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In the Matter of Suspension of	}	Before the United States Food and
Vaccine Drug Approvals	}	Drug Administration and
	}	Centers for Disease Control
Generic Docket FDA-S-2013-0610-0001	}	
-----	}	

**Citizens' Petition for Redress
Under the Administrative Procedures Act**

**Emergency Citizens' Petition for Immediate
Suspension of All Current Vaccine Drug Approvals
And Permanently Ban All Childhood and Adult Vaccines and Vaccine Drug Advertising**

In order to implement the legal requirements for vaccine safety under the National Childhood Vaccine Injury Act (NCVIA)¹ and the Federal and International Humanitarian Law principle of Informed Consent, on behalf of the signatory organizations and individuals and others who communicate their inclusion in this Petition to the Agency (herein, the Petitioners) the undersigned hereby Petition the Food and Drug Administration and the Centers for Disease Control (the Agency) to exercise regulatory discretion and issue Regulations to implement an immediate Suspension of all current vaccine drug approvals under the regulations pertaining to vaccine drug biologics (the Suspension)² and permanently ban all childhood vaccinations until the safety and efficacy provisions of the NCVIA are faithfully and fully implemented (the Childhood Vaccine Prohibition, herein, the Prohibition).

We, the undersigned, on our own behalf and for all the Petitioners herein or hereafter, hereby Petition the Agency, under the First Amendment Right to Petition for Redress, under the Administrative Procedures Act (APA) and 21CFR10.30, for an immediate ruling to promulgate Regulations on an emergency basis, implementing the Suspension and Prohibition, in the form attached hereto as Exhibit A, entitled "Vaccine Suspension and Prohibition Regulation" and made a part hereof, as though fully set forth herein (hereinafter, the Regulation).

The information web page for this APA Petition is <http://drrimatruthreports.com/petition-to-suspend-all-fda-vaccine-drug-approvals/>

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¹ The National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34)

² <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm149184.htm>

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[A] Actions Requested

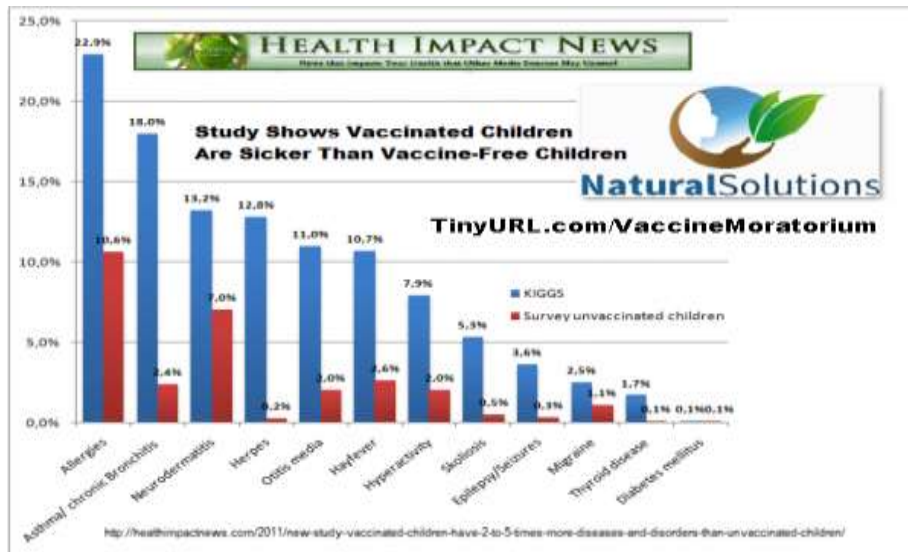
(1) Exercise of regulatory discretion to immediately promulgate the requested Regulation as an emergency ruling to protect the public health, and especially the health of children.

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

(3) Intervention by the President of the United States mandating Agency action.

Reservation of Rights: Petitioners reserve all rights, including violation of First Amendment by rules that censor speech about health; unclean hands by restraint of trade; *ultra vires* Congressional grant of authority; nothing herein shall be construed to be an admission of Agency authority to approve, recommend or mandate vaccines.

(4) The science is settled. Vaccinated children are less healthy than unvaccinated children. By recommending what should be considered illegal drugs and/or biologicals that harm the health of recipients the Agency is violating its stated and statutory mandates and bringing avoidable harm to the residents and citizens of the United States in enormous numbers, generating a costly and devastating health crisis that strict adherence to the law would have avoided.



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(5) The Agency and its supervising Federal Department have failed to implement the

³ <http://healthimpactnews.com/2011/new-study-vaccinated-children-have-2-to-5-times-more-diseases-and-disorders-than-unvaccinated-children/>

NCVIA in several important ways. The mandate from Congress that vaccines are to become safer has been flagrantly consistently and illegally ignored. The mandate from Congress that an Annual Vaccine Safety Report (hereinafter, Mandated Reports) shall be made to Congress has been flagrantly consistently and illegally ignored each and every year since the NCVIA required the Mandated Reports, starting in December, 1989.

The Informed Consent Action Network, represented by Robert F. Kennedy Jr, Esq., recently conclusively showed that the aforesaid Mandated Reports have never been given to Congress as admitted by the Agency and its supervising body. The Stipulation in the case of *Informed Consent Action Network vs United States Department of Health and Human Services*, 18-cv-03215 (USDC, Southern District of New York, July 9, 2018 - excerpts attached below) clearly indicates the failure to provide the Mandated Reports.

Case 1:18-cv-03215-JMF Document 18 Filed 07/09/18 Page 1 of 3

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 07/09/2018

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

INFORMED CONSENT ACTION NETWORK,
Plaintiff,
-against-
UNITED STATES DEPARTMENT OF HEALTH
AND HUMAN SERVICES
Defendant.

STIPULATION
18-cv-03215 (JMF)

WHEREAS, 42 U.S.C. § 300aa-27, entitled "Mandate for safer childhood vaccines," provides as follows: (a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary [of the Department of Health and Human Services], the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and . . .

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) of this section during the preceding 2-year period.

WHEREAS, HHS sent ICAN the following response to the FOIA Request:

The [Department]'s searches for records did not locate any records responsive to your request. The Department of Health and Human Services (HHS) Immediate Office of the Secretary (IOS) conducted a thorough search of its document tracking systems. The Department also conducted a comprehensive review of all relevant indexes of HHS Secretarial Correspondence records maintained at Federal Records Centers that remain in the custody of HHS. These searches did not locate records responsive to your request, or indications that records responsive to your request and in the custody of HHS are located at Federal Records Centers.

ICAN believes the foregoing response from HHS now resolves all claims asserted in this action.

Excerpts from Order: <http://icandecide.org/government/ICAN-HHS-Stipulated-Order-July-2018.pdf>

[B] Statement of Grounds

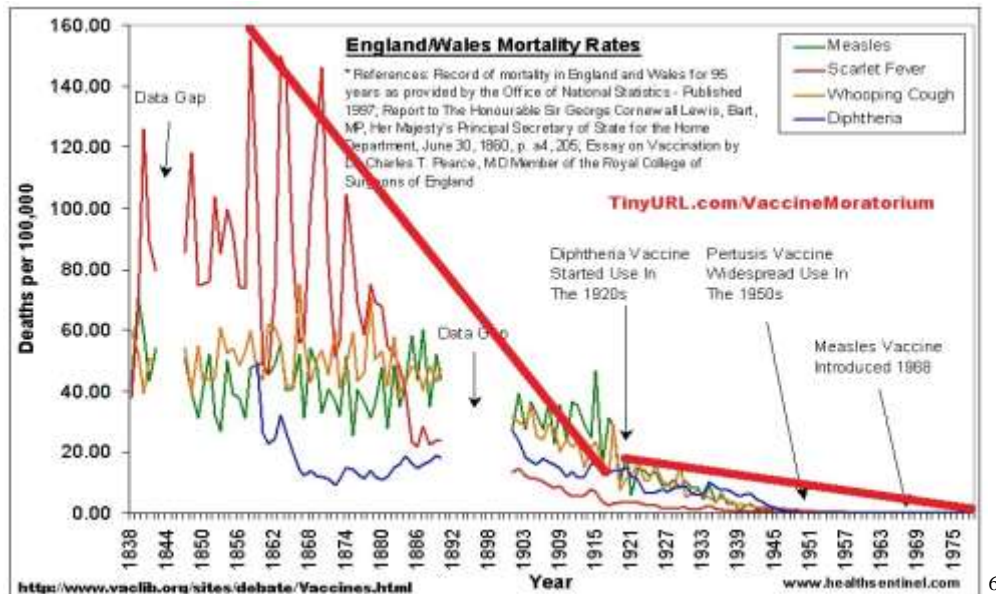
[1] Statement of Facts

1. The undersigned Petitioners are private individuals (including vaccine-injured or other children by their parents or guardians) and members of private associations aggrieved by the uninsurable risks of "unavoidably unsafe"⁴ vaccines which thereby violate Informed Consent.
2. The undersigned communicants engage in constitutionally protected expressive association communications regarding the risks of vaccination, including, but not limited to children.
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 undersigned communicate to the public with regard to the legal requirements that vaccines be safe and effective.
5. The undersigned advise the communicants regarding the exercise of their Right to Informed Consent to refuse Childhood Vaccines without regard to State or Federal vaccine mandates, but, in the absence of a clear Regulation, is unsure of the best practices with regard to exercising Informed Consent consistent with vaccine safety.
6. The communicants and undersigned are thereby prevented from fully exercising the Right of *Informed* Consent 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 Petitioners and communicants cannot effectively express their Informed Consent opinion speech without access to the Mandated Reports (which provides part of the "informed" aspect of valid consent); the non-existence of the Reports unconstitutionally burdens the Petitioners' Free Speech rights.
8. The Centers for Disease Control and the Food and Drug Administration, have failed the Public Trust and have lost public confidence.⁵ The Agency, like other Federal agencies, is viewed by the public as serving the interest of politically connected "crony" corporations, but not the safety and privacy interests of the public. Under such circumstances, the urgency of the redress for which this Petition is submitted should be compelling. The Public will not trust the Federal Public Health authorities without a clear Regulation faithfully implementing the NCVIA reporting mandate to permit truly Informed Consent as the *sine qua non* of Public Health interventions such as Childhood Vaccination and the requirements of the NCVIA law that same be both safe and effective.

⁴ See Justice Sotomayor's dissent in *Bruesewitz vs Wyeth*, 562 U.S. 223 (2011) where she discusses the history of "unavoidably unsafe." <https://www.law.cornell.edu/supct/html/09-152.ZD.html>

⁵ <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

9. The Public Interest can only be met by imposing on the regulated drug companies the requested Suspension and/or permanently requiring them to place on their vaccine labeling, "Not for Childhood Vaccination." Currently these items, for adults or for children, are misbranded since they contain known toxins and have never been shown to be safe and have been illegally approved so they should not be marketed, sold or administered under the current lack of legal justification for their use.



[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-0610-0001⁷. In so far as this Petition seeks the addition of certain information regarding Informed Consent to vaccine package inserts, it is grounded on the statutory authority of the FDA to specify the contents of drug packaging.⁸

2. The Legal Basis for the Proposed Regulatory Discretion is [A] the aforesaid Constitutional provision and the Bill of Rights Privacy and Association Rights, and Treaty Obligations which underpin Informed Consent, and Section 3512 of Title 19 and specifically, 19 USC 3512(a)(1) and (a)(2) and [B] the drug safety laws, as hereinafter described, including but not limited to 21 U.S.C.A. 321, 331, 351(a)(2)(B), 355, 360bbb-3, 393(b)(2), and 21 C.F.R. Part 210, 210.2, Part 211, 211.1, Part 601, 601.2(a), 601.4(a) and 610.15(a), and the 1986 NCVIA as applied to the

⁶ <http://www.vaclib.org/sites/debate/Vaccines.html>

⁷ As instructed by FDA at: <http://www.fda.gov/regulatoryinformation/dockets/comments/default.htm#petitions>

⁸ <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm188665.htm>

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*.⁹

(A) Informed Consent

Federal Regulation acknowledges Informed Consent for formal Institutional Review Board (IRB) overseen experimentation.¹⁰

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...”¹¹

Where there is unavoidable risk, as there is with Childhood and Adult Vaccination, the right to Informed Consent *must* be respected, but the Federal Government current practice of recommending over 50 Childhood Vaccines without effective implementation of the vaccine safety laws eviscerates the right to Informed Consent since the Agency is well aware that many governmental and non-governmental organizations and practitioners hold these recommendations to be evidence of sound and lawful science-based Public Health strategies and seek to implement them to their fullest ability and flagrantly and willfully ignores the mandates of Congress in the NCVIA.

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*, 535 U.S. 357 (2002):¹²

“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.”

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 Trials¹³ and subsequent exacting of justice through penalties, including the death

⁹ *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.”

¹⁰ <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126431.htm>

¹¹ <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm>

¹² *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002)

¹³ http://en.wikipedia.org/wiki/Subsequent_Nuremberg_trials

penalty. The Geneva Conventions, in binding international treaty law, require that the United States be bound by these international humanitarian principles.

5. Thus the United States is treaty-bound to implement fully Informed Consent with regard to Vaccinations, but since such vaccinations are "unavoidably unsafe" by judicial determination, there can be no true Informed Consent without the Agency stopping Childhood and Adult Vaccination until the requirement of Federal Law that vaccines be proven to be both safe and effective can be fully implemented.

6. Furthermore, since the NCVIA provides that childhood vaccines are to be made safer, and the progress toward such Congressionally mandated safety is to be provided annually to Congress through the non-existent Mandated Reports, all FDA vaccine approvals since the Agency failure to provide the first non-existent Mandated Report in 1989 are fraudulently or otherwise unlawfully granted and must immediately be deemed void *ab initio*.

(B) Vaccine Safety Laws and Regulations

6. The Food, Drug and Cosmetics Act (FD&C Act) Mission Statement requires that: "... '(B) human and veterinary drugs are safe and effective...' (21 USC §393(b)(2)). The Act had been amended repeatedly, to require that no drug be approved unless it is proven 'safe and effective'." This has never occurred. Therefore the existing vaccine approvals must be suspended until and unless the vaccines meet the legal standard.

7. The applicable Statutes and Regulations, including but not limited to 21 U.S.C.A. 321, 331, 351(a)(2)(B), 355, 360bbb-3, 393(b)(2), and 21 C.F.R. Part 210, 210.2, Part 211, 211.1, Part 601, 601.2(a), 601.4(a) and 610.15(a) establish a comprehensive regulatory system for the approval (of the licenses for) of the Vaccines, that is binding upon both the federal government and the vaccine companies.

8. Each vaccine manufacturer has an absolute, non-dischargeable duty to prove that each vaccine is safe to ALL of the applicable standards for safety established "under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine" [42 U.S.C. Sec. 300aa-22(b)(2)]. To establish that, for example, a dose of a preserved vaccine is "sufficiently nontoxic ...", the vaccine manufacturer must unequivocally first establish a scientifically sound and appropriate "No-Observed-Adverse-Effect Level" (NOAEL) for the "nontoxic" threshold for the substance. For vaccines administered to developing children, the NOAEL injected (for example) of a Thimerosal-preserved dose in the developing humans and then add an appropriate safety factor so that the actual dose of in the preserved vaccine's dose is "sufficiently nontoxic ..." Typically, for highly toxic bio-accumulative chemicals, like Thimerosal or Aluminum, the safety factor is 100 or greater but, in any case, no less than a factor of 10 to ensure that the vaccine dose is "sufficiently nontoxic ..." for the most susceptible of babies. Elderly and otherwise compromised individuals have compromised detoxification capabilities and are subject to the same concerns of toxicity as fetuses and children with regard to the materials in vaccines. The Agencies and manufacturers have failed to do so.

9. The Agency arbitrarily and capriciously failed to follow the statutes and regulations, thereby issuing unlawful and invalid approvals for the Vaccines. The Agency has failed to obtain from

the purported licensees all of the applicable proofs of safety and efficacy to the Agency in the manufacturer's Biologic License Application (BLA) (21 CFR § 601.2(a)) before the Agency can legally approve a vaccine (21 CFR § 601.4(a)).

10. The Agency failed to follow its own regulations with regard to the approval of the Vaccines, including specifically: (a) Section 351(a)(2)(B) that the manufacturer must "assure that such drug meets the requirements of this chapter as to safety...", (b) the provisions of 21 CFR § 601.2(a),(2)a that require the manufacturer certify that all requirements have been met, and (c) the provisions of 42 U.S.C.A. §300aa-27(a)(2) that mandate that the Secretary assure "safer" vaccines by reducing the risks of adverse reactions to said vaccines.

11. Further, the law requires that Federal Agencies produce and disseminate only truthful information to the people of the United States. The Agencies have woefully and repeatedly failed in that duty with regard to the frequency and severity of expected vaccine adverse reactions and are thereby in violation of the Data Quality Act under the 2001 Consolidated Appropriations Act, 106 PL 554, at Section 515. These requirements, under Chapter 35 of Title 44 of the United States Code, provide in part "policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies..."

12. The law is clear: 42 U.S.C. § 262, for biological drug products, including vaccines at § 262(a)(2)(C)(i)(I): "(C) The Secretary shall approve a biologics license application - (i) on the basis of a demonstration that - (I) the biological product that is the subject of the application is safe, pure, and potent; ..." The Childhood and Adult Vaccines in question in this Petition fail to meet this standard. Therefore, as a matter of law, the purported vaccine approvals must be suspended until and unless the legal standard can be met.

13. The law further requires proof that the vaccine meets all of the applicable safety requirements established for the vaccine, including, for preserved vaccines, the plain safety requirement minimum set forth in 21 U.S.C. § 351(a)(2)(B) and that the vaccine, a biological product, is "safe" as required by 42 U.S.C. § 262(a)(2)(C)(i)(I).

14. The 1988 US Supreme Court decision in *Berkovitz v. US* (486 U.S. 531, 108 S.Ct. 1954): held that the safety requirements were non-discretionary on the Agencies:

"On grant of certiorari, the Supreme Court, Justice Marshall, held that: (1) cause of action based on allegation that National Institutes of Health's Division of Biologic Standards licensed vaccine without first receiving required safety data was not barred by discretionary function exception to Tort Claims Act; (2) claim based upon Division's licensing of vaccine without determining compliance with standards or after determining failure to comply would not be barred by discretionary function exception; and (3) discretionary function exception to Tort Claims Act did not bar claim alleging that, under authority granted by regulations, the Food and Drug Administration adopted policy of testing all lots of oral polio vaccine for compliance with safety standards and preventing the public distribution of any lot that failed to comply, and that, notwithstanding that mandatory policy, FDA knowingly approved release of unsafe lot. Reversed and remanded."

15. This was a vaccine case decided after the National Vaccine Injury Compensation Program (NVICP) was enacted under the NCVIA, in which the Supreme Court unanimously ruled that a Federal Agency administrator has no discretion in complying with a clear binding regulation. In this case, the applicable regulation that binds the FDA is 21 CFR § 601.4(a), states:

“(a) A biologics license shall be issued upon a determination by the Director, Center for Biologics Evaluation and Research or the Director, Center for Drug Evaluation and Research that the establishment(s) and the product meet the applicable requirements established in this chapter. A biologics license shall be valid until suspended or revoked”

16. The phrase “this chapter” includes the requirements set forth in 21 CFR § 610.15(a). [21 CFR § 601.4(a) has been in effect since the beginning of 1977 (42 FR 4718, Jan. 25, 1977).]

17. Thus an FDA administrator has no administrative discretion to approve a preserved vaccine or any other preserved biologic drug product unless said preserved product has been proven to meet the clear safety requirement (“sufficiently nontoxic...”) set forth in 21 CFR § 610.15(a). Given this explicit restriction that is and was binding on the FDA and the restriction on vaccine licensing set forth in 42 U.S.C. § 262, the non-complying actions of the Secretary and/or the FDA cannot justify the continued practice of Childhood and Adult Vaccination.

(C) Emergent Relief

1. 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 the Childhood and Adult Vaccination Suspension may come into immediate effect.

2. Under ordinary circumstances, the Agency should 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 evidence shows a devastating increase in adverse reactions to the ever-increasing list of government recommended Childhood and Adult Vaccines.

3. 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.

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

5. 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 "impracticability" 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).

6. 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).

7. 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 avoidable harm to children and adults is 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.

8. The compelling circumstances include the increased number of vaccines using increasing numbers of toxic ingredients being used in children and adults and their individual and aggregate adverse event profile which scientific evidence shows is mounting rapidly.

For example, see the Agency's list of excipients added to vaccines:

<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf> .

See also the Government's information on ever-increasing VICP payouts now totaling in excess of \$4 Billion US and rising: <https://www.hrsa.gov/vaccinecompensation/data/index.html> .

(D) Environmental Impact

1. 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.

(E) Economic Impact

1. We are unable to fully ascertain the economic impact of being unable to effectively exercise our individual right to Informed Consent by rejecting multiple Childhood and Adult Vaccines. Children and adults will be injured by "unavoidably unsafe" vaccines and other related and subsequent medical interventions to their economic harm. The total cost to society of the foreseeable harm resulting from these unlawfully approved prescribed medical interventions is

very high.¹⁴

(F) Legitimate Government Regulation

1. The United States Government has no legitimate public interest in promoting FDA-approved vaccination mandates in violation of Informed Consent or of the Mandated Reports and safety provisions of the NCVIA and other cited statutes requiring vaccine safety. 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.

Further in *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.'"

2. The Agency should exercise regulatory discretion to support full implementation of the internationally recognized right to Informed Consent¹⁵ of compliantly safe vaccines.

3. 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"¹⁶ 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.¹⁷ The same is true of medical practice in "ordinary times".

¹⁴ See: <http://www.webdc.com/pdfs/deathbymedicine.pdf> for an estimate of the number of deaths caused by government-approved medical interventions.

¹⁵ <http://www.hhs.gov/ohrp/archive/nurcode.html>

¹⁶ "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

¹⁷ <http://www.who.int/mediacentre/news/statements/2014/ebola-ethical-review-summary/en/>

4. 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. With over four billion dollars paid by the taxpayers through the Vaccine Injury Compensation Program for injured and dead children, and with those payments rapidly increasing, those prohibitions and protections remain binding today.

5. 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...”¹⁸

6. The Geneva Conventions regulate acts of governments regarding both soldiers and civilians.¹⁹ Among the Post World War II protective codifications were the Universal Declaration of Rights, Geneva Declaration 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...” (Universal Declaration)²⁰

“I WILL NOT USE my medical knowledge to violate human rights and civil liberties, even under threat...” (Geneva Declaration)²¹

“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.” (Nuremberg Code)²²

¹⁸ http://en.wikipedia.org/wiki/Hippocratic_Oath

¹⁹ 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

²⁰ <http://www.un.org/en/documents/udhr/>

²¹ <http://www.wma.net/en/30publications/10policies/g1/index.html>

²² <http://www.hhs.gov/ohrp/archive/nurcode.html>

7. This salutary development of international law has continued with international standards promulgated, such as the UNESCO Universal Bioethics Declaration, UNESCO Universal Bioethics Declaration²³ 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.²⁴ The reference to "civilised nations" in this context could well introduce an ethical requirement to such evaluations that many contemporary developed nations may fail."

[3] Defending Informed Consent

1. "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."²⁵

2. 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.

3. 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

²³ http://portal.unesco.org/en/ev.php-URL_ID=31058&URL_DO=DO_TOPIC&URL_SECTION=201.html

This international Declaration 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..."

²⁴ <http://jme.bmj.com/content/31/3/173.full>

²⁵ http://en.wikipedia.org/wiki/Informed_consent

ruled illegal as the defendant “refused to consent.” Had McNeely remained silent, the blood test would have been allowed.²⁶

The Court opined, even a “...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).

4. 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” will also give rise to such legitimate legal concerns.

5. 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.

6. An earlier Supreme Court understood this, when in 1905 in *Jacobson v Massachusetts*, 197 U.S. 11 (1905), 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.”²⁷

[C] Conclusion

The failure of the Department (HHS), Administration (FDA) and the Centers (CDC) to see to the faithful implementation of the Law²⁸ negates the presumed validity of the previously issued vaccine drug approvals. There have been no annual Mandated Reports for nearly 30 years, indeed, there have been NO annual Mandated Reports; vaccines are not safer now than in 1986, as the increase in childhood disease and vaccine adverse events show.

Justice delayed is justice denied and United States administrative agencies have been consistently and persistently obstructing ignoring and negating their clear obligations under the law to the citizens of the United States, including the Petitioners herein.

Violation of the Right of Informed Consent is a form of slavery and involuntary servitude in which the condition of a person's body is controlled by someone else. The forced introduction of substances already determined by the Courts of the United States to be “unavoidably unsafe” into

²⁶ http://www.supremecourt.gov/opinions/12pdf/11-1425_cb8e.pdf

²⁷ *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11 (1905)

²⁸ “...shall take Care that the Laws be faithfully executed...” – Article II, Section 3, United States Constitution

unwilling persons violates every moral and legal standard of modern society and is totally unacceptable in a country governed by the United States Constitution which states "1. Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction." (Amendment 13, Clause 1) and "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." (Amendment 14, Clause 1).

The risks and damages of these unavoidably unsafe materials have been compensated by the Special Masters' Court under the NCVIA for more than four billion dollars

To make matters worse, every vaccine deployed in the United States is both an illegal substance and has been "approved" in violation of legislation which requires particular findings to be ascertained before approval. The Agency has violated its own mandates to assure that vaccines are both safe and effective. Not one vaccine has ever been independently tested and determined to be either safe or effective although every vaccine is required to be so tested and determined.

This means that recent public debate over the mandating of vaccination in various Federal and State government legislatures and agencies includes the forced introduction of materials which are illegal drugs into the bodies of citizens and other residents, including the Petitioners herein, without truly free Informed Consent.

This is not only unconscionable, but represents malfeasance and criminal behavior at high levels likely to result in virtually incalculable damage and irreparable harm to every person within the alleged jurisdiction of the aforesaid Federal and State legislatures and agencies.

Further, the Agency herein has failed to take the science of vaccines and vaccine dangers into account, relying instead on tainted studies like those authored in defiance of the data, by William Thompson, PhD and colleagues and other well-documented fraudulent studies relied upon by the Agency.²⁹

1. In this emergency situation the Agency must take a pro-active role in the full implementation of the Suspension to fully implement Vaccine Safety and Informed Consent without "the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion..." 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 risks of Childhood and Adult Vaccination, to the end that government approvals, requirements, mandates and recommendations are understood to be subject to the Right of Informed Consent and in compliance with the NCVIA.

2. 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 patient-centric, Rights-based Humane Law Informed Consent Regulation to protect the fundamental Right to Informed Consent, acknowledging Humane International Law, by suspending all existing vaccine approvals, until and unless the safety requirements of the NCVIA and other vaccine safety laws are met.

²⁹ <https://thinkingmomsrevolution.com/the-thompson-transcripts-shocking-revelations-by-the-cdc-whistleblower/>

3. The failure of the Agency and its supervising Department to provide the Mandated Reports must be remedied immediately.
4. 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 claimed to be 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.
5. In the *Jacobson* case, as previously cited, the United States Supreme Court reserved to the Federal Courts the authority to intervene in vaccination issues. The high court held that the judiciary is “competent to interfere and protect the health and life of the individual concerned.”
6. If the Agency fails to act expeditiously on this emergency Petition, imposing the Suspension made necessary by the Agencies' failure to abide by the safety laws applicable to vaccines, the Petitioners will have no choice but to seek further emergency redress.

[D] Relief Requested

7. Wherefore the Petitioners hereby PETITION the Agency to draft and adopt the Regulation requested in this Petition (recommended language attached hereto), suspending all vaccine approvals and mandate the inclusion of a Warning: "Not for Childhood Vaccination" in the package insert for all vaccines. Petitioners intend to communicate the proposed Regulation and be guided by it until and unless final lawful action of the Agency. The general terms of the Regulation, set forth in more detail in Exhibit A, to include:

ONE: Suspend current vaccine drug approvals thus prohibiting Childhood and Adult Vaccination;

TWO: Immediate notification of stakeholders;

THREE: Suspend the Vaccine Injury Compensation Program;

FOUR: Set up and fund a Blue Ribbon Panel of experts to create a report, the full contents of which will be made public within two years from the date of this Petition;

FIVE: Ban direct vaccine drug advertising under 21 C.F.R. 202.

7. We further Petition Donald J. Trump, President of the United States to intervene in this matter and direct the Agency to adopt the Regulation, under Section 3 of Article II of the Constitution for the United States of America which requires that the President “...shall take Care that the Laws be faithfully executed...” Petitioners reserve all rights including full judicial review and mandamus.

Certification, Signatures, Footnotes and Exhibit below.

[E] Certification

The undersigned, as of this 8th day of March, 2019 certify, that the Petitioners are Citizens of the United States, or a corporate person, or private association thereof 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 from the

Government sources cited herein, known to the Petitioners, which may be considered unfavorable to the Petitioners.

Signatories on behalf of the Petitioners next page.

Kent Heckenlively

Kent Heckenlively, JD
Member of the Bar of California

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