



### A Natural Solutions Foundation & Institute for Health Research

### WHITE PAPER IN SUPPORT OF A GLOBAL VACCINE MORATORIUM

Where There is Risk There Must be Choice



# VACCINES: THE SCIENCE IS *NOT* SETTLED THE SERIOUS RISK *IS* SETTLED:

Vaccines are "Unavoidably Unsafe" / Vaccination is an Uninsurable Risk

### **INTRODUCTION**

"The sky is blue, the science is settled, vaccines (sic) work." Hillary Clinton

"Science can never be settled because it is, by definition, always open to question. *Settled Science* is no longer science: It is religious, the exact opposite of science." Rima Laibow, M.D., *Medical Director*, *Natural Solutions Foundation* 

The Natural Solutions Foundation and the Institute for Health Research have prepared this public policy briefing dossier on whether vaccines rest on "settled science" or, indeed, on any science, including Pharmaceutical Industry claims supporting the alleged, and allegedly proven, safety and effectiveness of Vaccines.

The information presented must be viewed in the context of the 1986 legislation<sup>2</sup> requiring every vaccine to undergo rigorous, scientifically valid testing to assure BOTH its safety and efficacy before approval and deployment in the US. It must also be viewed against the reality that *not* one single vaccine has ever been so tested, evaluated and cleared for EITHER its safety or its efficacy.

This White Paper addresses the critically important question of vaccine safety and offers Public Policy Recommendations in conformity with both approved scientific methodology and legal requirements. Those recommendations include a call for a Global Vaccine Moratorium.

<sup>&</sup>lt;sup>1</sup> Advance Vaccine Directive Card: https://TinyURL.com/AVDcard

<sup>&</sup>lt;sup>2</sup> https://www.ncbi.nlm.nih.gov/books/NBK220067/





### SUMMARY OF FINDINGS AND GENERAL RECOMMENDATIONS:

Vaccination has long been held by US Courts to present, along with the nuclear power industry, an uninsurable risk under tort law.<sup>3</sup> This industry, which no underwriting pool can afford the risk of insuring, despite legal indemnity against tortuous liability has also been declared by US courts to be "unavoidably unsafe".<sup>4</sup>

Given the repeated findings of the Courts and the lack of the legally required safety and efficacy testing, there is no valid science supporting the claims that vaccines are safe, effective or both.

### **Policy Recommendations:**

- [1] Halt all Federal Funding for vaccine mandates, public "health" programs supporting the use of vaccines for any population since the use of vaccines is not shown by science to be either safe or effective.
- [2] Immediately cease all vaccinations of military and government employed personnel since the use vaccines is not shown by science to be either effective.
- [3] Issue immediate warning letters to all States and other agencies and organizations informing them that vaccines have not been shown by science to be either safe or effective and that their use should only be considered when the perceived benefits outweigh the unavoidable and uninsurable risks of vaccination.
- [4] The cumbersome and ineffective Vaccine Injury Compensation Program and the Special Masters Court, both created to allow special suits for compensation for vaccine damage be dissolved and tortuous immunity for vaccine manufacturers be immediately repealed.
- [5] Require that CDC Advisory Committee on Immunization Practices and all other bodies involved with vaccine policy, safety, labeling and approval members be free of all conflicts of interest with criminal penalties for violations of such requirements.
- [6] Adopt the proposed Freedom of Informed Refusal of Medication (FIRM) Act at the Federal level.
- [7] Encourage Alternatives to Vaccination which support a healthy blood brain barrier and fully functional immune system.
- [8] Produce educational material explaining to a well-indoctrinated medical and lay public that vaccines are uninsurable risks, unavoidably unsafe and not supported by objective science to diagnose, prevent, treat, mitigate or cure any condition and that the risks inherent in their use should be weighed against and potential perceived benefits.
- [9] Create a public education campaign to allow parents, workers, travelers, etc., to assert their personal or guardianship options for legal and non-contested Informed Consent opt outs for all vaccines.

<sup>&</sup>lt;sup>3</sup> See Bruesewitz v. Wyeth, 562 U.S. 223 (2011) for general status of vaccine claims under tort law.

<sup>&</sup>lt;sup>4</sup> See *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011) – Justice Sotomayor's Dissent for the history of "unavoidably unsafe."





- [10] Overturn all legislation that makes it permissible for a minor to give "consent" in the absence of parental or guardian agreement for vaccination since it is an unavoidably unsafe and uninsurable risk which has not been shown to be safe or effective as required by law.
- [11] Place an immediate moratorium on the use of all vaccines in the USA since they do not comply with law or public policy concerning the use of untested drugs and biologicals.

Ideally we seek a Global Vaccine Moratorium.

### **DECISIONS FLOW DOWNSTREAM**

Decisions made by regulators flow downstream to public health officials, medical administrators and, ultimately, to the clinicians - physicians and other health professionals - who put those decisions into action.

Public health system-wide decision making, like clinical decision-making, while informed by both scientific and resource management considerations is, in the modern world, often predicated upon political and commercial decisions. The actual experience of health care providers is marginalized, leading, in the case of vaccination pseudo-science, to horrific outcomes, including mass infertility and extraordinary increases in preventable chronic diseases and medical conditions such as autism.

# Decision-Making: Vaccination Government Statistics Demonstrated That Hygiene, Sanitation and Better Nutrition Ended the Pandemic Diseases *Prior to Vaccination!*

We illustrate the magnitude and gravity of the problem by examining in some detail the emotionally fraught subject of vaccines and vaccinations.

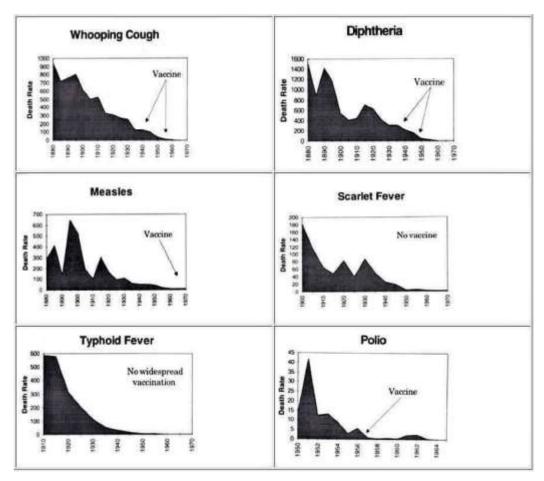
# Human survival moved along without vaccines for virtually our entire history on this planet.

Historically, government statistics from multiple countries indicate conclusively that infectious disease incidence as well as morbidity and mortality consistently declined sharply and steadily as clean water, sufficient nourishing food and hygienic practices which promote general and specific health became widely available *prior* to the introduction of vaccines.

This is equally true for those diseases for which vaccines were eventually developed (e.g. measles, mumps, rubella, small pox, cholera, plague, tuberculosis, etc.) and those for which no vaccine was ever developed or widely deployed (e.g., scarlet fever, typhoid fever, etc.)







Because excellent government records were kept in Western Europe before they were available in North America, our discussion will lean heavily on those data. The influence of the United States' "science", regulatory practices and clinical programs looms so large around the world that it, too, is deeply illustrative of the point: enormous amounts of resources, including human ones, are committed to the deployment of vaccines, indicated or not, when Big Pharma controls government regulation (and thereby clinical practice) rather than the reverse.

### Vaccines: Safe, Efficacious and Cost Effective?

As with any public health intervention, in order for vaccines to be considered as a meaningful public health measure, they must, by law, at least in the United States, be scientifically proved to be safe, efficacious and cost effective. In fact, that standard is established by US statute.

And, of course, the use of vaccines or any medical intervention is subject to the universal right of Informed Consent.<sup>5</sup>

<sup>&</sup>lt;sup>5</sup> http://drrimatruthrep<u>orts.com/a-brief-for-informed-consent/</u>





Ample case law<sup>6</sup> has established that no vaccine has ever been found to be safe *or* efficacious, let alone both, in the United States. That means that every vaccine is experimental and that every vaccine deployed in the United States fails to comply with US statutory and regulatory requirements. It is our position that therefore, every vaccine currently deployed in the United States is an illegal substance, in essence, an *un*approved drug.

### As such, every vaccine must be immediately withdrawn from the market

There will not be a loss of public well-being since, given that no vaccine has ever been found to be *either* safe *or* effective, and they are already known to be "unavoidably unsafe" and therefore uninsurable, their use is bad public policy and violates US law.

Few other public health interventions involve such vast amounts of money-in, or profit-out, to the purveyors of the intervention as vaccines yet is imperative to emphasize that not one single vaccine which has ever been approved and deployed in the United States meets that level of proof on any of these parameters.

Manufactures and purveyors, including the US government itself, which holds financial interest in dozens of vaccines, <sup>7</sup> are assured of vast profits from a combination of government development and purchase grant support, total legal protection from tort liability (although vaccines share the status of "uninsurable risk" with only one other category of industrial activity: nuclear power plants), financial reward to the purveyors and financial reward through any "aftermarket" benefits such as vaccine-related illnesses like leukemia and other cancers, infertility, autism, Alzheimer's Disease, Diabetes, etc., which increase the pharmaceutical profit picture dramatically.

Few other public health interventions have been the subject of such prolonged and intense professional and public relations brainwashing, leading to high tempers, righteous and wrathful indignation and a general substitution of passion for level-headed analysis on the part of regulators, journal editors, "medical ethicists" and reviewers and their downstream information recipients - doctors, other health professionals and the general public- around the topic.

Indeed, the very concept of "settled science", itself an oxymoron, has been created to justify the illogical and unsupported notion that somehow injecting foreign protein and dangerous chemicals like mercury, aluminum and formaldehyde into humans and animals offers some level of protection not demonstrated by the invoked tool – science.

CDC overview reports on flu vaccines<sup>8</sup> show very limited "effectiveness" against the seasonal flu.

<sup>&</sup>lt;sup>6</sup> Bruesewitz vs Wyeth, where she discusses the history of "unavoidably unsafe." https://www.law.cornell.edu/supct/html/09-152.ZD.html

http://drrimatruthreports.com/us-government-vaccine-patents/

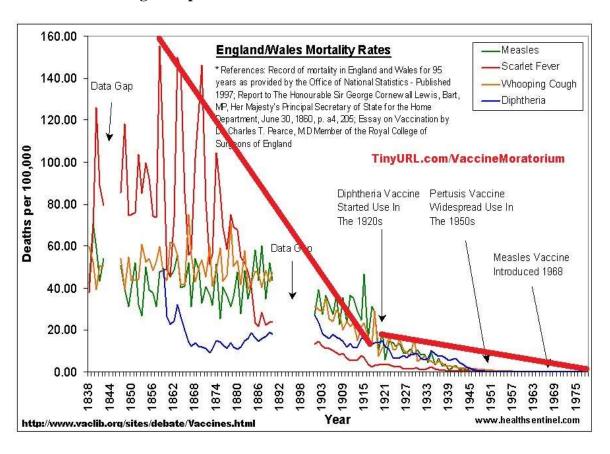
<sup>&</sup>lt;sup>8</sup> https://www.cdc.gov/flu/professionals/vaccination/effectiveness-studies.htm





Part of the efficacy debate rests on the compelling argument that we are safer now from morbidity and mortality from infectious diseases since the introduction of vaccines. If that were true, there might be a reason to consider vaccination for the population. However, the facts belie this glib assumption since every disease for which vaccines are used was in sharp decline as populations moved to modern sanitation and adequate food before the introduction of the disease specific vaccine presenting an alleged prevention or remedy for it.

### **Consider the following examples:**



### Overall Disease Incidence/ Vaccine Relationship

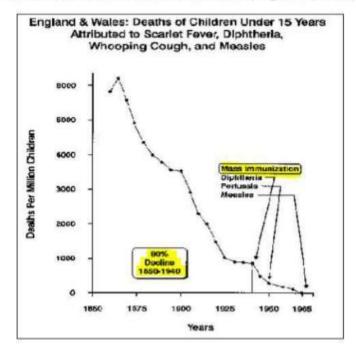
In England and Wales child mortality declined by 90% from the combined infectious diseases of scarlet fever, diphtheria, whooping cough and measles during the 90 years from 1850 - 1940. The first vaccine made available for diphtheria was in the early 1940's, whereas the pertussis (whooping cough) vaccine became available in the early 1950's and the measles vaccine in the late 1960's (no vaccine was ever provided for scarlet fever). 9

<sup>&</sup>lt;sup>9</sup> <a href="http://www.whale.to/vaccines/decline1.html">http://www.whale.to/vaccines/decline1.html</a> citing Immunization Graphs: Natural Infectious Disease Declines; Immunization Effectiveness; and Immunization Dangers Prepared by: Raymond Obomsawin Ph.D. 2009



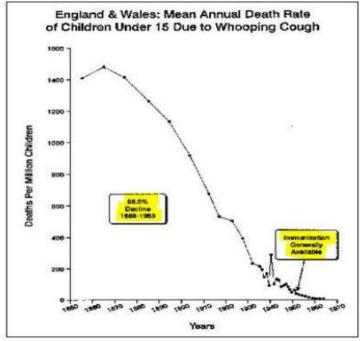


Table 1: Deaths of Children Under 15 Years (England & Wales)



The annual pediatric death rate of children under age 15 from whooping cough in England and Wales declined by roughly 98.5% in the period covering 1868 to 1953, when the pertussis vaccine became generally available. 10

Table II – Whooping Cough (England & Wales) England & Wales: Mean Annual Death Rate



 $<sup>^{10}\,\</sup>underline{\text{http://www.whale.to/vaccines/decline1.html}}\,$  loc. cit.





The annual death rate of children (under age 15) from measles in England and Wales declined from over 1,100 per million in the mid-nineteenth century, to virtually "zero" by the mid 1960's *prior* to immunization. <sup>11</sup>

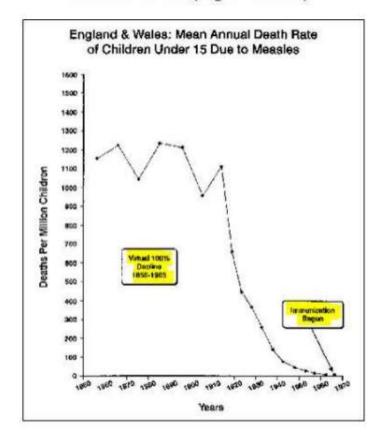


Table III: Measles (England & Wales)

There was a continuing decline in the annual death rate from smallpox in England and Wales with a reduction in mortality of roughly 300 per million to virtually 0 in the 60 year period following the middle of the 19th century. This table further illustrates that the progressive rate of decline was severely disrupted—with a roughly 275% increase in mortality from the disease—occurring immediately after smallpox vaccination laws were enforced by the British government.<sup>12</sup>

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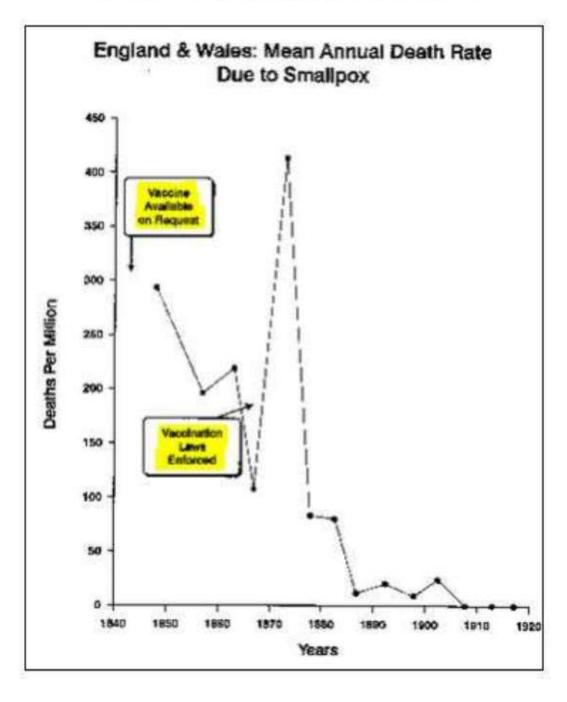
<sup>11</sup> http://www.whale.to/vaccines/decline1.html loc. cit.

<sup>12</sup> http://www.whale.to/vaccines/decline1.html loc. cit.





Table IV: Smallpox (England & Wales)



Approximately two thirds of the total decline in infant deaths from all childhood infectious diseases in Australia in the period covering 1881 to 1971 occurred before the introduction of mass immunization efforts. <sup>13</sup>

<sup>&</sup>lt;sup>13</sup> http://www.whale.to/vaccines/decline1.html loc. cit.





### Table V: Infant Mortality Rate (Australia)

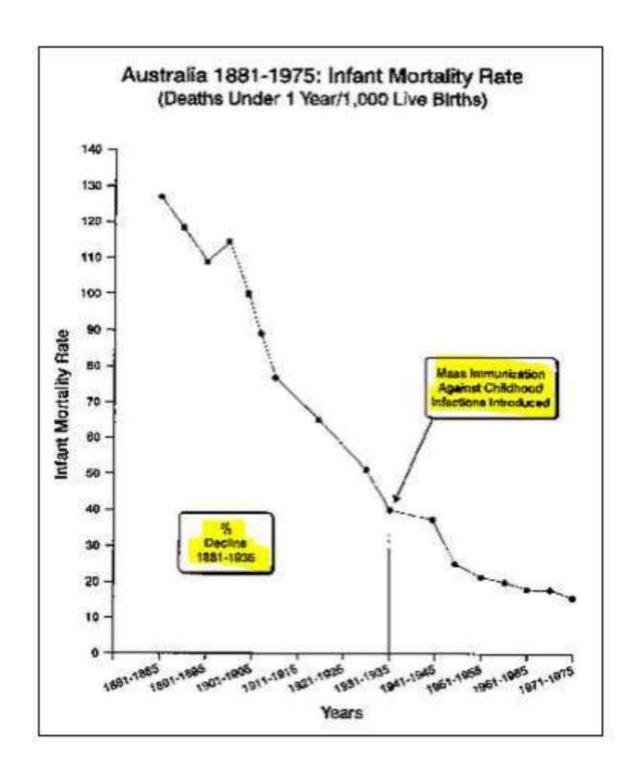
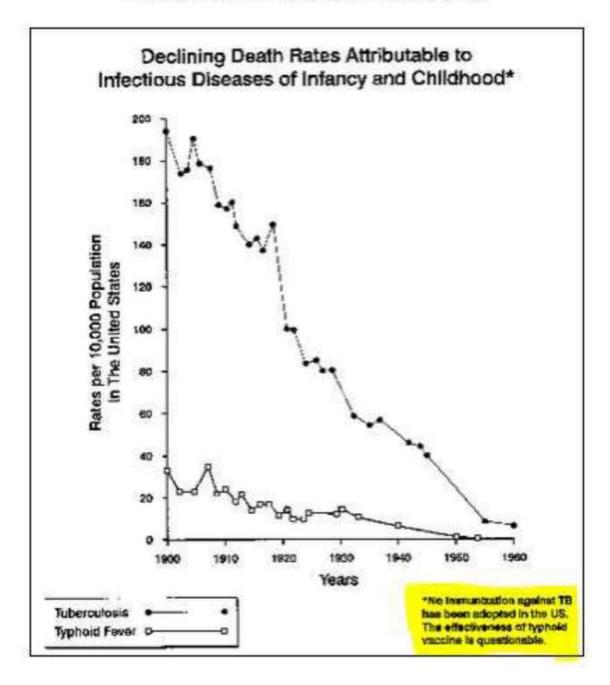






Table VI: Declining Death Rates (US)



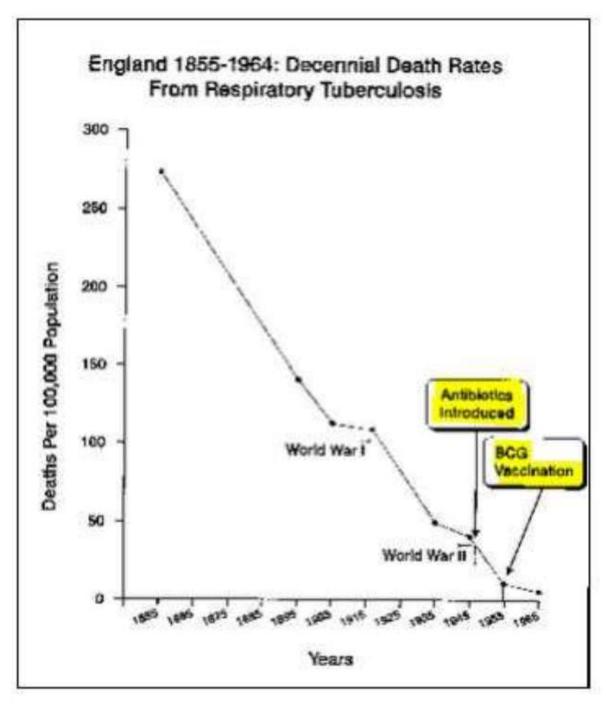
In the United States—without benefit of any vaccine—the tuberculosis mortality rate underwent a drop of roughly 96% in the first 60 years of the 20th century and that in slightly less than the same time span (although the effectiveness of the vaccine has been seriously questioned by reputed scientists) mortality from typhoid vanished.<sup>14</sup>

<sup>&</sup>lt;sup>14</sup> http://www.whale.to/vaccines/decline1.html loc. cit.





### Table VII: Declining Death Rates (England)



Death rates from respiratory tuberculosis in England underwent a roughly 87% decline in the period between 1855 and 1947 when antibiotics first came into wide use. A further decline of nearly 93% by 1953 preceded the introduction of the BCG vaccine.  $^{15}$ 

<sup>15</sup> http://www.whale.to/vaccines/decline1.html loc. cit.

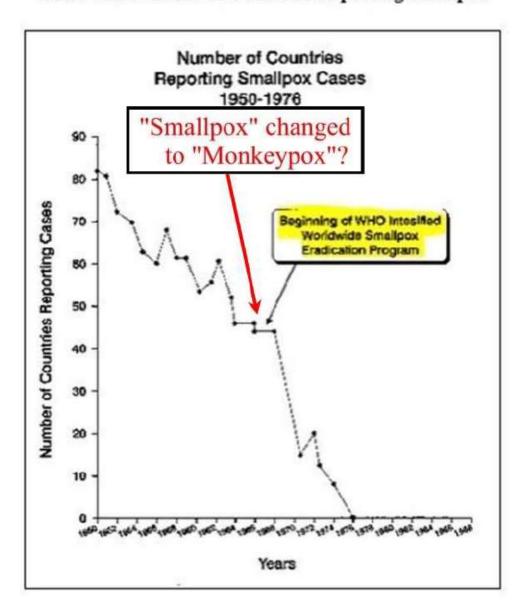




### Disease Eradication: Do the Stars Still Shine So Bright?

What of the shining stars of vaccine-based public health, smallpox and polio eradication?

Table VIII: Number of Countries Reporting Smallpox



During the 17 year period preceding the WHO Smallpox Eradication Program, a progressive drop to nearly one half occurred in the number of countries reporting smallpox morbidity. $^{16}$ 

<sup>&</sup>lt;sup>16</sup> http://www.whale.to/vaccines/decline1.html loc. cit.





# In the following years, *reported* small pox cases rapidly dropped to an alleged level of "zero."

The above graph is quite literally, unbelievable. There is good reason for us to doubt the truthfulness of this government claim, although the official line is clear, as the Center for Global Development summarizes:

"Health Condition: In 1966, there were approximately 10 to 15 million cases of smallpox in more than 50 countries, and 1.5 to 2 million people died of the disease each year. Smallpox has been eradicated from the globe, with no new cases reported since 1978....

"Impact: By 1977, the last endemic case of smallpox was recorded in Somalia. In May 1980, after two years of surveillance and searching, the World Health Assembly declared that smallpox was the first disease in history to have been eradicated....

Cost and Cost-Effectiveness: The annual cost of the smallpox campaign between 1967-1979 was US\$23 Million.10 In total, international donors provided US\$98 Million, while US\$200 million came from the endemic countries. The US saves the total of all its contributions every 26 days because it does not have to vaccinate or treat the disease." <sup>17</sup>

If the official line, that small pox had actually been eliminated, were *true*, then there are significant unintended negative consequences since that would mean that community immunity has been eliminated, too, with serious negative consequences. "Smallpox eradication had limited economic consequences but has left much of world's population highly susceptible to zoonotic orthopoxviruses and to the use of smallpox as a biologic weapon." <sup>18</sup>

However, the official reality is much less clear. Smallpox was, in fact, never eradicated despite huge propaganda and financial expenditure to the contrary. Its name was changed to protect the guilty.

Monkey Pox was first identified in humans in 1970. The two orthopoxviruses are 96.3% identical, although some differences are claimed to exist in their genomes.<sup>19</sup>

Monkey pox and smallpox are clinically similar so that without sophisticated laboratory equipment, the discrimination between their causative pathogens is not possible and, following official pronouncements that smallpox has been eradicated the clinician was – and is – under informational and political pressure to "see", and therefore "diagnose," monkey pox, not smallpox.

Thus, cases of smallpox are now either intentionally or unintentionally misdiagnosed as monkey pox.

<sup>&</sup>lt;sup>17</sup> http://www.cgdev.org/page/case-1-eradicating-smallpox

http://www.ncbi.nlm.nih.gov/pubmed/10681974

http://www.ncbi.nlm.nih.gov/pubmed/11734207





Total cost not adjusted either for inflation or ancillary costs of adverse events, etc., \$2.76 billion in unadjusted US dollars.

Despite laboratory confirmation that smallpox cases persist, diagnostic reporting was altered to implicate monkey pox instead of the true pathogen, smallpox. Thus the smallpox eradication campaign continues to be presented as a resounding "success" when it was, in fact, no such thing.

The New England Journal of Medicine reported, "A joint team from the WHO and the Democratic Republic of the Congo visited the province of Kasai Oriental and concluded that 511 cases of suspected monkey pox had occurred between February 1996 and October 1997.

Laboratory studies have since revealed that a substantial proportion of the suspected cases were actually cases of varicella:" [Emphasis added by the authors]<sup>20</sup>

Thus, smallpox/monkey pox is a prime example of how regulatory decisions are misinformed by self-serving pseudo-science to the detriment of meaningful health care.

What of Polio? Here is the official line from the CDC:

"Polio incidence has dropped more than 99 percent since the launch of global polio eradication efforts in 1988. According to global polio surveillance data from January 21, 2015, 356 polio cases have been reported to date in 2014 from Afghanistan, Cameroon, Equatorial Guinea, Ethiopia, Iraq, Nigeria, Pakistan, and Syria. In 2015, at least 1 case has been reported from Pakistan.

On March 27, 2014, Dr. Frieden15 and senior CDC immunization staff were present when India, along with the other 10 countries of the South East Asia Region, was certified *polio-free*. The country was once considered the most complex challenge to achieving global polio eradication. Four of the six regions of the World Health Organization have been certified polio-free: the Americas (1994), Western Pacific (2000), Europe (2002) and South East Asia (2014). 80% of the world's people now live in so-called polio-free areas.

While no official polio cases have been detected in India for more than three years, poliovirus transmission is ongoing in the three endemic countries – Afghanistan, Nigeria, and Pakistan.<sup>21</sup>



<sup>&</sup>lt;sup>20</sup> http://www.nejm.org/doi/full/10.1056/NEJM199808203390811

http://www.cdc.gov/polio/updates/





Non Polio Acute Flaccid Paralysis (NPAFP) is characterized by weakness, paralysis and sudden onset in children under 15 years of age The truth, which those in India know far better than the rest of the world, is that a "new" condition, *Non-Polio Acute Flaccid Paralysis (NPAFP)*, has replaced polio as the diagnosis of choice following vaccination "against" polio and, in fact, the incidence of NPAFP, which is twice as deadly as wild-type polio, has skyrocketed 12-fold BUT ONLY IN THOSE VACCINATED "AGAINST" POLIO.<sup>22</sup>

By 2012 it was clear that the \$8 Billion US polio eradication program had not only failed, it was a disastrous error causing incalculable human suffering and vast public health costs:

"It is argued that getting poor countries to expend their scarce resources on an impossible dream over the last 10 years was unethical. Furthermore, while India has been polio-free for a year, there has been a huge increase in non-polio acute flaccid paralysis (NPAFP). In 2011, there were an extra 47,500 new cases of NPAFP. Clinically indistinguishable from polio paralysis but twice as deadly, the incidence of NPAFP was directly proportional to doses of oral polio received."<sup>23</sup> [Emphasis added – REL]

### Keeping Up with the WHO/FDA/CDC Joneses

Worse yet, the entire Indian polio eradication disaster was not even carried out because of India's determination that the disease NEEDED to be eradicated. Professor William Muraskin, a specialist in international health policy and infectious disease, in *Polio Eradication and its discontents*, noted that the polio program was primarily designed to prove the fundamental usefulness of eradication as a public health tool by the *Pan American Health Organization* (PAHO) - the incubator of eradication campaigns.<sup>24</sup>

An initial overseas grant of \$20 Million US launched the Indian Polio eradication program ("Pulse Plus") in 1995<sup>25</sup> although public health experts in India felt that polio eradication was not the top priority for the country. 26

In fact, in 1998, Dr. T Jacob John wrote, "Today poliomyelitis is not the number one priority of public health in India. However, we must eradicate it for the sake of the rest of the world."<sup>27</sup>

Keeping up with the CDC/WHO/FDA Joneses has had cataclysmic financial and human costs for India.

<sup>&</sup>lt;sup>22</sup> http://www.naturalnews.com/035588\_polio\_vaccine India paralysis.html

http://www.issuesinmedicalethics.org/index.php/ijme/article/view/110/1065

<sup>&</sup>lt;sup>24</sup> Muraskin W. *Polio eradication and its discontents: an historian's journey through an international public health (un)civil war.* Hyderabad: Orient Blackswan. Forthcoming 2012 Aug.

<sup>&</sup>lt;sup>25</sup> Sathyamala C, Mittal O, Dasgupta R, Priya R. Polio eradication initiative in India: deconstructing the GPEI. *Int JHealth Serv.* 2005;35:361-83

<sup>&</sup>lt;sup>26</sup> http://www.issuesinmedicalethics.org/index.php/ijme/article/view/110/1065

<sup>&</sup>lt;sup>27</sup> John TJ. India's polio eradication efforts at the crossroads. *Indian Pediatr*. 1998;35:307-10





Having accepted the grant of \$20 million US, India had, by 2012, spent a hundred times as much. What might she have accomplished with this vast sum of money were it wisely spent on meaningful health expenditures?



In the 13 months before receiving its "Polio Free" status, 53,563 new cases of NPAFP were documented in India.<sup>29</sup>

While the national rate of NPAFP in India is 13.7 per 100,000 children, where coverage is higher, the rate of NPAFP is correspondingly higher.<sup>30</sup>,<sup>31</sup>

Polio vaccination coverage in highest in Uttar Pradesh and second highest in Bihar. The annualized NPAFP rate in Bihar is 21 per 100,000 and 34 per 100.000 children in Uttar Pradesh.<sup>32</sup>

Vaccine manufactures focus, incorrectly and, as we shall see, often disastrously, on the adaptive immune system (which they can manipulate and profit from) ignoring the vitally important innate immune system.

"Worse, they wrongly claim that evidence of adaptive immunity based on "antibody titer" and/or other similar evidence can be used as a valid surrogate for proof that a given vaccination

<sup>&</sup>lt;sup>28</sup> http://www.issuesinmedicalethics.org/index.php/ijme/article/view/110/1065

<sup>&</sup>lt;sup>29</sup> http://healthimpactnews.com/2014/the-vaccine-myth-of-polio-free-status-polio-vaccine-caused-53000-paralysisvictims-in-india-last-year/

<sup>&</sup>lt;sup>30</sup> Puliyel J, Vashisht N, Sreenivas V. Trends In Non-polio Acute Flaccid Paralysis Incidence In India. WebmedCentral *plus* PAEDIATRICS 1970;-39(1):WMCPLS0035

<sup>&</sup>lt;sup>31</sup> NPAFP increased with the OPV doses used. (R2=32.1%;P2=62.5). Per capita income of the state, female literacy and overall literacy showed negative correlation with NPAFP. This disappeared in a multivariable analysis when the number of doses of OPV was considered. On multiple regression analysis, the number of OPV doses was the only factor that showed a positive correlation with the NPAFP rate. NPAFP in UP and Bihar decreased in 2012 coinciding with a reduction in OPV administered. Puliyel J, Vashisht N, Sreenivas V. Trends In Non-polio Acute Flaccid Paralysis Incidence In India. WebmedCentral *plus* PAEDIATRICS 1970;-39(1):WMCPLS0035

<sup>32</sup> http://www.livemint.com/Politics/XS6vPor5jFX3vKkaE7Ri6H/India-to-get-poliofree-status-amid-rise-in-acuteflaccid-pa.html





program provides disease protection to most of those inoculated with a given vaccine according to some fairly rigid, nationally recommended, vaccination schedule." <sup>33</sup>

The truth is that despite the gloss and puffery, claims of scientific validity for vaccine programs and schedules can neither be supported by science, by cost effectiveness nor by outcomes. In fact, mass vaccinations are a source not only of enormous profit for the companies and economic loss for the countries that support them, but they are a major preventable cause of suffering and death on a scale unprecedented except for armed hostile conflict.

Since the US experience is the one that I know best, and since the US syringe print on world vaccine policies and profits is so enormous, let me take a moment to provide some details of that system.

In the US, vaccines are regulated as drugs<sup>34</sup> which are declared to be safe as required by statute <sup>35</sup> which stipulates "The Secretary shall approve a biologics license application on the basis of a

Application of Federal Food, Drug, and Cosmetic Act The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] applies to a biological product subject to regulation under this section, except that a product for which a license demonstration that the biological product that is the subject of the application **is safe, pure, and potent**; and ..."[Emphasis added – REL]

Critical to the issue, of course, is what "safety" means. FDA relies on the following definition of safely, "... the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time" <sup>36</sup>

Despite the clear statutory requirement for safely, potency and purity imposed on the regulatory agencies, these requirements are consistently not met and, in fact, vaccines are routinely recommended by the Center for Disease Control's Advisory Committee on Immunization Practices (ACIP) even when there is no evidence that any vaccine approved and deployed by the US meets the applicable requirements for safety NOR that it prevents the disease in question from developing in fully vaccinated populations.

Even when vaccines have been shown to fail to provide any protection for those who are fully vaccinated, as in the case of pertussis and influenza<sup>37</sup>, or viral influenza<sup>38</sup> the policy of policy makers is to add more doses of the ineffective vaccine without regard to any parameters of cost

<sup>&</sup>lt;sup>33</sup> http://dr-king.com/docs/20130501 Vaccines The Safest of Medicines or the Biggest Liequstn e b.pdf

<sup>&</sup>lt;sup>34</sup> 42 U.S.C. § 262(j)

<sup>&</sup>lt;sup>35</sup> 42 U.S.C. § 262(a)(1)(C)(i)(I), emphasis added, "... (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; and ..." 32 Title 21 of the United States Code of Federal Regulations (see, 21 C.F.R. § 600.3(p))

<sup>&</sup>lt;sup>36</sup> Title 21 of the United States Code of Federal Regulations (see, 21 C.F.R. § 600.3(p))

<sup>37</sup> http://drking.com/docs/120806\_PGKDrftRevu\_Anti\_vaccineMovementCausesTheWorstWhoopingCoughEpidemicIn70Yrs\_fnlr2b.pdf

<sup>&</sup>lt;sup>38</sup> "Influenza Vaccine: Review of Effectiveness of the U.S. Immunization Program, and Policy Considerations" by Geier DA, King PG, Geier MR







to the public as so-called "booster shots" so that even if the initial vaccination program were cost effective, the addition of any booster clearly renders it much less cost-effective or, more often, non-cost-effective.<sup>39</sup>

Additional segments of the population are brought under the vaccination schedule banner and exposed to unsafe and unnecessary vaccinations. The population, including pregnant women, the elderly and babies, provide market support to manufacturers for vaccines while vaccines provide immune and toxic assaults to the population.

Physicians and public health officials generally rely upon and trust the legality and logic of the recommendations handed down from central authorities without examining the basis, or lack thereof, upon which those recommendations rest has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act [21 U.S.C. 355]

Physicians and public health officials generally rely upon and trust the legality and logic of the recommendations handed down from central authorities without examining the basis, or lack thereof, upon which those recommendations rest. The medical profession must consider its responsibility when faced with unscientific, political and profit-driven health decision-making.

Physicians are trained to believe that they have a sacred calling to Do No Harm and to offer hope and help to the sick and suffering. What if reliance upon official pronouncements instead of clinically-informed medical judgment violates the responsibilities of that sacred trust?

It must be added that among the beneficiaries of increased immunization schedules, at least in the United States, is the United States itself. Since the US government receives \$0.75 per dose of influenza vaccine purchased, under the current recommendation levels, the US government will receive about \$100Million US for administration of the influenza vaccine, which it has admitted has virtually *no* clinical benefit.<sup>40</sup>

The CDC's recommendations for people who develop influenza after vaccination is then to take one of three dangerous failed or unproven antivirals.<sup>41</sup>

The litany of illogic at disastrous cost continues with each vaccine program we examine closely.

The exceptionally gifted scholar, Dr. Paul G. King, PhD<sup>42</sup>, upon whose work I draw extensively, makes the point excruciatingly clearly in his analysis of the costly and dangerous commercially driven, but scientifically barren, case of chicken pox vaccine:

"For the chickenpox disease, the initial criteria used to justify recommending the Merck Varivax® live-virus vaccine for Alphaherpes varicella zoster virus, medically termed as "varicella zoster virus" or "VZV", were: a) one dose would provide lifetime 'immunity' to those

<sup>39</sup> http://dr-king.com/docs/110128 DrftRevuNonCostEffectivenessOfVaxProgrmForN MeningitidisAnd b.pdf

<sup>40</sup> http://www.today.com/video/today/56803874#56803874

<sup>&</sup>lt;sup>41</sup> Oseltamivir, zanamivir or peramivir

<sup>42</sup> http://dr-king.com/ provides a treasure trove of publications detailing aspects of this issue with exquisite





who were vaccinated, b) there would be no serious adverse effects from the vaccine, and c) the added medical costs of the vaccination program would be offset by the reduced societal costs (if lost work time) incurred when parents cared for their sick children. When the actual experience showed that one-dose protected less than 60% of those inoculated from getting chickenpox within a couple of years after being vaccinated, the protection provided was not lifetime, and the costs from the excess shingles (medically called "herpes zoster") cases caused by the reactivation of the latent Alphaherpes varicella zoster virus sequestered in the body's root ganglia greatly exceeded the societal child-care costs "saved", sound medical science would require that this vaccination program be halted because it failed to meet all of the key criteria used to justify its approval. Instead, the CDC simply ignored the sound science and added a second dose of Varivax to its recommendations as well as, for elderly most at risk of shingles, a shingles vaccine (Merck's Zostavax®) for those over 60 years of age.

Even after widespread administration of the second dose of the Varivax vaccine, no more than 80% of those doubly inoculated develop adequate" anti-body titers, the vaccine provides protection that does not last more than 5 years in most who are vaccinated, the excess costs from the added shingles cases in the elderly now exceed US\$ 700 million annually and, though once rare, shingles cases in children have become increasingly common. Scientifically, the Varivax vaccine is a clear failure; it is a vaccine that does not provide long-term, much less lifetime, disease protection from chickenpox; it is a vaccination program that has clearly increased the harm to children and adults caused by the increases in shingles cases it has caused; and, when the serious adverse reactions and deaths attributable to the vaccine and the increased shingles treatment costs are considered, the annual increased medical costs exceed US\$ 1billion (1,000 million) annually.

### Yet CDC still recommends this failed vaccine program." 43,44

In determining whether a given vaccination program can be cost-effective, the following factors must be considered:

- a) All of the costs of the vaccination program
- b) The estimated number of disease cases prevented, and
- c) The estimated number of deaths from the disease for which the vaccine is claimed to be somewhat protective for some period of time.
- In general, for a preventive (prophylactic) vaccination to be cost-effective:
- a) The disease itself must be common (endemic) and have a significant (>10%) mortality rate in those with a clinical case of the disease (e.g., measles in children)
- b) The vaccine must be highly effective (providing true disease protection to more than 90% of those who are inoculated for their "lifetime")

43 http://dr-king.com/docs/20130501 Vaccines The Safest of Medicines or the Biggest Liequstn e b.pdf

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<sup>&</sup>lt;sup>44</sup> Goldman GS, King PG. Review of the United States universal varicella vaccination program: Herpes zoster incidence rates, cost-effectiveness, and vaccine efficacy based primarily on the Antelope Valley Varicella Active Surveillance Project data. Vaccine 2013 Mar 25; 31(13): 1680-1694, online May 31, 2012





- c) The vaccine, its administration costs, and its adverse-event costs must be sufficiently low so that the projected average cost savings from vaccination are significantly more than the average disease case-associated costs, and
- d) The serious adverse reactions (death, permanent disability and life-threatening events) caused by the vaccine must be significantly rarer than those caused by the disease before the vaccine approval and the other vaccination-associated costs (e.g., emergency room visits, hospitalizations and extended hospitalizations) must be sufficiently low so that their population costs are some small fraction of the population administration costs and, collectively, are much less than the costs associated with the disease in the absence of any effective vaccine

Unfortunately, the requirement that a vaccination program must be truly cost-effective when all of the preceding costs are considered is consistently ignored.<sup>45</sup>

Tragically, in the United States, in the current vaccine approval process, the submitter of the application is allowed to:

- a) Make unsubstantiated claims of vaccine effectiveness based on anti-body titer
- b) Ignore the costs of the adverse events associated with vaccination
- c) Make unproven claims as to the level of disease protection provided and the duration of the protection provided by the vaccination series proposed and
- d) Using all of the preceding devices, define the cost of any vaccination program in a manner that justifies the list price proposed by the manufacturer for the vaccine. 46

The US Advisory Committee on Immunization Practice (ACIP) to the Centers for Disease Control and Protection (CDC), apparently acting as a rubber stamp for the vaccine makers, simply presumes that the projections offered by the approved vaccine's manufacturer or the researchers whom they have given grants or have otherwise hired are valid and, before (in the case of the now withdrawn Wyeth RotaShield® rotavirus vaccine), or soon after, approval (in the case of the meningococcal meningitis vaccines (Sanofi's Menomune® and Menactra®, and Novartis' MenVeo®) and the HPV vaccines (Merck's Gardasil® and GlaxoSmithKline's Cervarix®) simply adds the vaccines to the recommended vaccination schedule without any long-term study of:

- a) The in-use performance of the vaccine and
- b) The delayed-adverse-reaction profile for the vaccine.

Then, as mentioned, after the vaccine fails, it is not removed from the schedule: more shots are added to the "recommended" schedule, as "boosters" <sup>47</sup>, courtesy of the CDC – with no further clinical testing.

### Case in point: One Dose Meningococcal Meningitis Vaccination Program

47 Ibid

<sup>45</sup> http://dr-king.com/docs/110128 DrftRevuNonCostEffectivenessOfVaxProgrmForN MeningitidisAnd b.pdf

<sup>46</sup> Ibid





With the preceding realities in mind, let us consider the cost-effectiveness of the original "one dose" meningococcal meningitis vaccination program for children ages 11- or 12- years old, or 13 to 18 years of age if they missed the vaccination at age 11 or 12, and a second dose to college freshman living in dormitories, with the understanding that the ACIP now recommenders a second dose to all children at age 16 because the claimed but unsubstantiated 10-year protection interval used to get the vaccines approved has been found to be overly optimistic. An equally unsubstantiated 5-year period of protection is now being claimed.<sup>48</sup>

### Calculations are based on:

- a. Cost per dose, at least \$150<sup>49</sup>
- b. Minimum number in population segment requiring vaccination, at least 4,000,000 per year since approval granted January 2004
- c. Maximum effectiveness estimated at 85% (unsubstantiated) by manufacturers for the recommended vaccines
- d. Average **maximum** disease 0.67 strain-prevalence fraction for the covered strains, means that with a 100% coverage rate, the mass vaccination program would
  - a. Prevent less than 57% of the disease cases seen annually in the US
  - b. Would have an average cost in excess of \$600,000,000 per year<sup>50</sup>
  - c. Ignore the second shot costs for college students.

The cost for the United States mass meningococcal program significantly exceeds \$1Billion US.

Before Menactra was approved in 2004 and added to the vaccination schedule, there were 1,360 cases of meningococcal meningitis. By 2008 with 41.8% of the children between 13 and 18 vaccinated, there were 1170 cases, or a maximum 0f 190 cases less at an apparent **cost of about** \$1.4 Million US per prevented case. [Emphasis added – REL]

Generous estimates suggest that since approximately 10% of diagnosed cases die, the cost per each of the 19 "prevented deaths" would be about \$14 Million US. [Emphasis added – REL] However since by 2010 CDC only claimed about 9 lives saved through this program, the cost per saved life was about \$30 Million US.<sup>51</sup> [Emphasis added – REL]

Interestingly, however, the while the press rallies around mass vaccinations and vast numbers of children and young adults are inoculated with the meningococcal meningitis vaccine, the reported cases have continued to decline dramatically in both the vaccinated and the unvaccinated [Emphasis added – REL] so that by 2010, the number of cases was at its lowest point in 67 years.

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<sup>48</sup> Ibio

<sup>&</sup>lt;sup>49</sup> This probably underestimates the cost significantly

<sup>&</sup>lt;sup>50</sup> Ibic

<sup>51</sup> http://www.fiercepharma.com/story/cdcpanel-backs-additional-vax-doses/2010-10-28?utm\_medium=nl&utm\_source=internal





It is clear, even before any other associated costs are considered, although they must be, that there is no justification on the basis of either massive public health impact or economic cost effectiveness for this massive vaccination campaign. [Emphasis added – REL]

But any meaningful calculation of the real costs of a public health program must also include the costs of adverse consequences of the program, both in human and in financial terms.

The US Vaccine Adverse Event Reporting System, VAERS<sup>52</sup>, is a voluntary reporting option which is widely believed to capture between 1 and 10% of the relevant episodes of short term vaccine-related adverse events.

Using the most conservative figures, we will multiply the VAERS data by 10 assuming an exceedingly generous 10% capture instead of the more realistic 1-2% capture rate.

From January 2005 through 2010, about 7,095 adverse events for children in the age range in which vaccines for N. meningitides were part of the ACIP schedule. These VAERS reports included:

20 deaths reported in VAERS
98 life-threatening adverse events
49 cases of permanent disability
3007 hospitalizations
19 extended hospitalizations
2,412 emergency-room visits

As Dr. Paul G. King, PhD, points out

"On this basis, to save less than 130 N. meningitides infections and the CDC's about "9" deaths annually, the current 'one dose' vaccination program at an uptake level of about 70 % probably annually causes in excess of 66 deaths, 161 permanent disabilities, 312 life threatening events, 1,006 hospitalizations, 63 extended hospitalizations and 7,900 emergency room visits" [Emphasis added – REL]

Whether considering the enormous public health burden, the human burden or the staggering economic burden, it is clear that this program is neither justified nor supportable except to those whose commercial interests are at stake.

We therefore conclude, that if "The Science is Settled" the one point that can be made with scientific certainty is that vaccines are "unavoidably unsafe." Each vaccination is risky.

The universal right of Informed Consent must certainly apply where there is risk.

In order 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 refuse any vaccination must be respected, whether

<sup>52</sup> http://www.cdc.gov/vaccinesafety/Activities/vaers.html

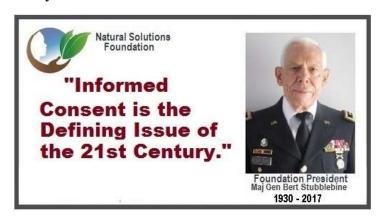
<sup>53</sup> http://dr-king.com/docs/110128 DrftRevuNonCostEffectivenessOfVaxProgrmForN MeningitidisAnd b.pdf





that refusal is grounded in philosophical, medical, religious or no reasons at all. For a detailed review of the Law of Informed consent, see Counsel Fucetola's *Brief for Informed Consent*. <sup>54</sup>

"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



### SUMMARY AND RECOMMENDATIONS FOR IMMEDIATE REMEDIAL ACTION

This White Paper addresses the primary question regarding vaccination, whether vaccines are "safe and effective." At the start of this paper we proposed 11 long-term policy steps needed to address the uninsurable "unavoidably unsafe" status of vaccines. In this conclusion we highlight several of those steps for immediate action to address the crisis in Vaccine Public Policy. With children at risk, immediate action is needed.

Our conclusion: Vaccination is an uninsurable risk that has been declared by courts to be "unavoidably unsafe." The science, as described above, supports that assertion and does not support the opposite, that vaccines are "safe and effective."

The Immediate Policy Recommendations we therefore propose, in summary, are:

- [1] Stop all Federal Funding for vaccine mandates
- [2] Require that CDC Vaccine Committee members be free of all conflicts of interest; end pharmaceutical company tort liability exemption and the Vaccine Injury Compensation Program (VICP)
- [3] Adopt the proposed FIRM Act, Freedom of Informed Refusal of Medication Act and all other steps needed to affirm the universal right to Informed Consent.
- [4] Encourage Alternatives to Vaccination: a Normal Immune System

### RECOMMENDATIONS

Clearly, a solution to the problems of infectious diseases is urgently needed which is cost effective in financial *and* in human terms.

<sup>&</sup>lt;sup>54</sup> http://drrimatruthreports.com/a-brief-for-informed-consent/





[Recommendation #1] Regarding the vaccines themselves, the solution is simple: remember the First Rule of humane medicine: Do No Harm. *Vaccination is Violation*. Mandated vaccine programs must be abolished. All medical, philosophical and religious conscientious objections to vaccination must be honored. In that context, Natural Solutions Foundation sponsors the Advance Vaccine Directive card, asserting the holder's universal right of Informed Consent to refuse all vaccines. More here: <a href="http://TinyURL.com/AVDcard">http://TinyURL.com/AVDcard</a>



[Recommendation #2] The effective mechanism to accomplish this policy goal is the FIRM Act which establishes a Federal Cause of Action to protect the universal right to Informed Consent. Courts must be empowered to issue injunctions to protect fundamental personal privacy rights with regard to any mandated medication.

More about the FIRM Act here: <a href="http://drrimatruthreports.com/support-the-firm-act-freedom-ofinformed-refusal-of-medication-act/">http://drrimatruthreports.com/support-the-firm-act-freedom-ofinformed-refusal-of-medication-act/</a>

[Recommendation #3] Forbid conflicts of interest in the CDC; end pharmaceutical company tort liability exemption and the government injury compensation program that has paid out over \$3 billion in tax money.

The tort exemption violates our First Amendment right to petition government for redress of grievances and guarantees illicit drug company vaccine profits. The conflicts of interest in the CDCs committee system for "recommending" vaccines have become so blatant that self-interested members no longer have to recuse themselves, but must merely reveal their interests when voting. One well-known physician voted to recommend a vaccine in which he had an interest, resulting in tens of millions in personal profit. <sup>55</sup>

Assuming that vaccines provided protection, there would be no need for concern among the vaccinated when they came into contact with the unvaccinated. If they do not work, there is no justification for forcing them on anyone – or indeed, for that matter, for giving them to anyone.

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<sup>55 &</sup>lt;u>http://www.ageofautism.com/2009/02/voting-himself-rich-cdc-vaccine-adviser-made-29-million-ormore-after-using-role-to-create-market.html</u>





[Recommendation #4] Find alternatives to Vaccination. The solution for preventing infections and mitigating risk must be inexpensive, active against every pathogen of any type, easily obtained, robust to temperature extremes, stable at ambient temperature, totally non-toxic so that whatever immunological or nutritional state the recipient is in, there is no toxic impact for even the most vulnerable, self-sterilizing, acceptable to take or use, simple to dose with a very large safety margin to prevent accidental overdose.

There is, to our knowledge, one and only one substance which meets those criteria and it is, in fact, manufactured here in India as well as other countries, which can be used as a safe, inexpensive and effective nutritional support for immune system function.

The substance is called Nano Silver 10 PPM and it meets, and exceeds the requirements set forth above. It has been tested and reviewed in more than 1000 formal safety and efficacy studies and has an unparalleled record of such significant immune system support and safety that it can be safely given to everyone in the community whatever their age, gender, nutritional or immunological status. It stands to reason, after all, that if the immune system can respond quickly and efficiently to every pathogen's challenge, then there is no need for vaccines at all.

Basic principles of Science and of Justice tell us that Vaccination is an uninsurable risk that is unavoidably unsafe. It must be the Public Policy of the United States Public Health System to end reliance on vaccines and reposition public health efforts at reinforcing hygiene, sanitation and better nutrition: the real weapons in the war against pandemic disease. At the same time it should be the Public Policy of the United States to fully support the universal right of Informed Consent. Where there is risk there must be consent.

### Authors:

**Rima E. Laibow, MD** graduated from Albert Einstein Medical College in New York in 1970 and has practiced drug-free psychiatry and environmental medicine ever since. She is Medical Director of the Natural Solutions Foundation (www.GlobalHealthFreedom.org) and a Trustee of the Institute for Health Research

**Ralph Fucetola, JD** graduated from Rutgers College (BA with Distinction) in 1967 and from Rutgers Law School (JD) in 1971. He practiced law for 35 years and is President of the Institute for Health Research. (www.InHeRe.org)

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