococcal conjugate

vaccine, Menactra. This finding caused a GBS history to become a contraindication to the vaccine. Further controlled studies are currently underway to research this issue.

HHS says 85-90% of the 30,000 or so VAERS reports filed yearly describe mild effects —fever, sore arm, crying or mild irritability. The remaining reports are serious—the event resulted in permanent disability, hospitalization, life-threatening illness, or death. These problems happen after vaccination, but according to HHS, are rarely caused by the vaccine.

PunditFact checked 2,170 VAERS cases reported in 2014 and found 1,244 hospitalizations, 416 disabilities, 122 deaths, and 388 life-threats. Excluding double counts (i.e., disabilities leading to deaths) the 2014 total dropped to 1,737.[137] VAERS and *PunditFact* both caution that an adverse event report shows correlation, not a vaccine caused event.[138]

The National Vaccine Injury Compensation Program paid total compensation from its inception in 1988 to 2016 of approximately $3.3 billion, according to the HHS Health Resources and Services Administration.[139] In the 27 years, the fund determined 4,526 individual claims to be compensable.[140] Again HHS cautions that payment does not establish vaccine injury.

Looking through the lens of informed consent ethics contained in The National Childhood Vaccine Injury Act might help clarify, and possibly resolve, some mandatory vaccine controversy issues. Informed consent moves health care responsibility closer to the individual and/or his or her guardians. Informed consent assumes that well informed individuals contribute to good individual and community health.

Mandatory Vaccine Controversy

While neither VAERS nor injury compensation payments establish that a vaccine caused the injury reported or compensated, the language of the Act reflects an acknowledgement that vaccines can and do cause injuries. Many parents who find themselves with an injured or dying child after vaccination are skeptical of government assurances of vaccine safety.[141]

In fact, parents who believed the DPT shot disabled their children played a key role in passage of the National Childhood Vaccine Injury Act in 1986.[142] Today the same group of parents, organized as the National Vaccine Information Center, seeks repeal of the law.[143] They argue that the table has been unscientifically narrowed, the no-fault compensation program has turned adversarial undermining fair hearings, and VISs and VAERS reporting have been needlessly limited.[144]

One parent, NVIC co-founder and Vice President Kathi Williams, said in 2015, “In good faith, parents of vaccine injured children worked with Congress on the 1986 National Childhood

Vaccine Injury Act. Today, most children getting government mandated vaccines are denied vaccine injury compensation and the vaccine safety, informing, reporting, recording and research provisions that NVIC secured in the law are not being enforced. The system is broken beyond repair."[145]

On July 29, 2015 Florida Congressman Bill Posey, who had previously held hearings on vaccine safety,[146] underscored the critics by taking the House floor and castigating the CDC for suppressing research information that might cast doubt on vaccine safety.[147] Robert F. Kennedy Jr. magnified Posey's critique with a December 1, 2015 statement reporting that CBS Reporter Ben Swann had exposed the CDC Vaccine cover-up.

Kennedy had published, in April 2015, a *USA Today* ad criticizing CDC.[148] He previously challenged vaccine safety in *Rolling Stone*,[149] had the challenge retracted by the magazine,[150] and republished in 2015 by Global Research.[151] On December 1, 2015 Kennedy published an expanded version of his manifesto on mercury and vaccines.[152] Swann added to the battle on January 26, 2016 by posting 100,000 CDC documents supplied to him by Posey.[153]

Media supporters of the official view attacked each aspect of the CDC critique. December 1, 2015 Respectful Insolence deconstructed the Posey case against CDC.[154] This post supplemented a July 30, 2015 critique of Posey's stance on vaccine research.[155] Other online journals like *Science Based Medicine* joined the repudiation of CDC criticism.[156] Forbes doubted the "whistleblower" on whom Posey based his charges.[157]

The differences between certain worried parents and their allies and the official view of vaccine safety and its supporters, including parents worried that exposure to unvaccinated children will harm their own, fuels state legislative and media battles. Federal regulators clearly say healthcare providers must consult legal counsel to learn additional state vaccine rules. Federal vaccine information requirements merely supplement any applicable State laws.[158]

Applicability of State Law

States regulate vaccine use. All states mandate vaccines for school children. There are three kinds of exceptions to mandates. All states permit a medical exemption if a child's health is at risk. All states except West Virginia and Mississippi permit exemptions based on religious beliefs. Fewer than half the states permit exemptions for personal beliefs.[159]

The state battles revolve around expanding the vaccine mandates. Advocates of broad mandates propose increasing the number of vaccines required and some combination of narrowing medical exemptions and narrowing or eliminating completely religious and personal

belief exemptions. Advocates of narrow or no mandates seek personal belief exemptions for all or virtually all vaccinations.

Advocates for broad mandates argue that mandates will stop the spread of dangerous diseases and cause little harm. Opponents of broadening the mandates argue that the science does not support broad mandates; that vaccine products need product by product evaluation of both their viral and non-viral components, and that science supports expanding rather than narrowing all three mandates.

This paper leaves aside the substantive debate on the nature of vaccines and their mandates. It addresses the question of what kinds of processes might be used and procedural questions asked to help resolve the state by state battles constructively. Looking at vaccine mandates from the perspective of the ethics of informed consent, already a part of national vaccine law, might clarify the procedural questions.

Vaccine Mandates and Informed Consent

First, to repeat, health care workers meet their federal informed consent requirements for administering vaccines by providing all their patients with the appropriate CDC prepared Vaccine Information Statements. To also repeat, such workers need to consult, probably through their own lawyer, the exact nature of state vaccine requirements, including state informed consent rules.[160]

Mandates

The requirement that all individuals get health insurance in the Affordable Care Act (ACA),[161] signed by President Obama in 2010, set off a national debate about health mandates that continues today. In upholding the constitutionality of the Affordable Care Act, the Supreme Court gave guidance on how the law approaches health mandates.

Chief Justice Roberts said the individual mandate is not a valid exercise of Congress's power under the Commerce or Necessary and Proper Clauses of the US Constitution, the clauses on which the government relied to support its constitutionality. He said, "[t]he Commerce Clause is not a general license to regulate an individual from cradle to grave, simply because he will predictably engage in particular transactions. Any police power to regulate individuals as such, as opposed to their activities, remains vested in the States."[162]

Chief Justice Roberts also found that since no power existed under the Commerce Clause there was no predicate to engage the Necessary and Proper Clause. "Just as the individual mandate cannot be sustained as a law regulating the substantial effects of the failure to purchase health

insurance, neither can it be upheld as a 'necessary and proper' component of the insurance reforms. The commerce power thus does not authorize the mandate."[163]

The Court did uphold the ACA's constitutionality by treating as a "tax" the "shared responsibility payment" that is stated as a "penalty" in the law.[164] The Court also called unconstitutional the ACA section that said states must expand Medicaid or face the possibility of losing all their Medicaid funds. The total fund loss was an unconstitutional penalty for the state opting out of the program.[165] The Chief Justice found the ACA constitutional and federal health mandates unconstitutional.

The Chief Justice's opinion made clear that only the states, using their "police power," can regulate individual behavior. The American vaccine program follows the dual sovereignty structure of the American system. The Federal government makes national vaccine policy, including recommendations to the states. The states choose how to act. However, the U.S. Supreme Court can review the constitutionality of a state's use of its police power.

Today's vaccine mandate advocates rely on a 1905 U.S. Supreme Court case, *Jacobson v. Massachusetts*, as key legal support for mandates.[166] In that case, decided 7 to 2, the court upheld a Massachusetts law charging a fine ($5 in this case) to anyone refusing a smallpox vaccine as a proper exercise of the state's police power to protect the public's health. Justice Harlan wrote "[T]he liberty secured by the Constitution . . . does not import an absolute right in each person to be . . . wholly freed from restraint."[167]

Georgetown University Professor Lawrence O. Gostin, J.D., says that in the *Jacobson* case Justice Harlan set out four constraints on the exercise of police power the court found constitutional—necessity, reasonable means, harm avoidance, proportionality. "These standards, while permissive of public health intervention, nevertheless required a deliberative governmental process to safeguard liberty."[168] Such a process can begin with informed consent/choice.

Informed Consent/Choice

Constraints on Police Powers

The National Childhood Vaccine Injury Act of 1986 (NCVIA) calls for meaningful informed consent in the use of vaccination. Meaningful consent includes choice—the option of opting out of the offered intervention. While states may legally exercise the power to compel vaccination, a meaningful legal question is what limitation the U.S. Constitution places on that

power. Professor Gostin suggests that Justice Harlan's four constraints begin to describe those constitutional limitations. He says:

Necessity requires that "The state must act only in the face of a demonstrable health threat." At a minimum, 1) the subject must pose a threat to the community, 2) police powers must be based on the "necessity of the case," 3) not exercised in "an arbitrary, unreasonable manner," or 4) go "beyond what was reasonably required for the safety of the public."[169]

Reasonable Means says that "Jacobson adopted a means/ends test that requires a reasonable relationship between the public health intervention and the achievement of a legitimate public health objective. …the methods adopted must have a 'real or substantial relation' to protection of the public health and cannot be 'a plain, palpable invasion of rights.'"[170]

Proportionality "…a public health regulation is unconstitutional if the human burden imposed is wholly disproportionate to the expected benefit. '[T]he police power of a State,' said Justice Harlan, 'may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong . . . and oppression.'" [171]

Harm Avoidance "The control measure itself, however, should not pose a health risk to its subject. Justice Harlan emphasized that Henning Jacobson was a 'fit person' for smallpox vaccination, but he asserted that requiring a person to be immunized who would be harmed is 'cruel and inhuman in the last degree.'"[172]

Informed Choice

Justice Harlan's 1905 opinion in *Jacobson* underscored the tension between protecting a community and preserving human rights. At the time of his opinion Massachusetts was one of seven states (of the then-45) with a mandatory vaccination law. Knowledge about infectious diseases and vaccines was rudimentary. The number of vaccines was limited. Now all states mandate vaccines. The number of individual vaccines has risen to 47, with many more in the "pipeline." The law recognizes that some number of individuals will be crippled or die from vaccines.

In this context, reevaluation of the balance drawn by Justice Harlan makes sense and is underway. The authors of a 2008 *Harvard Law Review* note entitled "A TWENTY-FIRST-CENTURY JACOBSON V. MASSACHUSETTS"[173] suggest the need to reevaluate *Jacobson* and present one approach to doing it.

They begin their note by saying:

> Biomedical advances are pushing the foundational public health law case Jacobson v. Massachusetts towards obsolescence. The 1905 Supreme Court decision established the constitutionality of state compulsory vaccination laws when they are "necessary for the public health or the public safety." But the case addressed issues of medicine, disease, and society that are increasingly irrelevant.

They suggest different policy approaches for "sorting among vaccines that combat diseases that are spread in different ways … [e.g., airborne vs. personal contact]." They suggest that "for sexually transmitted diseases (STDs) like HPV, compulsory vaccination is not a medical necessity because individuals can protect themselves through some combination of sexual knowledge, disease screening, safe sex, and abstinence."[174] They say, citing cases narrowing state mandates, "The application of state police power to non-airborne diseases, like hepatitis B, appears to have troubled judges."[175]

They also call attention to a fundamental debate going on in legal circles by quoting from "Jacobson v. Massachusetts: It's Not Your Great-Great-Grandfather's Public Health Law," by Wendy K. Mariner, JD, LLM, MPH, George J. Annas, JD, MPH, and Leonard H. Glantz, JD:

> Public health programs that are based on force are a relic of the 19th century; 21st-century public health depends on good science, good communication, and trust in public health officials to tell the truth. In each of these spheres, constitutional rights are the ally rather than the enemy of public health. Preserving the public's health in the 21st century requires preserving respect for personal liberty.[176]

Using the example of AIDS, Professor Annas says, "Public health officials recognized early that draconian mandatory HIV screening measures, for example, would simply help drive the epidemic underground where it would spread faster and wider." He says compulsory health measures are "much more likely to cost lives than to save them."[177] Professor Gostin, the authors say, vehemently counters Professor Annas's view. Public health often involves difficult trade-offs—i.e., whether to adopt a coercive measure against a disease-carrying individual to lower the risk that the individual will spread disease.[178]

They conclude their note by saying:

> In assessing whether government action is necessary to protect the public health, recognizing a qualitative distinction between vaccines that are medically necessary and practically necessary is an important step in the direction of a more nuanced evaluation. Vaccine policymakers, state legislators, and courts should cooperate in finding a way to recognize this distinction.

The U.S. vaccine system rests on informed consent. To be maximally effective, such a system must include the right to choose. Informed citizens making sound choices contribute to both the health of the community and their own health. State governments have the power, under prescribed circumstances, to mandate vaccination. How and when the Constitution permits this state action is an open question of major concern and intense debate.

This paper highlights these issues less to resolve them than to make clear the volatility of matters of health choice in contemporary society. Whether it be ownership of cell lines, controversy about treatment modalities or programs, the functioning of research oversight committees, or vaccine mandates, national and international discourse flourishes. In this context, informed consent fueling informed choice creates the best path toward sound policies.

Conclusion: Informed Choice--Backbone of a Healthy Society

America in the twentieth century made significant strides in improving research ethics and patient treatment based on informed consent/choice. Practitioners following the AMA stated principle that "the patient's right of self-decision can be effectively exercised only if the patient possesses enough information to enable an informed choice"[179] will meet their responsibility to properly inform patients. These informed patients will make better choices and advance their health and health of the community.

Each practitioner needs to develop an informed consent/choice plan and procedures for his or her practice. This undertaking continues the development of an informed citizenry being advised by professional practitioners on how best to maintain and improve their health. This also allows the practitioner to move to the more advisory role while the patient/client has personal autonomy, sound information and meaningful dialogue in order to make optimum health decisions.

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[3] U.S. Holocaust Memorial Museum, Exhibitions and Collections, "The Doctors Trial: The Medical Case of the Subsequent Nuremberg Proceedings," at http://www.ushmm.org/information/exhibitions/online-features/special-focus/doctors-trial. *See also*, Robert Jay Lifton, *The Nazi Doctors: Medical Killing and the Psychology of Genocide* (http://www.amazon.com/The-Nazi-Doctors-Psychology-Genocide/dp/0465049052).
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[6] *See, e.g.*: Universal Declaration of Human Rights (http://www.un.org/en/universal-declaration-human-rights/); European Convention for the Protection of Human Rights and Fundamental Freedoms (http://www.echr.coe.int/Documents/Convention_ENG.pdf); International Covenant on Economic, Social and Cultural Rights (http://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx); National Childhood Vaccine Injury Act of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34) (http://www.nvic.org/injury-compensation/origihanlaw.aspx); and FDA labeling requirements at 21 CFR 310.501 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=310.501) and 21 CFR 310.515 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=310.515).
[7] *Ibid*.
[8] Op. cit., FN 1.
[9] Each state and each designated local medical regulator establishes specific requirements for informed consent and choice. While a practitioner complying with the AMA opinion on informed consent meets the primary objectives of informed consent and informed choice every practitioner should consult with a local attorney versed in health regulations of their local area to insure that they comply with all local requirements. Practitioners with specific questions can ask their private legal counsel to consult with the legal advisors of The Association of Reorganizational Healing Practice for general guidance. The forms provided in Appendix One of this paper meet general legal obligations for clinical practice and in Appendix Two for research subjects.
[10] Appendix Two A is an informed consent template from the World Health Organization's Research Ethics Review Committee (WHO ERC) for participation in a clinical study. Appendix Two B is an informed consent template from WHO ERC for storage of patient samples. Appendix Two C is an informed consent template from WHO ERC for participation in a qualitative study. Appendix Two D is an informed consent template from the University of Pennsylvania Abramson Cancer Center for participation in a clinical study.
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[12] Association for Reorganization Healing Practice (http://reorganizational.org/)
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[18] California Attorney General Opinion 15-402, issued 9/ 10/15.

[19] Letter from Oklahoma's Attorney General to Governor Mary Fallin, July 6, 2015.

[20] The story summarized here is told in more detail in "Nuances of Informed Consent: The Paradigm of Regional Anesthesia" by Douglas S.T. Green, MD, and C. Ronald McKenzie, MD, one of many valuable summaries of the legal development of informed consent, posted by the US National Library of Medicine National Institutes of Health at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504103/.

[21] *Schloendorff v. Society of New York Hospitals*, 211 N.Y. 125, 105 N.E. 92 (NY Ct. App. 1914), opinion by Justice Benjamin Cardozo.

[22] *Salgo v. Leland Stanford Jr. University Board of Trustees*, 317 P.2d 170 (Cal. Ct. App. 1957). This case involved a patient named Martin Salgo who awoke paralyzed after aortography, having never been informed that such a risk existed. The decision held that failure to disclose risks and alternatives was cause for legal action on its own, reaching further than a case of battery. For nuances of informed consent, see FN 16, supra.

[23] *Natanson v. Kline*, 186 Kan. 393, 411, 350 P. 2d 1093 (Kan., 1960).

[24] *Cobbs v. Grant*, 8 Cal. 3d 229, 502P.2d 1 (Cal., 1972).

[25] *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

[26] *Gates v. Jenson*, 595 P.2d 919 (Wash. 1979).

[27] *Jandre v. Physicians Insurance Co. of Wisconsin*, 792 N.W.2d 558 (Wis. Ct. App. 2010).

[28] *Nixdorf v. Hicken*, 612 P.2d 348 (Utah 1980).

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[30] Physicians are not required to disclose particular statistical life expectancy rates to a patient suffering from pancreatic cancer, mainly on the grounds that statistics do not usefully relate to an individual's future. *Arato v. Avedon*, 858 P.2d 598 (1993).

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[32] The Minnesota Natural Health Coalition, the Minnesota group that worked for passage of the Minnesota law, lists Health Freedom Laws Passed in the following states 2013: Colorado Senate Bill 13-215 - Colorado Natural Health Consumer Protection Act; 2009 New Mexico Enacted the Unlicensed Health Care Practice Act; 2008 Arizona Revised Statutes Sections 32-2911 Amended; 2005 Louisiana Revised Statutes 20-37 VI-B; 2003 Rhode Island Statute 23-75 - Unlicensed Health Care Practices; 2001 California SB577 - California Complementary and Alternative Health Care Practitioners; 1999 Minnesota Statute 146A - Minnesota Freedom of Access to Complementary and Alternative Health Care Practitioners; 1994 - Oklahoma Statute 59-480 (Oklahoma Parameters for Jurisdiction of Physician Licensing Act) - Oklahoma Allopathic and Surgical Licensure and Supervision Act; 1976 - Idaho 54-1804 (Idaho Exemptions to the Medical Practice Act) - Unlicensed Practice. Penalties and Remedies Relating to Unlicensed Practice. (http://www.nationalhealthfreedom.org/InfoCenter/laws_passed.html.) Again, these laws are specific to their state, and practitioners desiring to know how they apply should contact a local attorney for effective legal representation.

[33] Minnesota Statutes §§ 144.651, 144.652 (https://www.revisor.mn.gov/statutes/?id=144.651). The text of the Minnesota Heath Care Bill of Rights can be found at Appendix Four of this paper.

[34] Minnesota Statutes § 146A.11 (https://www.revisor.mn.gov/statutes/?id=146A.11).

[35] *See* Minnesota Natural Health Coalition website at http://www.minnesotanaturalhealth.org/safeharborexemptionlaw.html.

[36] *Op. cit.*, FN 31.
[37] The Wikipedia entry on the Guatemala syphilis experiment states: "This resulted in at least 83 deaths," and cites the article, "Guatemalans 'died' in 1940s US syphilis study," by BBC News, 29 August 2011 (https://en.wikipedia.org/wiki/Guatemala_syphilis_experiment.)
[38] "Obama Apologizes to Guatemala for Syphilis Research," Nicholas Johnston, Bloomberg Business, October 1, 2010 (http://www.bloomberg.com/news/articles/2010-10-01/obama-apologizes-to-guatemala-for-infecting-prisoners-with-stds-in-1940s).
[39] "Intentional Infection of Vulnerable Populations in 1946-1948, Another Tragic History Lesson," JAMA, November 10, 2010—Vol 304, No. 18 (http://jama.jamanetwork.com/article.aspx?articleid=186859). The directors stated: "Unfortunately, such studies were not rare at the time. For example, intentional infection of prison inmates with gonorrhea and syphilis was conducted in Terre Haute, Indiana, and Sing Sing prison, respectively. They cited http://www.sciguru.org/newsitem/4545/intentional-infection-of-vulnerable-populations-in-1946-1948
[40] For a summary of the "Tuskegee Study of Untreated Syphilis in the Negro Male," see the website of the Centers for Disease Control and Prevention (CDC) at http://www.cdc.gov/tuskegee/timeline.htm. () This CDC website states: "**1974**: A $10 million out-of-court settlement is reached and the U.S. government promised to give lifetime medical benefits and burial services to all living participants. The Tuskegee Health Benefit Program (THBP) was established to provide these services." The site also states: "**2001**:
President's Council on Bioethics http://www.bioethics.gov/ was established."
[41] *Op. cit.*, FN 18.
[42] The text of the agreements are included in appendix.
[43] "The Nuremberg Code was introduced in August 1947, after the Nuremberg trials. In these trials, Nazi doctors were convicted of the crimes committed during human experiments on concentration camp prisoners. It attempted to give clear rules about what was legal and what was not when conducting human experiments. The code consists of ten points. The first and most important is that anyone participating in an experiment must give *informed consent*. This means nobody can be forced to participate in human experiments. All participants must understand the potential risks. …" Science Museum (http://www.sciencemuseum.org.uk/broughttolife/%20techniques/nurembergcode).
[44] Cohen, Jonathon, and Ezer, Tamar, "Human Rights in Patient Care: A Theoretical and Practical Framework," Health and Human Rights Journal, Dec. 10, 2013, Vol. 15 No. 2 (http://www.hhrjournal.org/2013/12/10/human-rights-in-patient-care-a-theoretical-and-practical-framework/).
[45] Constitution of the World Health Organization (http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf?ua=1).
[46] Presently, 164 countries are State Parties to the ICESCR, six countries are Signatories, and twenty-seven countries have taken no action. A "State Party" is a state that has expressed its agreement, by ratification, accession, or succession, for the treaty's entry into force, while a "Signatory" is a state that has provided a preliminary endorsement of the treaty and its intent to examine the treaty domestically and consider ratifying it. While most countries are State Parties to the ICESCR, the United States is a mere Signatory, along with Cuba, Myanmar, Comoros, Palau, and Sao Tome and Principe.
[47] World Health Organization, Office of the United Nations High Commissioner for Human Rights, "The Right to Health," Fact Sheet No. 31 (http://www.ohchr.org/Documents/Publications/Factsheet31.pdf).
[48] European Convention on Human Rights (ECHR) (formally the Convention for the Protection of Human Rights and Fundamental Freedoms) (http://www.echr.coe.int/Documents/Convention_ENG.pdf).
[49] Council of Europe (http://www.coe.int/en/web/about-us/who-we-are).
[50] The Guardian, "What is the European convention on human rights?" (http://www.theguardian.com/law/2014/oct/03/what-is-european-convention-on-human-rights-echr).
[51] *Op. cit.*, FN 45.
[52] Encyclopedia Britannica, "European Convention on Human Rights (ECHR)" (http://www.britannica.com/event/European-Convention-on-Human-Rights-Europe-1950).
[53] *Id*.
[54] *Id*.
[55] *Id*.

[56] World Medical Association Declaration of Lisbon on the Rights of the Patient (http://dl.med.or.jp/dl-med/wma/lisbon2005e.pdf).
[57] Jukka Varelius, affiliated with Center for Professional Ethics, University of Central Lancashire, "The value of autonomy in medical ethics" (http://link.springer.com/article/10.1007/s11019-006-9000-z/fulltext.html).
[58] This paragraph and the next are based on Varelius, *ibid*. *See also*, Glover, 1977, pp. 80–81; Buchanan and Brock, 1990, pp. 38–39; Beauchamp and Childress, 2001, pp. 176–187; 1 Gillon, 2003, p. 310; Harris, 2003, p. 11.
[59] This note and the next are from Varelius, and Beauchamp and Childress (2001, pp. 185– 187) and Glover (1977, p. 75 *cf*. p. 81). All philosophers accepting the view that patients should be allowed to make choices that these patients admit to be bad, or at least not as good as they could be, do not specify whether they think there to be some cases where autonomous patients' self-regarding actions can be restricted.
[60] Harris would seem to hold this kind of view, *op. cit.* FN 53. Harris (2003, p. 11) writes as follows: "Concern for welfare ceases to be legitimate at the point at which, so far from being productive of autonomy, so far from enabling the individual to create her own life, it operates to frustrate the individual's own attempts to create her own life herself."
[61] This conclusion departs from Varelius, who concludes by excluding all but instrumental values in supporting informed consent. This approach moves back toward practitioner centered decision making and assumes that practitioners know, or can know, better that clients, what is best for clients. This is a position that could run afoul of current informed consent laws (or not) depending on the individual circumstances and the state of politics in the jurisdiction where the issues might arises. Reading Varelius, though British, stimulates thinking about these issues for individual in all jurisdictions in including the US.
[62] *Id*.
[63] *Op. cit.*, International Covenant on Economic, Social and Cultural Rights. See full text at Appendix
[64] A policy brief written for a 2008 WHO European Ministerial Conference on Health Systems recognizes that patients can play a valuable role in protecting their own health, choosing appropriate treatments, and managing chronic disease. Coulter, Angela, Parsons, Suzanne, and Askham, Janet, "Where Are the Patients in Decision-Making About Their Own Care?" Policy Brief written for the WHO European Ministerial Conference on Health Systems, 25–27 June 2008 (http://www.who.int/management/general/decisionmaking/WhereArePatientsinDecisionMaking.pdf). The policy paper discusses shared decision-making between physicians and patients. The heart of shared decision-making is the exchange of information between the patient and physician.
An article defines shared decision-making as "a process in which patients are involved as active partners with the clinician in clarifying acceptable medical options and in choosing a preferred course of clinical care". Sheridan SL et al., "Shared decision making about screening and chemoprevention: a suggested approach from the U.S. Preventive Services Task Force," American Journal of Preventive Medicine, 2004, 26(1):56–66 (http://www.ncbi.nlm.nih.gov/pubmed/14700714). The WHO policy paper provides that shared decision-making is beneficial in "preference-sensitive decisions" – cases where several different options exist, no option is clearly superior, therefore making the patient's values of high importance.

[65] New York Law School, Institute for Information Law & Policy in cooperation with the Justice Action Center and Healthcare Information for All by 2015, White Paper Series 11/12 #01, "Access to Health Information under International Human Rights Law," May 2012 (http://www.nyls.edu/documents/institute_for_information_law_and_policy/access_to_health_information/access-to-health-information-white-paper.pdf).
[66] John F. Kennedy, Special Message to the Congress on Protecting the Consumer Interest, March 15, 1962 (http://www.presidency.ucsb.edu/ws/?pid=9108).
[67] The American Hospital Association (AHA) Patient Bill of Rights, replaced by the text of the AHA's "The Patient Care Partnership" can be found at http://www.aha.org/advocacy-issues/communicatingpts/pt-care-partnership.shtml.
[68] United Nations Guidelines for Consumer Protection of 1985. For example: "A. Physical safety…10. Appropriate policies should ensure that goods produced by manufacturers are safe for either intended or normally foreseeable use. Those responsible for bringing goods to the market, in particular suppliers, exporters, importers, retailers and

the like (hereinafter referred to as "distributors"), should ensure that while in their care these goods are not rendered unsafe through improper handling or storage and that while in their care they do not become hazardous through improper handling or storage. Consumers should be instructed in the proper use of goods and should be informed of the risks involved in intended or normally foreseeable use. Vital safety information should be conveyed to consumers by internationally understandable symbols wherever possible…B. Promotion and protection of consumers' economic interests…20. Promotional marketing and sales practices…should be guided by the principle of fair treatment of consumers and should meet legal requirements. This requires the provision of the information necessary to enable consumers to take informed and independent decisions, as well as measures to ensure that the information provided is accurate. F. Education and information programs…31. Governments should develop or encourage the development of general consumer education and information programs, bearing in mind the cultural traditions of the people concerned. The aim of such programs should be to enable people to act as discriminating consumers, capable of making an informed choice of goods and services, and conscious of their rights and responsibilities. In developing such programs, special attention should be given to the needs of disadvantaged consumers, in both rural and urban areas, including low-income consumers and those with low or non-existent literacy levels."

[69] Vilnes and Others v. Norway, at ¶235 (decided December 5, 2013) (http://hudoc.echr.coe.int/eng?i=001-138597#{%22itemid%22:[%22001-138597%22]}). The Court ordered the Norwegian government to pay damages to the divers, ranging individually from €8,000–€50,000.

[70] Consumer Bill of Rights and Responsibilities (http://archive.ahrq.gov/hcqual/press/cbor.html).

[71] A webpage of the Department of Health and Human Services. (http://www.hhs.gov/healthcare/about-the-law/index.html.)

[72] *Ibid*.

[73] *Ibid*.

[74] President's Consumer Bill of Rights and Responsibilities Chapter Four Participation in Treatment Decisions Statement of the Right Last Revised: Thursday, June 25, 1998 http://archive.ahrq.gov/hcqual/cborr/chap4.html

[75] Washington Post editorial November 28, 2015

[76] *Ibid*.

[77] *Ibid*.

[78] "California's dark legacy of forced sterilizations" by Elizabeth Cohen and John Bonifield, CNN, March 15, 2012 (http://www.cnn.com/2012/03/15/health/california-forced-sterilizations/). 60,000 people in 31 states nation wide were sterilized. "California's movement was so effective that in the 1930s, members of the (German) Nazi party asked California eugenicists for advice on how to run their own sterilization program… Germany used California's program as its chief example that this was a working, successful policy." Christina Cogdell, cultural historian at the University of California-Davis and author of Eugenic Design. She stated, "They modeled their law on California's law."

[79] "Virginia governor apologizes for eugenics law," USA Today, May 2, 2002 (http://usatoday30.usatoday.com/news/nation/2002/05/02/virginia-eugenics.htm).

[80] Id.

[81] *Buck v. Bell*, 274 U.S. 200 (1927).

[82] Holmes listed the safeguards: "…the superintendent… may have the operation (sterilization) performed upon any patient afflicted with hereditary forms of insanity, imbecility, &c., on complying with the very careful provisions by which the act protects the patients from possible abuse…the superintendent first presents a petition to the special board of directors of his hospital…verified by affidavit. Notice of… the hearing…the inmate may attend the hearings …the evidence is all to be reduced to writing and, … the inmate, or his guardian, may appeal to the Circuit Court of the County… (which) may consider evidence as may be offered, and may affirm, revise, or reverse the order of the board ...Finally any party may apply to the Supreme Court of Appeals… to hear the case upon the record of the trial."

[83] "Eugenics & The Story of Carrie Buck," Margarita Tartakovsky, M.S., Associate Editor, World of Psychology (http://psychcentral.com/blog/archives/2011/01/24/eugenics-the-story-of-carrie-buck/).

[84] *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942) (*citing Buck v. Bell*, 274 U.S. 200, 538). (https://www.law.cornell.edu/supremecourt/text/316/535#.)

[85] *Ibid*. at 545.
[86] *Ibid*. at 541.
[87] Paul A. Lombardo, Ph.d, J.D., Three Generations, No Imbeciles: Eugenics, the Supreme Court and Buck v. Bell, Johns Hopkin University Press (2008, paper 2010) (http://buckvbell.com/index.html). Lombardo interviewed Carrie Buck, who died January 28, 1983. In "Carrie Buck's Daughter" (Natural History magazine, July 1984), Stephen Jay Gould writes: "As scholars and reporters visited Carrie buck and her sister what a few experts had known all along became abundantly clear to everyone. Carrie Buck was a woman of obviously normal intelligence." (https://conservancy.umn.edu/bitstream/handle/11299/164572/02_02_Gould.pdf.)
[88] Peguin Press an unorend if Oeguin Randum House LLC 375 Hudson street New York New York copyright © 2016 Adam cohen
[89] Justice Holmes cited *Jacobson v. Massachusetts*, 197 U. S. 11 (1905), which upheld a Massachusetts law that established a fine for refusing a mandatory vaccination.
[90] For the opinion and overview of the case, see http://law.jrank.org/pages/24660/Buck-v-Bell-Other-Applications-Result-from-Buck-v-Bell.html and http://law.jrank.org/pages/13291/Buck-v-Bell.html.
[91] *Op. cit.*, FN 42.
[92] "Are Good Doctors Bad for Your Health?" November 21, 2015, New York Times. Dr. Emmanuel co-authored the JAMA Article "Four models of the physician-patient relationship" (o*p. cit.*, note 11).
[93] The article discussed by Dr. Emanuel was "Mortality and Treatment Patterns Among Patients Hospitalized With Acute Cardiovascular Conditions During Dates of National Cardiology Meetings," Anupam B. Jena, MD, PhD; Vinay Prasad, MD4; Dana P. Goldman, PhD; John Romley, Ph.D, Journal of the American Medical Association Internal Medicine (http://archinte.jamanetwork.com/article.aspx?articleid=2038979).
[94] (AMI) Acute Myocardial Infarction occurs when myocardial ischemia, a diminished blood supply to the heart, exceeds a critical threshold and overwhelms myocardial cellular repair mechanisms designed to maintain normal operating function and homeostasis. Ischemia at this critical threshold level for an extended period results in irreversible myocardial cell damage or death (http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/acute-myocardial-infarction/).
[95] "(PCI), Percutaneous coronary intervention also known as coronary angioplasty, is a nonsurgical technique for treating obstructive coronary artery disease, including unstable angina" (http://emedicine.medscape.com/article/161446-overview).
[96] "Feasibility Study of a Systematic Approach for Discontinuation of Multiple Medications in Older Adults," Doron Garfinkel, MD, Derelie Mangin, MBChB, Arch Intern Med. 2010; 170(18): 1648-1654 (http://archinte.jamanetwork.com/article.aspx?articleid=226051). The study involved elderly patients.
[97] Dr. Knut Sroka, "Do heart catheters and the insertion of stents really help?" (http://heartattacknew.com/faq/do-heart-catheters-and-the-insertion-of-stents-really-help/).
The Mayo Clinic study referred to the article, "Indications for Coronary Artery Bypass Surgery and Percutaneous Coronary Intervention in Chronic Stable Angina Review of the Evidence and Methodological Considerations," Charanjit S. Rihal, MD; Dominic L. Raco, MD; Bernard J. Gersh, MB, ChB, DPhil; Salim Yusuf, FRCP, DPhil. The article is accessible on a website of the American Heart Association at http://circ.ahajournals.org/content/108/20/2439.full.
[98] World Health Organization, "Antimicrobial Resistance" Fact sheet N°194, updated April 2015 (http://www.who.int/mediacentre/factsheets/fs194/en/).
[99] *Op. cit.*, FN 17.
[100] *Ibid*.
[101] Dr. Emanuel effects and reflects these cultural currents. He has an M.D. and a Ph.D. in political philosophy from Harvard. He did his internship and residency, and then an oncology fellowship at Boston's Beth Israel Hospital and the Dana-Farber Cancer Institute respectively. He served on the faculties of Harvard, Johns Hopkins and Stanford Medical Schools. He was a visiting professor at UCLA and New York University Law School. He has written and edited 9 books and over 200 scientific articles. He is currently a columnist for the New York Times. He appears regularly on television shows including Morning Joe and Hardball with Chris Matthews. He sits at the crossroad of academic medicine and public information (news) observing and shaping events and opinions.

[102] In the U.S., Indiana passed a law in 1909, California's law ended in 1979, and Virginia's law was in force from 1924 to 1974.

[103] Tuskegee syphilis experiment Wikipedia, the free encyclopedia summarizes The Tuskegee Study of Untreated Syphilis in the Negro Male, also known as the Tuskegee Syphilis Study or Tuskegee Syphilis Experiment ("Tuskegee" = /tʌsˈkiːgiː/) saying it was an infamous clinical study conducted between 1932 and 1972 by the U.S. Public Health Service studying the natural progression of untreated syphilis in rural African-American men in Alabama under the auspices of receiving free health care from the United States government.
https://en.wikipedia.org/wiki/Tuskegee_syphilis_experiment

[104] **Guatemala syphilis experiment,** American medical research project that lasted from 1946 to 1948 and is known for its unethical experimentation on vulnerable human populations in Guatemala. The intent of the study was to test the value of different medications, including the antibiotic penicillin and the arsenical agent orvus-mapharsen, in the prevention of symptom emergence following infection with certain sexually transmitted diseases (STDs). A diagnostic testing arm of the study investigated methods to refine STD screening techniques. The total study population included more than 5,500 Guatemalan prisoners, sex workers, soldiers, children, and psychiatric patients, about one-quarter of whom were deliberately infected with syphilis, gonorrhea, or chancroid and all of whom were enrolled in the experiments without their consent. Encyclopedia Britannica
http://www.britannica.com/event/Guatemala-syphilis-experiment

[105] The Willowbrook Study: From 1963 to 1966, in order to study the history of the hepatitis when left untreated and later to assess the effects of gamma globulin as a therapeutic intervention, researchers infected a group of children diagnosed with mental retardation, who lived at the Willowbrook State Hospital in Staten Island, New York with the hepatitis virus. Early subjects were fed extracts of stools from infected individuals and later subjects received injections of more purified virus. Investigators defended the injections by pointing out that the vast majority of the children acquired the infection anyway while at Willowbrook, and it would be better for them to be infected under carefully controlled research conditions. The study's purpose was to study the history of the disease when left untreated and later to assess the effects of gamma globulin as a therapeutic intervention. (http://www.und.edu/instruct/wstevens/PROPOSALCLASS/MARSDEN&MELANDER2.htm.)

[106] "Ugly past of U.S. human experiments uncovered," Mike Stobbe, Associated Press, 2/27/2011 (http://www.nbcnews.com/id/41811750/ns/health-health_care/t/ugly-past-us-human-experiments-uncovered/#.VvKxOhD4Jm8).

[107] *Op. cit.*, note 101.

[108] "Informed Consent for Medical Treatment and Research: A Review," Marcela G. del Carmen and Steven Joffe, July 15, 2005, The Oncologist (http://theoncologist.alphamedpress.org/content/10/8/636.full#ref-18).

[109] 45 C.F.R. 46.116 (Part 45 – Protection of Human Subjects, Subpart A – Basic HHS Policy for Protection of Human Research Subjects, Sec. 46.116 – General Requirements for Informed Consent).

[110] 21 C.F.R. 50.25 (Part 50 – Protection of Human Subjects, Subpart B – Informed Consent of Human Subjects, Sec. 50.25 – Elements of Informed Consent).

[111] Department of Health and Human Services, Frequently Asked Questions (http://www.hhs.gov/ohrp/policy/faq/informed-consent/what-does-coercion-or-undue-influence-mean.html#).

[112] *Ibid*.

[113] *Ibid*.

[114] Appelbaum PS, Roth LH, Lidz CW et al. "False hopes and best data: consent to research and the therapeutic misconception." Hastings Cent Rep 1987;17:20–24.

[115] Lederer SE. Subjected to Science: Human Experimentation in America Before World War II. Baltimore: Johns Hopkins University Press, 1995:1–192.

[116] The Declaration of Helsinki is discussed above in section III, History and Policy: Legal and Ethical Rules Governing Informed Consent/Choice, at p. 9 of this paper.

[117] A good summary of this issue is presented by attorney Sherman Silverstein at http://www.sskrplaw.com/the-double-blind-placebo-controlled-trial-the-fool-s-gold-standa.html.

[118] The Declaration of Helsinki includes the following footnote to Section 29: Note of clarification on paragraph 29 of the WMA Declaration of Helsinki:

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:
- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or
- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

[119] "A Family Consents to a Medical Gift, 62 Years Later," Aug. 7, 2013, Carl Zimmer, The New York Times (http://www.nytimes.com/2013/08/08/science/after-decades-of-research-henrietta-lacks-family-is-asked-for-consent.html?_r=0).
[120] California Senate Bill No. 277 (https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB277).
[121] SB 277 requires the following vaccines: Polio (OPV or IPV); Diphtheria, Tetanus, and Pertussis (DTaP, DTP, DT, or Tdap); Measles, Mumps, and Rubella (MMR or MMR-V); Hepatitis B (Hep B or HBV); Varicella (chickenpox, VAR, MMR-V or VZV) (http://eziz.org/assets/docs/IMM-222School.pdf).
[122] The Vaccine Injury Table can be found at http://www.hrsa.gov/vaccinecompensation/vaccinetable.html.
[123] The CDC meets its obligation to inform about injury compensation by stating the following in every Vaccine Information Sheet (VIS): "The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines. Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling 1-800-338-2382 or visiting the VICP website. There is a time limit to file a claim for compensation."
[124] Centers for Disease Control and Prevention, "Instructions for Using VISs" (http://www.cdc.gov/vaccines/hcp/vis/about/required-use-instructions.html).
[125] The vaccine injury table is created in accordance with section 312(b) of the National Childhood Vaccine Injury Act of 1986, title III of Pub.L. 99–660, 100 Stat. 3779 (42 U.S.C. 300aa–1 note) and section 2114(c) of the Public Health Service Act (42 U.S.C. 300aa–14(c)).
[126]Department of Health and Human Services (http://www.hrsa.gov/vaccinecompensation/index.html).
[127] *Ibid*.
[128] The Vaccine Adverse Event Reporting System is co-sponsored by the Centers for Disease Control and Prevention and the Food and Drug Administration (https://vaers.hhs.gov/index).
[129] *Op. cit.*, note 122.
[130] http://www.hrsa.gov/vaccinecompensation/
[131] 42 U.S.C. Chapter 6A (Title 42 – The Public Health and Welfare, Chapter 6A – Public Health Service, Subchapter XIX – Vaccines) (https://www.law.cornell.edu/uscode/text/42/chapter-6A/subchapter-XIX).
[132] The U. S. Court of Federal Claims decides who will be paid. Three Federal government offices have a role in the Vaccine Injury Compensation Program: the U.S. Department of Health and Human Services; the U.S. Department of Justice; and the U.S. Court of Federal Claims.
[133]Vaccine Injury Compensation Trust Fund Monthly Reports are accessible at http://www.treasurydirect.gov/govt/reports/tfmp/vaccomp/vaccomp.htm.
[134] Vaccine Adverse Event Reporting System, "About the VAERS Program"(https://vaers.hhs.gov/index/about/index).
[135] Intussusception (in-tuh-suh-SEP-shun) is a serious condition in which part of the intestine slides into an adjacent part of the intestine. Intussusception is the most common cause of intestinal obstruction in children younger than 3. (http://www.mayoclinic.org/diseases-conditions/intussusception/home/ovc-20166951.)
[136]Guillain-Barré syndrome (GBS) is a disorder in which the body's immune system attacks part of the peripheral nervous system. The first symptoms of this disorder include varying degrees of weakness or tingling sensations in the legs. When severe, the person is almost totally paralyzed. In these cases the disorder is life threatening. (http://www.ninds.nih.gov/disorders/gbs/detail_gbs.htm.)
[137] "What CDC statistics say about vaccine-related illnesses, injuries and death," Aaron Sharockman, February 3, 2015, PunditFact (http://www.politifact.com/punditfact/statements/2015/feb/03/bob-sears/what-cdc-statistics-say-about-vaccine-illnesses-in/).
[138] Vaccine Adverse Event Reporting System, "VAERS Data" (https://vaers.hhs.gov/data/index).

[139] U.S. Department of Health and Human Services, "Vaccine Injury Compensation Data" (http://www.hrsa.gov/vaccinecompensation/data/index.html).
[140] *Ibid*.
[141] "Healthy Children & Adults Vaccinated with Flu Short are Dying," Jan. 4, 2015, VaxTruth (http://vaxtruth.org/2015/01/flu-shot-kills/).
[142] The parents formed the National Vaccine Information Center (NVIC) (http://www.nvic.org/), and were original supporters of the National Childhood Vaccine Injury Act of 1986 (http://www.nvic.org/injury-compensation/origihanlaw.aspx).
[143] "The 1986 National Childhood Vaccine Injury Act is a failed experiment in tort reform and should be repealed so vaccine manufacturers are accountable and liable in a civil court of law for product safety," said NVIC co-founder and president Barbara Loe Fisher. "The federal vaccine injury compensation program Congress created under that law has become a drug company stockholder's dream and a parent's worst nightmare." Business Wire, Nov. 10, 2015 (http://www.businesswire.com/news/home/20151110005610/en/National-Vaccine-Information-Center-NVIC-Calls-Repeal).
[144] For a new generation of activist parents, see the following websites: Stop Mandatory Vaccination: Vaccines Don's Save Lives, Healthy Immune Systems Do! at http://www.stopmandatoryvaccination.com/public-health/; Fearless Parent at http://fearlessparent.org/; and Fearless Parent Radio at http://fearlessparent.org/fearless-parent-radio/radio-cohosts/louise-kuo-habakus/. For science-based perspectives, see Vaccine Epidemic: How Corporate Greed, Biased Science, and Coercive Government Threaten Our Human Rights, Our Health, and Our Children by Louise Kuo Habakus (Editor) and Mary Holland (Editor) (http://www.amazon.com/Vaccine-Epidemic-Corporate-Coercive-Government-ebook/dp/B004ULLOIC).
[145] *Ibid*.
[146] Posey hearings (https://www.youtube.com/watch?v=uNWTOmEi_6A).
[147] Congressman Posey Floor Statement (https://www.youtube.com/watch?v=qxr-cv-JuI8).
[148] Robert F. Kennedy, Jr., "Mercury & Vaccines, RFK, JR manifesto on mercury and vaccines" (http://www.robertfkennedyjr.com/vaccines.html).
[149] Robert F. Kennedy Jr., "Deadly Immunity, Government Cover-up of a Mercury/Autism Scandal," Rollingstone.com, July 2005 (http://www.robertfkennedyjr.com/articles/deadly_immunity.2005.html).
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[162] *National Federation of Independent Business v. Sebelius*, 567 U.S. ___, 132 S. Ct 2566, (2012) Opinion of Chief Justice Roberts.
[163] *Ibid*., p. 4 to 16 for entire discussion.
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[165] *Ibid*., p. 43 and 44.
[166] *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).
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[168] Prof. Lawrence O. Gostin, J.D., of the Center for the Law and the Public's Health, Georgetown University Law Center, "Jacobson v Massachusetts at 100 Years: Police Power and Civil Liberties in Tension," April 2005 (http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1449223/).
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[170] *Ibid*. "… a public health regulation is unconstitutional if the human burden imposed is wholly disproportionate to the expected benefit."
[171] *Ibid*. Professor Gostin states: "Public health authorities have a constitutional responsibility not to overreach in ways that unnecessarily invade personal spheres of autonomy. This suggests a requirement for a reasonable balance between the public good to be achieved and the degree of personal invasion. If the intervention is gratuitously onerous or unfair, it may overstep constitutional boundaries."
[172] *Ibid*. "If there had been evidence that the vaccination would seriously impair Jacobson's health, he may have prevailed in this historic case. Jacobson-era cases reiterate the theme that public health actions must not harm subjects. Notably, courts required safe and habitable environments for persons subject to isolation or quarantine on the grounds that public health powers are designed to promote well-being and not punish the individual."
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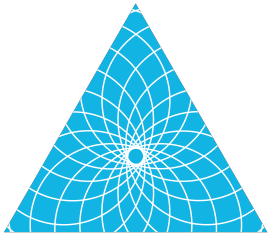
[179] American Medical Association Code of Medical Ethics, Opinion 8.08 –Op Cit note 1.



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