What You Should Know About Informed Consent and COVID Vaccines

The federal government, military, big businesses and more than 450 U.S. colleges and universities have attempted to mandate COVID vaccines for their employees, members or students while using a national pandemic to justify diluting informed consent.

Individuals are not being informed about the true dangers and risks of receiving a COVID vaccine, nor are they being informed of inexpensive and effective COVID treatment options that could save their lives. Many patients have died in hospitals as administrations refuse to allow access to certain FDA-approved medications, and thousands have experienced disabling vaccine injuries, including death, as U.S. health agencies refuse to publically acknowledge the injured.

People with natural immunity to COVID are being forced to receive a vaccine that gives them no benefit while subjecting them to risks, pregnant women across the country are being

forced to receive a vaccine that has never been tested for safety or efficacy in pregnant women, patients on the transplant list are being told they will not receive the organs they need to live unless they receive a vaccine that is shown to be ineffective in the immunocompromised and children are receiving a vaccine for a disease that is extremely mild in that age group, has an almost 100% survival rate and contains ingredients that were not in the vaccine actually used in clinical trials.

These actions are unprecedented in our society, and many believe it will ultimately result in Nuremberg 2.0 – the first of which occurred in 1947 where judges from the four allied powers sat in judgment of twenty-three Nazi defendants, 20 of whom were physicians, accused of conducting horrific experiments on human subjects in concentration camps during the Holocaust.

Informed consent to medical treatment is a fundamental right in both ethics and law, and refers to the obligation of the physician to disclose to a patient all of the potential benefits, risks and alternatives involved with any medical procedure or course of treatment – and requires the physician obtain the patient's written consent (absent very limited exceptions) to proceed.

The concept of informed consent is based on the principle that a physician has a duty to disclose information to the patient so he/she can make a reasonable, voluntary decision regarding treatment.

According to the American Academy of Pediatrics, the doctrine of informed consent was birthed from the legal concept of battery and the ethical principle of bodily autonomy – the right of individuals to make their own decisions when it comes to their bodies.

Informed consent became a vital part of patients' rights in

the 1970s when the court in Canterbury v. Spence found that a patient must be fully informed by the physician or other health care provider so that he or she can make an intelligent choice as to which medical procedure if any, to undergo.

As it pertains to vaccines, doctors and nurses administering vaccines are required by law to provide informed consent, (although it goes without saying that they too should be properly informed by U.S. health agencies). Any medical treatment, including vaccination, in the absence of properly informed consent, can subject one to civil and criminal liability.

To exercise the right of informed consent, a patient is entitled to information of a sufficient nature to allow him/her to make an informed decision on whether or not to consent or refuse treatment. This means considering the patient's condition, proposed benefits of the treatment, long-term outcomes, material risks and potential side effects, alternative options and benefits/risks of each option.

It also requires the information be given to the patient in an easy-to-digest way, and that he/she is allowed time to make an informed, voluntary decision.

Physicians must communicate information to their patients that is "material" to the decision at hand, including all risks associated with the procedure that might influence the patient's decision. A risk is "material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."

In other words, if a physician fails to inform a patient of risks that he or she knows are important or that may have an impact on the patient's decision about the proposed therapy, then the physician is legally liable for not fully informing

the patient.

According to the American College of Obstetrics and Gynecology (ACOG), "informed consent is a core component of the ethical clinical relationship. As with all forms of medical therapy, informed consent should precede vaccination administration."

> *"In the informed consent discussion, health care professionals should present information central to the decision-making process for vaccination, including the indications, risks and benefits of the vaccine and available alternatives […]. Withholding vaccination, or information about vaccination, is unacceptable because it violates the ethical obligations to respect patient autonomy and promote patient well-being."*

The Nuremberg Code, arguably the most important document in the history of medical research ethics, arising out of the Nuremberg Military Tribunal's decision in U.S. v. Karl Brandt, defined permissible medical experimentation on human subjects and serves as a blueprint for informed consent.

The Nuremberg Code states that voluntary consent of the human subject is absolutely essential, and qualifies "voluntary consent" as follows:

> *"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, overreaching 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.*
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> *"The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and*

> *responsibility which may not be delegated to another with impunity."*

The fundamental right of bodily integrity has also been recognized in U.S. law. For example, in Union Pac. Ry. Co. v. Botsford, the Supreme Court held, "No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law."

In Washington v. Harper, the court held, "The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty."

Applying Jacobson v. Massachusetts – the famous smallpox vaccination case – to present times, scholars at Boston University wrote:

> *"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.*
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> *"Even in an emergency, when there is a rapidly spreading contagious disease and an effective vaccine, the state is not permitted to forcibly vaccinate or medicate anyone."*

In 2014, the U.S. Food and Drug Administration created draft guidance for informed consent that represents the agency's "current thinking on this topic." The draft guidance states that the conditions under which "informed consent is sought and the relationship between the subject and the person

obtaining consent must be carefully considered to minimize the possibility of coercion or undue influence."

Citing the Belmont Report, the FDA said "coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance."

In addition, informed consent requires a description of the clinical investigation, a description of foreseeable risks, a description of any benefits, alternative treatments, compensation for any injury, confidentiality, voluntary participation and a statement that the particular treatment or procedure may involve risks to the subject" (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable."

According to the Centers for Disease Control and Prevention (CDC) for each COVID vaccine authorized under an Emergency Use Authorization (EUA), the FDA requires that vaccine recipients or their caregivers are provided with certain information to help them make an informed decision about vaccination. This, the CDC says, is accomplished by providing an EUA "Fact Sheet for Recipients and Caregivers."

However, the EUA fact sheets do not provide complete or accurate information. For example, the thousands of neurological conditions and deaths reported to the CDC's Vaccine Adverse Event Reporting System following administration of the Pfizer/BioNTech vaccine are not included on the list of "adverse events reported with the vaccine" on the FDA's Pfizer fact sheet given to patients.

The Johnson & Johnson EUA fact sheet fails to list aborted fetal cells as an ingredient in their COVID vaccine, although aborted fetal cells from the PER.C6 cell line are an

ingredient in their vaccine and is listed in the fact sheet for healthcare providers.

Several EUA fact sheets state the vaccine "prevents COVID-19," despite thousands of breakthrough cases reported to the CDC, waning immunity, and statements by vaccine manufacturers that their products are designed to reduce disease severity at best.

In order to have proper informed consent with COVID vaccines, all risks must be disclosed, data must be provided accurately by pharmaceutical companies and U.S. health agencies, patients must be informed of alternatives and receiving a COVID vaccine must be voluntary.

If a person is coerced or placed under duress to receive a COVID vaccine, than arguably, informed consent is not present and this would not only violate bodily autonomy, but human rights and numerous laws.