----------}

In the Matter of	**}**	**Before the United States**
Informed Consent	**}**	**Food and Drug Administration**

----------}

Citizens' Petition for Redress
Emergency Citizens' Petition for Issuance of Informed Consent Regulation

In order to implement the applicable International Humanitarian Law principle of Informed Consent, on behalf of Natural Solutions Foundation (hereinafter, Foundation) and on behalf of the communicants of the Foundation and others who communicate their inclusion in this Petition to the Agency (herein, the Petitioners) the undersigned hereby Petition the Food and Drug Administration (the Agency) to exercise regulatory discretion and issue Regulations to implement International Humanitarian Law regarding Informed Consent to any and all medical interventions, including vaccination, even during any declared local, national or international Health Emergency.

We, the Trustees of the Natural Solutions Foundation undersigned, on our own behalf and for the Foundation and its communicants, hereby Petition the Agency, under the First Amendment Right to Petition for Redress, under the Administrative Procedures Act and 21CFR10.30, for an emergency ruling to promulgate Regulations on an emergency basis, implementing International Humanitarian Law regarding Informed Consent, in the form attached hereto as Exhibit A, entitled "Informed Consent Regulation" and made a part hereof, as though fully set forth herein (hereinafter, the Regulation).

[A] Actions Requested

(1) Exercise of regulatory discretion to immediately promulgate the requested Regulation as an emergency ruling to protect the public health, and to require the inclusion in the package insert for any approved drug, including vaccine, of reference and link to the Regulation.

(2) Hold hearing(s), permit public comments, issue permanent regulations, consistent with our expressive association rights and humanitarian law, implementing the emergency discretion and emergency Regulation on a regular basis.

Reservation of Rights: Petitioners reserve all rights, including violation of First Amendment by rules that censor speech about health; unclean hands by restraint trade; ultra vires Congressional

grant of authority; nothing herein shall be construed to be an admission of Agency authority.

[B] Statement of Grounds

[1] Statement of Facts

1. Natural Solutions Foundation is a private association the trustees of which are organized as a nonprofit Nevada corporation. The Foundation is an international Non-Governmental Organization (NGO) engaged in charitable, educational, literary, public policy and scientific research activities.

2. For its private communicant associates it provides access to constitutionally protected expressive association communications.

3. The communicant associates seek guidance regarding the exercise of their fundamental expressive association right to Informed Consent with regard to any and all medical interventions, including vaccinations or other health-related strategies and procedures recommended or mandated by governmental authority.

4. The Foundation communicates to the public what it does in private association, so that members of the public may exercise their First Amendment rights and enter into private association with the Foundation.

5. The Foundation advises its communicants regarding the exercise of their Right to Informed Consent, but, in the absence of a clear Regulation, is unsure of the best practices with regard to exercising Informed Consent.

6. The communicants and Foundation are thereby prevented from fully exercising the Right by failure of the Agency to provide clear guidance that conforms to Humanitarian Law; this unlawfully restricts the Petitioners' exercise of their First Amendment Expressive Association Rights.

7. The Centers for Disease Control, under the aegis of the Food and Drug Administration, have failed the Public Trust and have lost public confidence.[1] The agency, like so many other Federal agencies, is viewed by the public as serving the interest of politically connected "crony" corporations, but not the safety interests of the public. Under such circumstances, the urgency of the redress for which this Petition is submitted should be compelling. The

[1] http://www.bmj.com/content/350/bmj.h2362 - "Centers for Disease Control and Prevention: protecting the private good?" – British Journal of Medicine, *BMJ* 2015; 350 doi: http://dx.doi.org/10.1136/bmj.h2362 (Published 15 May 2015)Cite this as: BMJ 2015;350:h2362

Public will not trust the Federal Public Health Authorities without a clear Regulation faithfully implementing Informed Consent as the *sine qua non* of Public Health interventions. The Public Interest can only be met by imposing on the regulated drug companies the obligation to include in their Package Inserts strong acknowledgment of the Right to Informed Consent..

[2] Legal Authority

1. The Legal Basis for this Petition is the First Amendment to the Constitution of the United States: "Congress shall make no law… abridging the… the right of the people… to petition the Government for a redress of grievances." This Citizens' Petition is submitted pursuant to 21CFR10.30 and a copy of it is being submitted through *http://www.regulations.gov* at Generic Docket No. FDA-2013-S-0610-0001[2]. In so far as this Petition seeks the addition of certain information regarding Informed Consent to drug (including vaccine) package inserts, it is grounded on the statutory authority of the FDA to specify the contents of drug packaging.[3]

2. The Legal Basis for the Proposed Regulatory Discretion is the aforesaid Constitutional provision and the Bill of Rights Privacy and Association Rights which underpin Informed Consent, and Section 3512 of Title 19 and specifically, 19 USC 3512(a)(1) and (a)(2) and the general law as applied to the protection of human life, mandated, in the instance of vaccination, by the United States Supreme Court in the case of *Jacobson vs Commonwealth of Massachusetts*[4].

Federal Regulation acknowledges Informed Consent for formal Institutional Review Board (IRB) overseen experimentation.[5] 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…"[6]

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

[2] As instructed by FDA at: http://www.fda.gov/regulatoryinformation/dockets/comments/default.htm#petitions
[3] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm188665.htm
[4] *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905) wherein 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.]
[5] http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm
[6] http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm

the Government. The Supreme Court indicated, in *Thompson v Western States*[7]:

> **"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."**

"Section 3512. Relationship of agreements to United States law and State law

(a) Relationship of agreements to United States law

(1) United States law to prevail in conflict. No provision of any of the Uruguay Round Agreements, nor the application of any such provision to any person or circumstance, that is inconsistent with any law of the United States shall have effect.

(2) Construction: Nothing in this Act shall be construed –

(A) to amend or modify any law of the United States, including any law relating to -
(i) the protection of human, animal, or plant life or health,
(ii) the protection of the environment, or
(iii) worker safety, or
(B) to limit any authority conferred under any law of the United States, including section 2411 of this title, unless specifically provided for in this Act."

3. Additionally, the Statutes authorizing the Agency contain general provisions that support the actions requested in this petition. Federal Law includes provisions that grant the Cabinet Secretaries broad authority to promulgate rules and regulations "necessary to carry out the Act[s]."

4. The United States is bound to observe the Nuremberg Code by virtue of the Subsequent Nuremberg Trials[8] and subsequent exacting of justice through penalties, including the death penalty. The Geneva Conventions require that the United States be bound by these international humanitarian principles. Thus the United States is treaty-bound to implement fully Informed Consent.

5. The Agency should promulgate the Requested Policy as an Interim Final Rule without first completing Notice and Comment, Risk Assessment, and Cost-Benefit Analysis, so that reference to

[7] Thompson v. Western States Medical Center - 01-344, decided on April 29, 2002 - 535 U.S. 357)
[8] http://en.wikipedia.org/wiki/Subsequent_Nuremberg_trials

the Informed Consent Regulation may immediately be included in all approved drug and vaccination package inserts.

Under ordinary circumstances, the Agency must comply with procedural requirements under both the Administrative Procedures Act (APA) and the USDA Reorganization Act of 1994, including the use of notice-and-comment rulemaking and the completion of a risk assessment and cost-benefit analysis before issuance of a new rule. However, both acts provide for exceptions to those requirements for circumstances such as those present here, where the United States has suggested an imminent threat to public safety (from measles or other infectious disease outbreaks, including antibiotic-resistant, novel and genetically-engineered infections and diseases, and any delay in policy making would be contrary to the public interest.

The Agency should avail itself of those statutory exceptions and promulgate the requested policies without first providing the public with notice and an opportunity for comment and before completing a full risk assessment and cost-benefit analysis. The agency should first adopt the policy as an "interim-final rule," which would become binding upon publication (or shortly thereafter), and subsequently provide adequate time and opportunity for public comment and complete its risk assessment and cost-benefit analysis.

The Requested Regulations Satisfy the "Good Cause" Exception to the Administrative Procedure Act's Requirement for Notice and Comment.

The APA provides that full notice-and-comment rulemaking is not required when an agency "for good cause finds (and incorporates the finding and a brief statement of the reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. §553(b)(B). The good cause exception "is an important safety valve to be used where delay would do real harm." United States Steel v. EPA, 595 F.2d 207, 214 (5th Cir. 1979). According to the legislative history of the provision, "'impracticable' means a situation in which the due and required execution of the agency functions would be unavoidably prevented by its undertaking public rule-making proceedings." S. Rep. No. 752, 79th Cong., 1st Sess., at 16 (1945). As a court has already held, determining "impracticality" requires "analysis in practical terms of the particular statutory-agency setting and the reasons why agency action could not await notice and comment." American Transfer & Storage Company v. ICC, 719 F.2d 1283, 1295 (5th Cir. 1983).

There are numerous other instances in which courts have upheld an agency's decision to invoke the "good cause" exception and issue a rule without providing for notice and comment where a delay would threaten public safety or the environment. See, e.g., Hawaii Helicopter Operators Ass'n v. FAA, 51 F.3d 212, 214 (9th Cir. 1995) (good cause exception satisfied in view of "the threat to public safety reflected in an increasing number of helicopter accidents"); Northern Arapahoe Tribe v. Hodel, 808 F.2d 741, 750-52 (10th Cir. 1987) (good cause exception satisfied in view of urgent need for hunting regulations where herds were threatened with extinction); Northwest Airlines-v. Goldschmidt, 645 F.2d 1309, 1321 (8th Cir. 1981) (good cause exception satisfied in view of urgent need to allocate landing slots at major airport).

The rationale underlying those decisions, that compliance with time-consuming procedural requirements would "do real harm" by delaying implementation of urgently needed policies to safeguard public health, is equally applicable here, where a Global Health Security Threat may be occurring and delay will have a negative impact on U.S. consumers. Clearly, the exigent circumstances necessary to satisfy the APA's good cause exception are present.

The compelling circumstances include the imminent spread of deadly vaccine and antibiotic-resistant pathogens[9] and the notable increase in vaccine adverse event reports[10], the increased number of vaccines being used in children and adults and their individual and aggregate adverse event profile which scientific evidence shows is mounting rapidly.[11]

[C] Environmental Impact

The Petitioners hereby state that the relief requested in this petition will have no direct environmental impact; therefore, an environmental assessment is not required under 21 C.F.R. Section 25.30.

[D] Economic Impact

We are unable to fully ascertain the economic impact of being unable to effectively exercise our individual right to Informed Consent. Individuals will be injured by "unavoidably unsafe" vaccines and other medical interventions to their economic harm. The total cost to society of the foreseeable harm resulting from lawfully prescribed medical interventions is very high.[12]

Conclusion

In this emergency situation the Agency 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…"[13] 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 Regulation, to the end that government approvals, requirements, mandates and recommendations are understood to be subject to the Right of Informed Consent.

Legitimate Government Regulation

[9] http://www.cbc.ca/news/health/antibiotic-resistance-threatens-everyone-who-warns-1.2626844
[10] http://www.ncbi.nlm.nih.gov/pubmed/16689554
[11] http://www.phrma.org/media/releases/nearly-300-vaccines-development-prevention-treatment-disease
[12] See: http://www.webdc.com/pdfs/deathbymedicine.pdf for an estimate of the number of deaths caused by government-approved medical interventions.
[13] http://www.hhs.gov/ohrp/archive/nurcode.html

The United States Government has no legitimate interest in promoting FDA-approved vaccination mandates in violation of Informed Consent.

In the case of *State v Biggs* (46 SE Reporter 401, 1903) 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. Biggs was acquitted.

There is no compelling government interest in controlling non-commercial, non-profit, private associations where people associate together for the improvement of their well-being.

The North Carolina Supreme Court concluded, nearly 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).

The Agency should exercise regulatory discretion to support full implementation of the right to Informed Consent.

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"[14] 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[15]. The same is true of medical practice in "ordinary times".

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

[14] "*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
[15] http://www.who.int/mediacentre/news/statements/2014/ebola-ethical-review-summary/en/

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…:[16]

Among the Post World War II protective codifications were the Universal Declaration of Rights, Geneva Declaration[17]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…"[18]

- "I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat…"[19]

- "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."[20]

---

[16] http://en.wikipedia.org/wiki/Hippocratic_Oath

[17] 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

[18] http://www.un.org/en/documents/udhr/

[19] http://www.wma.net/en/30publications/10policies/g1/index.html

[20] http://www.hhs.gov/ohrp/archive/nurcode.html

This salutary development of international law has continued with international standards promulgated, such as the UNESCO Universal Bioethics Declaration, UNESCO Universal Bioethics Declaration[21] 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*.[22] The reference to "civilised nations" in this context could well introduce an ethical requirement to such evaluations that many contemporary developed nations may fail.[22]

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."[23]

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.

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.[24]

The Court opined,

---

[21] 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… [Emphasis added]

[22] http://jme.bmj.com/content/31/3/173.full

[23] http://en.wikipedia.org/wiki/Informed_consent

[24] http://www.supremecourt.gov/opinions/12pdf/11-1425_cb8e.pdf

"…diminished expectation of privacy does not diminish their **privacy interest in preventing a government agent from piercing their 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"[25] 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.][26]

In a regime of verbal obscuration of fundamental Right, only the clear assertion of the Right will prevent degradation of the Right "by a thousand (bureaucratic) cuts…"

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 a clear Regulation that protects the Right whether exercised by Advanced Medical Directive or otherwise, in situations that do not involve a formal IRB.

Natural Solutions Foundation seeks, and then shares, Natural Solutions to pressing health freedom issues. We consider meaningful Informed Consent to be the *sine qua non* of humane health care required by International Humanitarian Law. Such meaningful response to Informed Consent requires that a definitive public record be made and formally noted.

Therefore, to permit individuals to make a public record that they have "denied consent or refused to consent" we submit this formal Petition requesting that the Agency adopt a clear

[25] 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
[26] *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905)

patient-centric, Rights-based Humane Law Informed Consent Regulation to protect the fundamental Right to Informed Consent, acknowledging Humane International Law.

There can hardly be a more fundamental or central freedom issue than whether agents of government can force one to receive a medical treatment. That the treatment may be vaccination, which is not merely experimental and (sic) preventative but uninsurable and "unavoidably unsafe" gives greater emphasis to the unconscionable personal sacrifice the individual is mandated to make. Such a mandate is inconsistent with status as a free person, rather than a slave. No free society can tolerate any such imposition.

> "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." – Thomas Jefferson[27]

Wherefore the Petitioners hereby PETITION the Agency to adopt the Regulation provided in this Petition and mandate the inclusion of access to the Regulation in the package insert for all approved drugs, including vaccines. Petitioners intend to communicate the Regulation and be guided by it until and unless final lawful action of the Agency. We reserve all rights including full judicial review and mandamus.

Certification

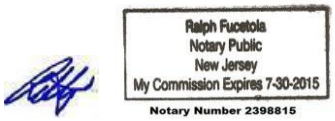
The undersigned, as of this 11th day of June, 2015 certify, that the undersigned is a Citizen of the United States, or a corporate person, and that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner which are unfavorable to the Petition.


Albert N. Stubblebine III


Rima E. Laibow


Ralph Fucetola

Certified True Copy of the Citizens' Petition



Ralph Fucetola – Secretary

We acknowledge, with our thanks, Jim Turner, JD of Swankin and Turner and Larry Becraft, JD for their comments during the drafting of this Petition. The contents, however, are the sole responsibility of the Trustees.

[27] http://www.successwallpapers.com/wallpapers/0068-liberty.php

Exhibit A

DRAFT INFORMED CONSENT REGULATION

[A] Informed Consent

Informed Consent may not be assumed, deemed, or implied. Informed Consent must be actual and individual– and may be conveyed by a signed, notarized Advanced Medical Directive or any other verifiable written communication.

[1] Informed Consent may only be given by the individual involved, or his or her natural guardian[28] and no guardian may be appointed without full judicial process and only in cases of *non-compos mentis*[29]. A conscious individual is always deemed capable of making an Informed Consent decision which must be "without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion." - http://www.hhs.gov/ohrp/archive/nurcode.html

[2] Informed Consent may only be obtained after full Disclosure of All Risk memorialized with a written document signed by the consenting individual or natural guardian.

[3] Informed Consent may never be assumed, deemed or implied.

[4] The requirement for prior Informed Consent applies to all medical interventions, and

[5] Informed Consent is subject to International Humanitarian Law: "The voluntary consent of the human… 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." - http://www.hhs.gov/ohrp/archive/nurcode.html

[B] Disclosure of All Risks

1) Clinical evaluation of risks that evaluate both reactions to the vaccine`s or other interventional target (i.e. measles) and reactions to any latent pathogenic agents, contaminants or components (viruses, metals, foreign DNA, chemicals, excipients, cell fragments, drugs, adjuvants, bacteria, fungi) carried within the vaccine or other intervention should be within the fundamental definition of `risks`.

2) A public record of latent agents, both pathogenic and non-pathogenic) after screening for every known and sequenced virus, bacteria, fungus and parasite with a current all-

[28] Natural parent: http://definitions.uslegal.com/n/natural-guardian/
[29] http://www.thefreedictionary.com/non+compos+mentis

encompassing microbial detection array, particulate and chemical profile of the proffered treatment or procedure substance or component(s) should be published for each batch of vaccine or other interventional material, device or substance.

3) Prohibition against use of mathematical models to determine or communicate risk to potential patients whose Informed Consent is being sought. Epidemiology, statistics, etc. should be eliminated in determination of risk since they are so easily manipulated to show desired, rather than actual, risk realities. For example, with regard to measles: Epidemiology studies only look for measles after measles immunization, not for contaminants from the VERO cells (African green monkey cell line) which may be carried by the vaccine. Another example: with regard to misleading (and under this proposal, prohibited) under-estimation of risk: polio vaccine caused encephalopathies from CMV contamination, but the risk factors were only based on the number of polio related lawsuits filed each year alleging polio caused by the vaccine.

4) Should any agent or clinical reaction not be publicly reported by manufacturer or CDC, the statute of limitations shall be tolled for filing vaccine claims against either manufacturer or FDA. Statute of limitations for claims arising prior to enactment shall be waived until three years after subsequent discovery. (i.e. SV-40 in cancers of both vaccine recipients and non-vaccine recipients).

5) Any and all government employees or manufacturer employees, and their superiors, determined to minimize vaccine or other intervention reactions shall be subject to personal liability. Any employee reporting vaccine or other intervention reactions, which have not been heretofore timely disclosed or which are disclosed in a timely fashion, shall be per se entitled to Whistleblower status.

[C] Rule of Interpretation and Implementation

This regulation shall be interpreted to afford the greatest scope for Informed Consent. This Regulation, including an Internet link to it, shall be referenced in all approved drug (including vaccine) package inserts.