Informed Consent Ralph Fucetola JD

ABSTRACT

The first right is *self-ownership*. Each person has the sole right to determine what may happen to his or her own body. No one's body may be invaded without that person's consent. *Informed Consent* is a fundamental human right protected against diminishment through legislative and administrative agency denial of philosophical or religious conscientious objections to medical interventions, including mandated vaccination. Informed Consent is separate from statutory exemptions and may not be abolished by legislative act. The right to informed consent is meaningless without the right to refuse any medical intervention, including vaccination. Government agents and those acting under color of law are forbidden by long-standing national and international law from coercing vaccination.

"If a man has the right to self-ownership, to the control of his life, then in the real world he must also have the right to sustain his life..." Murray N. Rothbard1

This article has been written to vindicate International Humanitarian Law regarding Informed Consent to any and all medical interventions, including vaccination, even during any declared local, national or international "health emergency." The right to Informed Consent must be respected, whether that refusal is grounded in philosophical, medical, religious or no reasons at all.

Abstract

Point One: The Legal Basis for Informed Consent

Point Two: Government Regulation

Point Three: International Law Protects Informed Consent Point Four: The Right Must Be Asserted to Be Protected

Point Five: The Right May Not Be Defeated by Unconstitutional Conditions

Conclusion

Point One: The Bill of Rights' Speech, Privacy and Association Rights are the Basis for Informed Consent.

Implementing the general law as applied to the protection of human life is mandated, in the instance of vaccination, by the United States Supreme Court, which held that the courts "are not without power..." regarding vaccination in the case of *Jacobson vs Commonwealth* of *Massachusetts*2

In 1914, Judge (later Supreme Court Justice) Benjamin Cardozo validated the concept of voluntary consent when he noted that every human being has a right to decide what shall be done

¹ Murray Newton Rothbard (1978). "For a New Liberty: The Libertarian Manifesto", p.52, Ludwig von Mises Institute

² Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11 (1905)

with his or her body, deeming medical intervention without Informed Consent an unlawful trespass:

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."3

Federal Regulation acknowledges Informed Consent for formal Institutional Review Board (IRB – required for FDA approved medical experiments) overseeing experimentation.4 The recognition of the application of Informed Consent during the less formal "final stage" of experimentation on drugs (including vaccines) released to the public is not adequately implemented by law or regulation, "...Phase 4 trials are conducted after a product is already approved and on the market to find out more about the treatment's long-term risks…"5

With regard to all communications about health care decisions, the members of the public have the right to make informed consent decisions, even if a decision may be considered a "bad" decision by the Government. The Supreme Court indicated, in *Thompson v Western States*:6

"We have previously rejected the notion that the Government has an interest in preventing the dissemination of truthful commercial information in order to prevent members of the public from making bad decisions with the information."

The United States is bound to observe the Nuremberg Code by virtue of the Subsequent Nuremberg Trials7 and subsequent exacting of justice through penalties, including the death penalty. The Geneva Conventions (the international treaties that go vern humanitarian requirements)8 require that the United States be bound by these international humanitarian principles. Thus the United States is treaty-bound to implement fully Informed Consent.

Even in an emergency situation the Government Agencies involved must take a pro-active role in the full implementation of Informed Consent without "the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion..."9

The public has a right to know, and the governments on the federal and state levels have an obligation to provide, clear information regarding the Informed Consent, to the end that government approvals, requirements, mandates and recommendations are understood to be subject to the Right of Informed Consent. Intervention by the courts must vindicate this Right.

Point Two: Government Regulation

³ Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914)

⁴ http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm

⁵ http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm

⁶ Thompson v. Western States Medical Center, 535 U.S. 357 (2002)

⁷ http://en.wikipedia.org/wiki/Subsequent Nuremberg trials

⁸ https://en.wikipedia.org/wiki/Geneva Conventions

⁹ http://www.hhs.gov/ohrp/archive/nurcode.html

Government Agencies have No Legitimate Interest in Promoting FDA-Approved Vaccination Mandates in Violation of Informed Consent.

In the case of *State v Biggs* 10 the North Carolina Supreme Court dealt with a person who was advising people as to diet, and administering massage, baths and physical culture. In the *Biggs* case, the defendant "advertised himself as a 'nonmedical physician'... [and] held himself out to the public to cure disease by 'a system of drugless healing'..." p.401.

That Court held that there could be no "state system of healing" p.402 and while "Those who wish to be treated by practitioners of medicine and surgery had the guaranty that such practitioners had been duly examined... those who had faith in treatment by methods not included in the 'practice of medicine and surgery' as usually understood, had reserved to them the right to practice their faith and be treated, if they chose, by those who openly and avowedly did not use either surgery or drugs in the treatment of diseases..." p.402.

There is no compelling government interest in controlling people associating together for the improvement of their well-being.

The North Carolina Supreme Court concluded, a century ago in *State v Biggs, supra.*, at p.405:

"Medicine is an experimental, not an exact science. All the law can do is to regulate and safeguard the use of powerful and dangerous remedies, like the knife and drugs, but it cannot forbid dispensing with them. When the Master, who was himself called the Good Physician, was told that other than his followers were casting out devils and curing diseases, he said, 'Forbid them not.'" (p.405).

FDA approved drugs, including vaccines, remain in an experimental state, which the FDA calls "Phase 4" of the clinical trials system.11

Unless affirmatively and effectively asserted an individual's Fundamental Right to Informed Consent, the legal ability to resist unwanted medical interventions, such as vaccines and other invasive techniques, may be ignored by the medical system under government directive. Based on the ancient legal principle that "silence is acquiescence" 12 martial law or medical emergency authorities may presume that you consent to even experimental medical interventions, as we saw imposed by WHO dictum during the 2014 Ebola Panic 13. The same is true of medical practice in "ordinary times".

¹⁰ State v Biggs (46 SE Reporter 401, 1903)

^{11 &}quot;Phase 4 trials are conducted after a product is already approved and on the market to find out more about the treatment's long-term risks, benefits, and optimal use, or to test the product in different populations of people, such as children." Downloaded July 8, 2015: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm 12 "qui tacet consentire videtur" – "Thus, silence gives consent." Sometimes accompanied by the proviso "ubi loqui debuit ac potuit", that is, "when he ought to have spoken and was able to".

 $http://en.wikipedia.org/wiki/List_of_Latin_phrases_\%\,28Q\%\,29$

¹³ http://www.who.int/mediacentre/news/statements/2014/ebola-ethical-review-summary/en/

After the horrors of the Second World War, including the murder and abuse of millions with the complicity of the "health care" authorities of various warring parties, the international community developed conventions and declarations to the end that "Never Again!" would – or could – the health system or health professionals be used to harm either individuals or whole populations. Those prohibitions and protections remain binding today.

A key element in the international protections secured by the Allied Victory and subsequent codification of health-related international law was recognition that no person could be forced to accept any medical intervention that was contrary to conscience and that all medical interventions were to be carried out only with fully informed [and therefore meaningfully willing] consent.

This has been international law for millennia, starting with the Hippocratic Oath in which doctors swore "I will take care that [my patients] suffer no hurt or damage" and "Nor shall any man's entreaty prevail upon me to administer poison to anyone…" 14

Point Three: International Law Protects the Right of Informed Consent

Among the Post World War II protective codifications were the Universal Declaration of Rights, Geneva Declaration 15 and the Nuremberg Code which state, concerning the rights of all human beings and the obligation for ethical action by health personnel:

"Everyone has the right to life, liberty and security of person... No one shall be subjected to ... inhuman or degrading treatment ... Everyone is entitled in full equality to a fair and public hearing by an independent and impartial tribunal, in the determination of his rights... No one shall be subjected to arbitrary interference with his privacy, family, home or correspondence..."16

"I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat..."17

"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

¹⁴ http://en.wikipedia.org/wiki/Hippocratic_Oath

¹⁵ The Geneva Conventions comprise four treaties, and three additional protocols, that establish the standards of international law for the humanitarian treatment of war. The singular term Geneva Convention usually denotes the agreements of 1949, negotiated in the aftermath of the Second World War (1939–45), which updated the terms of the first three treaties (1864, 1906, 1929), and added a fourth. http://en.wikipedia.org/wiki/Geneva_Conventions 16 http://www.un.org/en/documents/udhr/

¹⁷ http://www.wma.net/en/30publications/10policies/g1/index.html

sufficient knowledge and comprehension of the elements of the subject matter involved, as to enable him to make an understanding and enlightened decision."18

This salutary development of international law has continued with international standards promulgated, such as the UNESCO Universal Bioethics Declaration 19 about which it has been said:

Even apart from article 7 of the ICCPR, ethical requirements for informed consent before medical or scientific treatment probably constitute international law as involving "general principles of law" under article 38 (1) (c) of the *Statute of the International Court of Justice*. The reference to "civilised nations" in this context could well introduce an ethical requirement to such evaluations that many contemporary developed nations may fail.20

Defining Informed Consent

"Informed consent is a process for getting permission before conducting a healthcare intervention on a person... In the United Kingdom and countries such as Malaysia and Singapore, informed consent in medical procedures requires proof as to the standard of care to expect as a recognized standard of acceptable professional practice (the Bolam Test), that is, what risks would a medical professional usually disclose in the circumstances (see Loss of right in English law). Arguably, this is "sufficient consent" rather than "informed consent." ... Medicine in the United States, Australia, and Canada take a more patient-centric approach to "informed consent." Informed consent in these jurisdictions requires doctors to disclose significant risks, as well as risks of particular importance to that patient. This approach combines an objective (the reasonable patient) and subjective (this particular patient) approach."21

Point Four: The Right Must Be Asserted to Be Preserved

Where there is no recognition of the legal duty to obtain informed consent, the individual or guardian *must* assert the Right or it may unlawfully assumed or deemed to have been waived. International Humanitarian Law is clear: without clear, affirmative, memorialized informed consent, it must be concluded that Informed Consent has been withheld.

¹⁸ http://www.hhs.gov/ohrp/archive/nurcode.html

¹⁹ http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html which provides: 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. Article 28 – Nothing in this Declaration may be interpreted as implying for any State, group or person any claim to engage in any activity or to perform any act contrary to human rights, fundamental freedoms and human dignity...

²⁰ http://jme.bmj.com/content/31/3/173.full

²¹ http://en.wikipedia.org/wiki/Informed_consent

The essential importance of asserting the Right to preserve it is shown by the 2013 US Supreme Court case of *Missouri vs McNeely*, where the warrantless extraction of blood was ruled illegal as the defendant "refused to consent." Had McNeely remained silent, the blood test would have been allowed.22

The Court opined,

Even a "...diminished expectation of privacy does not diminish the... privacy interest in preventing a government agent from piercing the... skin. And though a blood test conducted in a medical setting by trained personnel is less intrusive than other bodily invasions, this Court has never retreated from its recognition that any compelled intrusion into the human body implicates significant, constitutionally protected privacy interests..." (page 15; emphasis added).

If the removal of blood "implicates significant, constitutionally protected privacy interests..." it is fair to assume that other invasive medical techniques including the introduction of vaccine toxins into the body that have been held to be "unavoidably unsafe"23 will also give rise to such concerns.

The Constitution of the United States recognizes certain Rights held by people and delegates certain limited Powers to the government. Without clear respect for those Rights, the judicial system and the administration of government will fail to protect the truly fundamental interests of civil society, including the Right to Informed Consent.

An earlier Supreme Court understood this, when in 1905 in *Jacobson v Massachusetts*, the Court declared the judicial power to extend to protecting people from forced vaccination.

While giving due deference to the State authorities, the Supreme Court reserved for the Federal Courts the right to intervene in matters where health and life may be at stake:

"...if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination or that vaccination, by reason of his then condition, would seriously impair his health or probably cause his death." [Emphasis added.]24

In a regime of verbal obfuscation of fundamental Right, only the clear assertion of the Right will prevent degradation of the Right "by a thousand (bureaucratic) cuts..." If McNeely had not engaged in protected speech stating he did not consent, the taking of his blood would probably have been allowed.

²² *Missouri vs McNeely*, 569 US 141 (2013) – The recent June 27, 2019 Supreme Court case of *Mitchell vs Wisconsin* (No. 18-6210), in holding that a warrant is not needed for a blood-draw from an *unconscious arrested* person further shows the important role of *expressing* one's refusal to grant Informed Consent.

²³ See Justice Sotomayor's 2011 dissent in *Bruesewitz vs Wyeth*, where she discusses the history of "unavoidably unsafe." https://www.law.cornell.edu/supct/html/09-152.ZD.html

²⁴ Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11 (1905)

The question then becomes, "How is one to effectively assert the Right to Informed Consent, enshrined in International Humanitarian Law, for oneself and those over whom one has guardianship?" Thus, there is a need for strong Statutory and Regulatory protections for the Right, whether exercised by <u>Advanced Medical Directive</u> or otherwise, in situations that do not involve a formal Institutional Review Board (IRB)25.

Point Five: Government Action Imposes an Unconstitutional Condition on the Constitutionally Protected Right to Informed Consent

The well-established law of Unconstitutional Conditions has particular relevance in the case before any Court wherein a party is faced with the harsh choice of vaccinating the child or having the child banned from the public benefit of public education, required by law for all children. Any law, regulation or policy imposing school vaccine mandates where the parent is faced with denying his or her own expressed beliefs or preferences (beliefs thereby protected under the First Amendment) or denying the child access to public education, is an action "under color of law" that forces coerced consent..

This is precisely the type of duress condemned by the Nuremberg Code.

It is also clearly conditioning the acceptance of a public benefit on the surrender of a right.

The law of Unconstitutional Conditions is well-represented in the jurisprudence of the United States Supreme Court and the Courts it oversees.

We do not pretend to more expertise on the issue than the Court's own pronouncements.

The Supreme Court first mentions the phrase in *Doyle v. Continental Ins. Co26* (Badley, J., dissenting) "Though the State may have the [police] power... it has no power to impose unconstitutional conditions..."

In *Frost v Railroad Commission*27 the Court held it "would be a palpable incongruity to strike down an act of state legislation which, by words of express divestment seeks to strip the citizen of rights guaranteed by the federal Constitution, but to uphold an act by which the same result is accomplished under the guise of a surrender of a right in exchange for a valuable privilege which the state threatens otherwise to withhold... it may not impose conditions which require the relinquishment of constitutional rights."

More recently the Court applied the principle to First Amendment speech rights arising from expressive association issues directly in point here where First Amendment protected religious expressive association is involved. In *Speiser v Randall*28

²⁵ http://www.inhere.org/institutional-review-board/

²⁶ Doyle v. Continental Ins. Co., 94 U.S. 535, 543 (1876)

²⁷ Frost v Railroad Commission, 271 U.S. 583,594 (1925)

²⁸ Speiser v Randall, 357 U.S. 513, 526 (1958)

"In practical operation, therefore, this procedural device must necessarily produce a result the State could not command directly. It can only result in a deterrence of speech which the Constitution makes free."

And finally, of particular note is the statement in *Perry v Sindermann*:29

"...this court has made it clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely. It may not deny a benefit to a person on a basis that infringes his constitutionally protected interests — especially, his interest in freedom of speech. For if the government could deny a benefit to a person because of his constitutionally protected speech or associations, his exercise of those freedoms would in effect be penalized and inhibited. This would allow the government to "produce a result which (it) could not command directly."

Government Agents and those "Acting Under Color of Law" are forbidden by long-standing United States and International Law from coercing vaccination. The 14th Amendment to the US Constitution also guaranteed that the "privileges or immunities" of Federal Citizens may not be invaded by state and local governments.

The original civil rights acts, enacted after the Civil War, protected those "privileges or immunities" from persons "acting under color of law" or acting without "due process" (which means without an order signed by a Judge). Those protected against must include, at least, persons employed by governments, or receiving funding from governments, or working for entities that receive funding from governments (or that, like the drug companies that push vaccines, are granted special privileges, such as protection from legal responsibility for their "unavoidably unsafe" vaccines). It must also include persons, claiming lawful authority, intending to "pierce the skin" of someone not giving Informed Consent.

"No State shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any State deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws." 14th Amendment, Section 1.

CONCLUSION

It was not for *no* reason that the Founders grouped together in the First Amendment Religious Liberty, Speech, Assembly and Petition Rights. Rather, these stated Rights have been held by the Supreme Court to be, together, "*expressive association*."

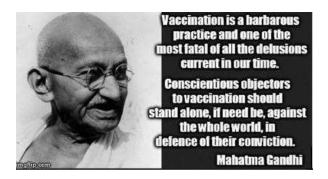
We consider meaningful Informed Consent to be the *sine qua non* of humane health care required by International Humanitarian Law. Truly, no free person should be forced to consent to mandated medical interventions.

There can hardly be a more fundamental or central freedom issue than whether agents of government, or persons acting under color of state law, as are those who act to abrogate conscientious objections to mandated vaccines, can force a free and competent adult (or a child under the protection of such adult) to receive any medical treatment. That the treatment may be vaccination, which is not merely experimental and (sic) preventative but uninsurable and, according to many courts, "unavoidably unsafe" gives greater emphasis to the unconscionable personal sacrifice the individual is mandated to make "in the public interest". Such a mandate is inconsistent with status as a free person, rather than a slave. No free society can tolerate any such imposition.

"Once the principle is admitted that it is the duty of the government to protect the individual against his own foolishness, no serious objections can be advanced against further encroachments." 30 Ludwig von Mises

"Liberty is to the collective body what health is to every individual body. Without health no pleasure can be tasted by man; without liberty, no happiness can be enjoyed by society."31 Thomas Jefferson

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"Vaccination is a barbarous practice and one of the most fatal of all the delusions current in our time... Conscientious objectors to vaccination should stand alone, if need be, against the whole world, in defense of their conviction." 32

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³⁰ Ludwig Von Mises (1949). "Human Action: a Treatise on Economics" - https://mises.org/library/direct-government-interference-consumption

³¹ http://www.successwallpapers.com/wallpapers/0068-liberty.php

³² Mahatma Gandhi (1922), "A Guide to Health", Chapter VI - http://www.gutenberg.org/ebooks/40373