



# NaturalSolutions

F O U N D A T I O N

**Regulation and Results:  
The Real Cost of Medical Decision-Making in a  
Commercialized, Politicized Health Care System**  
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**Abstract:** Allegedly scientific information advanced in medical and scientific journals and presented to regulators influences medical perception and practice upon which both public policy makers and clinicians base their decisions while corporate influence (including deeply institutionalized conflicts of personal and professional interest) further skew decision-making toward corporate, not health, interests.

The economic health, indeed, possibly the survival, of a nation hangs on the decisions of those public policy makers while individual health, and possible demise, hangs on the decisions of the clinicians influenced by, and controlled by, those decisions.

Ideally, both scientific literature and regulatory policies are developed free from commercial agendas. In practice, at least in the United States, that is absolutely not the case.

Although the specific remit of this learned Congress is Medical Education (and, ultimately, the medical decision-making to which it leads) in India, the realities of international scientific literature and practices, and the overlarge impact of US scientific literature and decision making through the FDA, CDC and its ACIP makes the impact of its decision-making and public policy practices, commercially driven as they are, worthy of examination for educators, policy makers and, ultimately, clinicians.

Public policy and personal healthcare decisions must ultimately be informed by considerations of efficacy, efficiency and economy. Taking vaccines and vaccine schedules as the exemplar, this presentation will examine the interface with, and failure because of, the conflation of the commercial and scientific spheres and the disastrous economic and health damage done through that conflation on a both the public and on a personal level.

A simple, practical and inexpensive solution replacing vaccines with a universally tolerated universal anti-microbial will be presented.



## Introduction

### Decisions Flow Downstream

Decisions made by regulators flow downstream to public health officials, medical administrators and, ultimately, to the clinicians - physicians and other health professions - 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 to horrific outcomes, including mass infertility and extraordinary increases in the preventable chronic diseases and medical conditions such as autism.

The decision-making process is, of course, inevitably flawed in its essential nature since the data set upon which decisions are made is taken at one moment in time, which the actual situation evolves: flow of better models and better tools is continual in the modern internet world necessitating continual revision of those decisions.

Effective medical education is, therefore, the cornerstone upon which national and personal health decisions rest.

Inevitably, today's public health decision will be tomorrow's naïve error, to be, we hope, corrected by tomorrow's better informed decision. There will always be human and fiscal costs associated with those unavoidable errors. But what if the data set and decisions are skewed by corporate and/or personal interest?

What happens, personally and institutionally, when the errors are avoidable so that wasteful, and worse, dangerous or deadly, decisions are made because of institutional or extra-institutional deceit, distortion, dissembling and downright mendacity? At the personal level, this type of graft and corruption is at least theoretically punishable as the criminal activity that it is. It should, of course, be punishable at the larger level as well. Practically speaking, it practically never is. Even the large fines repeatedly levied upon mendacious drug companies are such a small penalty compared to their profits that there is no incentive to do better.

I submit that public health and regulatory decision-making, ultimately informing clinical decision-making, when based on the commercial interests of corporations and not the well-being of the patient, has a vast and unacceptable cost in every sense of that word. No country can ultimately afford pay that price. No person should be asked to pay that price.

Precious financial resources would be much better spent on meaningful health options like education, nourishing, abundant food, clean water and hygiene rather than wasted on dangerous and costly corporate medical piracy.

### General Example of Commercial Decision-Making: Vaccination



In this brief presentation I will illustrate the magnitude and gravity of the problem – and propose a simple, inexpensive and effective solution, by examining in some detail the emotionally fraught subject of vaccines and vaccinations.

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

Happily, infectious disease incidence as well as morbidity and mortality consistently declined sharply and quite 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.

Please note that my discussion will lean heavily on the US/Canadian/Western European experience so there may be some differences between that and the Indian experience. I believe, however that the foot print, or one might say, syringe print, of the United States' "science", regulatory practices and clinical programs looms so large around the world that it is an experience worth examining closely since it is deeply illustrative of the point: enormous precious resources are wasted, including human ones, when profit controls 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 be safe, efficacious and cost effective. In fact, that standard is established by US statute.

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

Manufacturers and purveyors 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 "after-market" benefits such as vaccine-related illnesses like leukemia and other cancers, infertility, autism, Alzheimer's Disease, Diabetes, etc., which increase the 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.

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 Chart

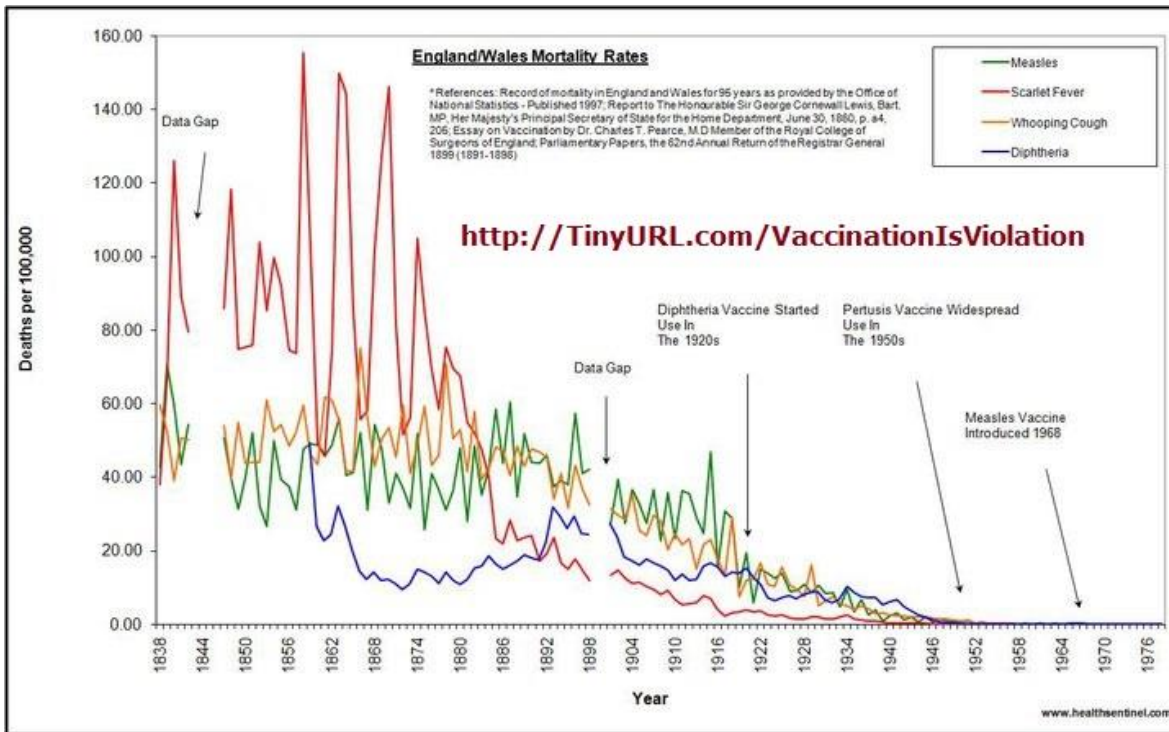
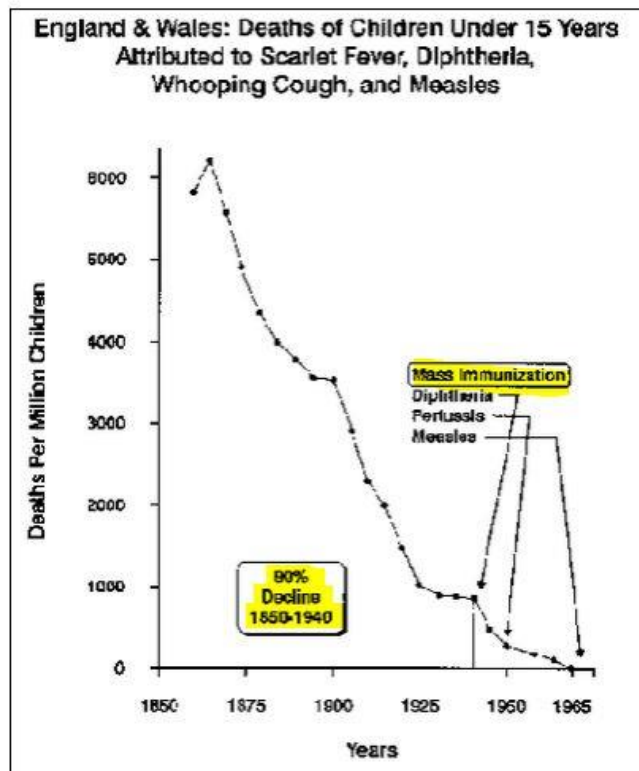


Table 1: Deaths of Children Under 15 Years (England & Wales)

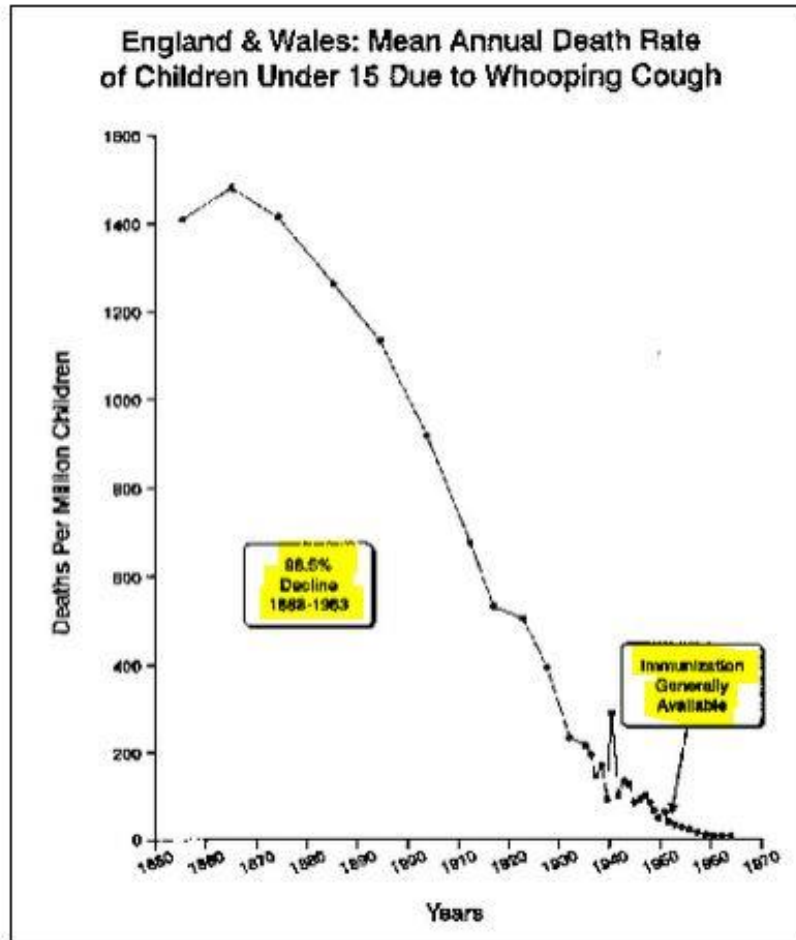


In England and Wales child mortality declined by 90% from the combined infectious diseases of scarlet fever, diphtheria, whooping cough and measles during the 90 years from 1850 - 1940.



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).<sup>1</sup>

**Table II: Whooping Cough (England & Wales)**



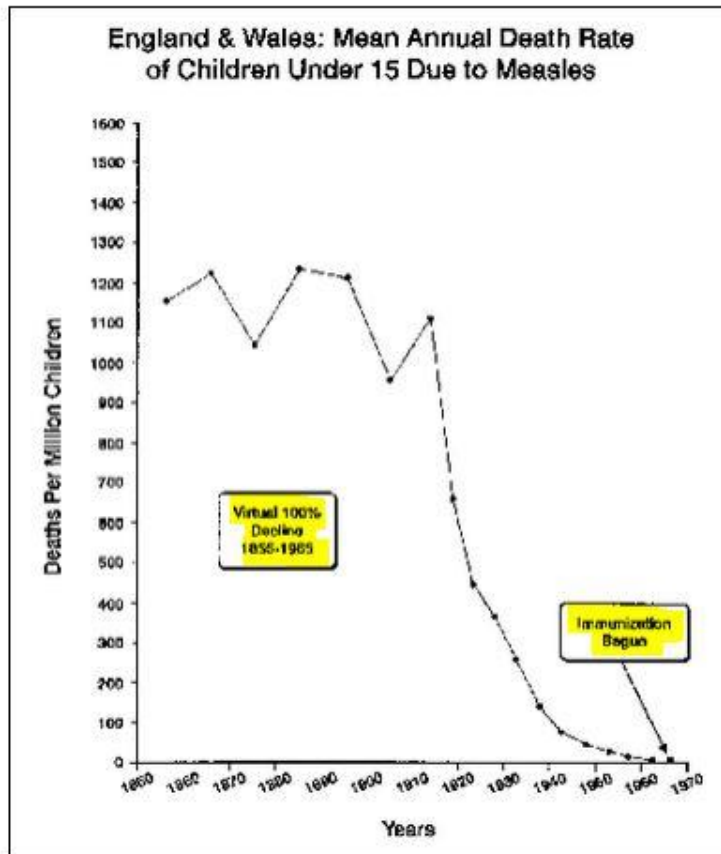
The annual pediatric death rate of children under age 15 from whooping cough in England and Wales declined by roughly 98.5% in the period covering 1868 to 1953, when the pertussis vaccine became generally available.<sup>2</sup>

<sup>1</sup> <http://www.whale.to/vaccines/decline1.html> citing [Immunization Graphs: Natural Infectious Disease Declines; Immunization Effectiveness; and Immunization Dangers Prepared by: Raymond Obomsawin Ph.D. 2009](#)

<sup>2</sup> <http://www.whale.to/vaccines/decline1.html> loc. cit.



**Table III: Measles (England & Wales)**

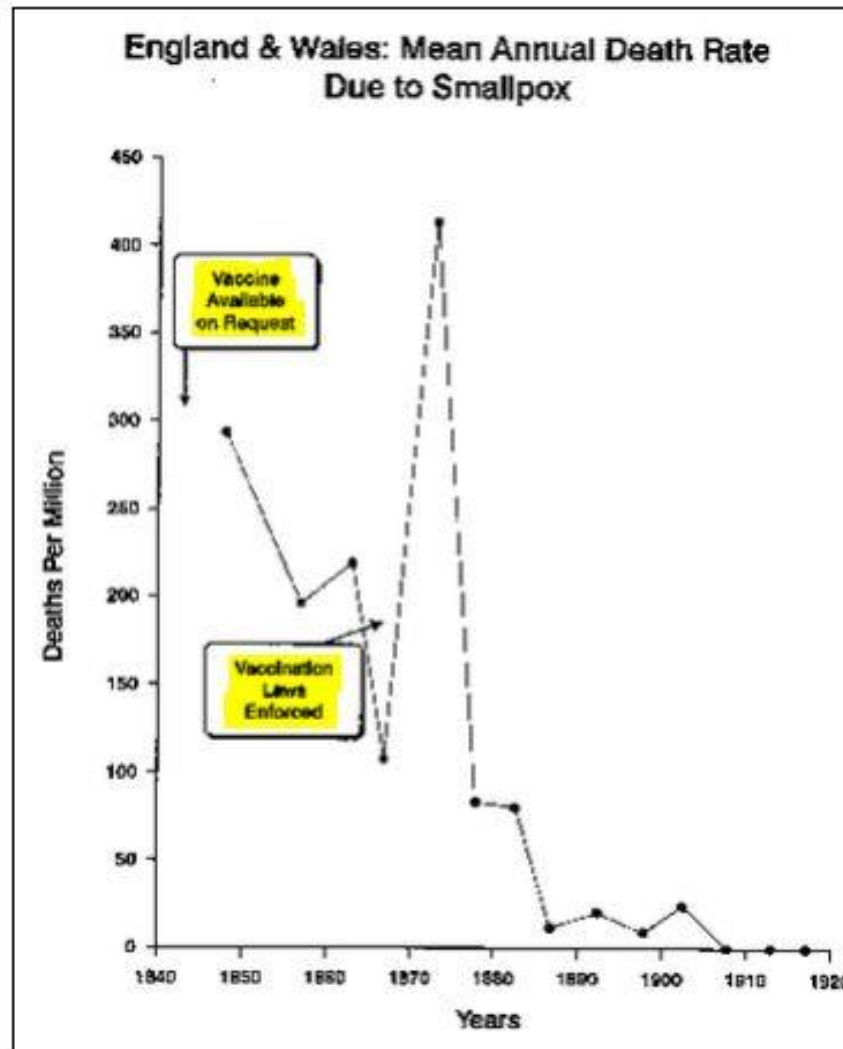


The annual death rate of children (under age 15) from measles in England and Wales declined from over 1,100 per million in the mid-nineteenth century, to virtually 0 by the mid 1960's prior to immunization.<sup>3</sup>

<sup>3</sup> <http://www.whale.to/vaccines/decline1.html> loc. cit.



**Table IV: Smallpox (England & Wales)**

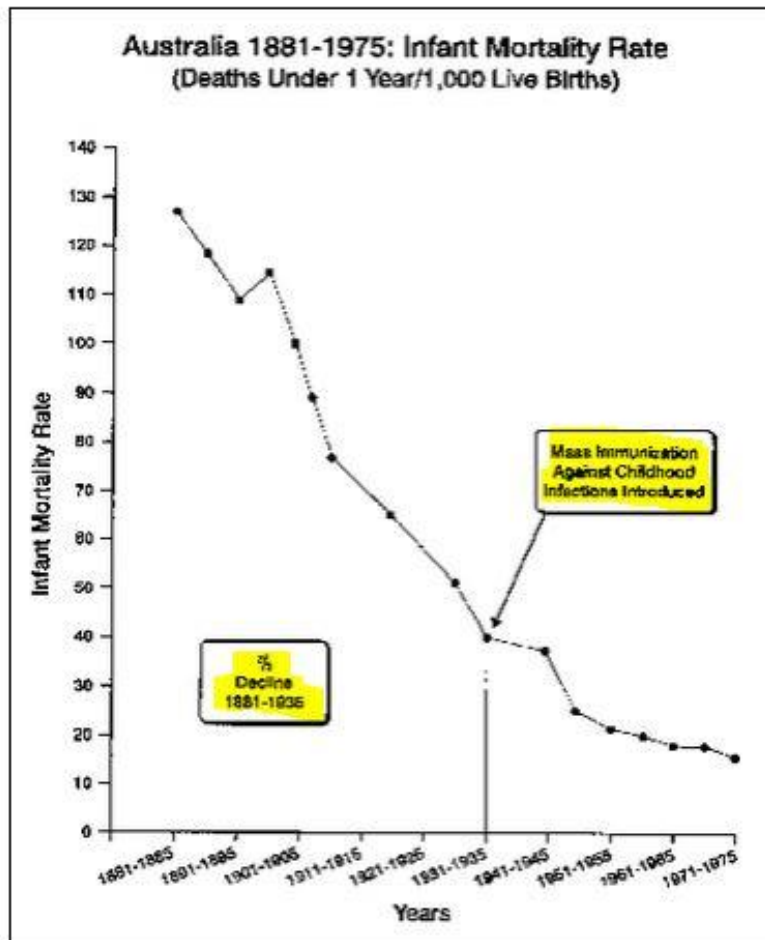


There was a continuing decline in the annual death rate from smallpox in England and Wales with a reduction in mortality of roughly 300 per million to virtually 0 in the 60 year period following the middle of the 19<sup>th</sup> century. This table further illustrates that the progressive rate of decline 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>4</sup>

<sup>4</sup> <http://www.whale.to/vaccines/decline1.html> loc. cit.



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



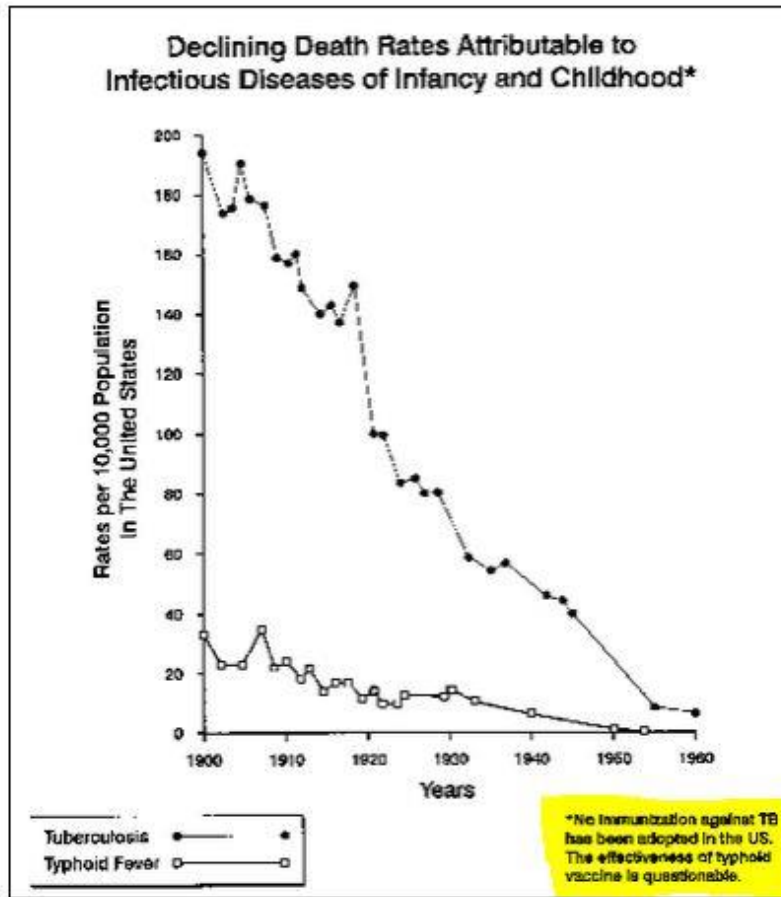
Approximately two thirds of the total decline in infant deaths from all childhood infectious diseases in Australia in the period covering 1881 to 1971 occurred before the introduction of mass immunization efforts.<sup>5</sup>

<sup>5</sup> <http://www.whale.to/vaccines/decline1.html> loc. cit.





Table VI: Declining Death Rates (US)

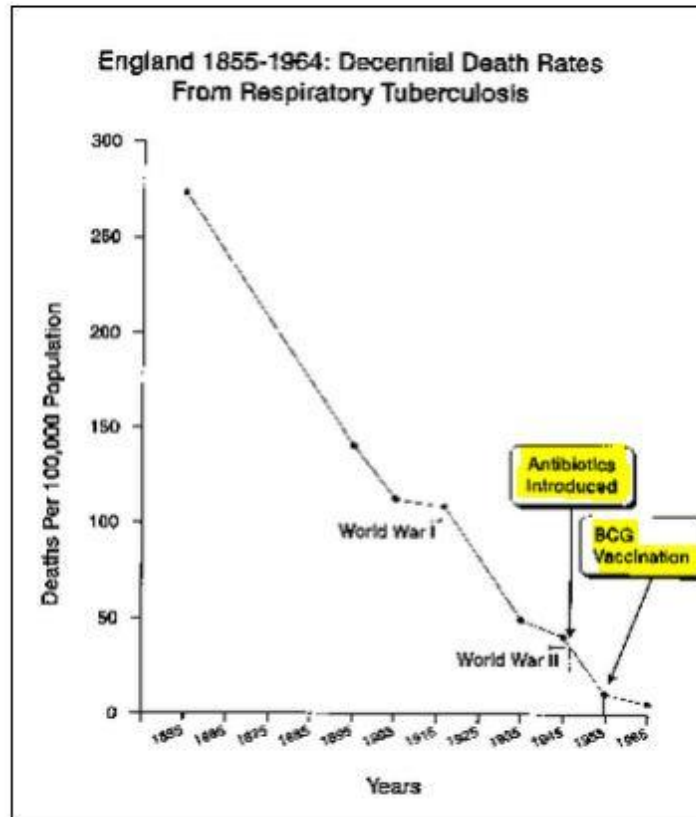


In the United States—without benefit of any vaccine—the tuberculosis mortality rate underwent a drop of roughly 96% in the first 60 years of the 20<sup>th</sup> century and that in slightly less than the same time span (although the effectiveness of the vaccine has been seriously questioned by reputed scientists) mortality from typhoid vanished.<sup>6</sup>

<sup>6</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.<sup>7</sup>

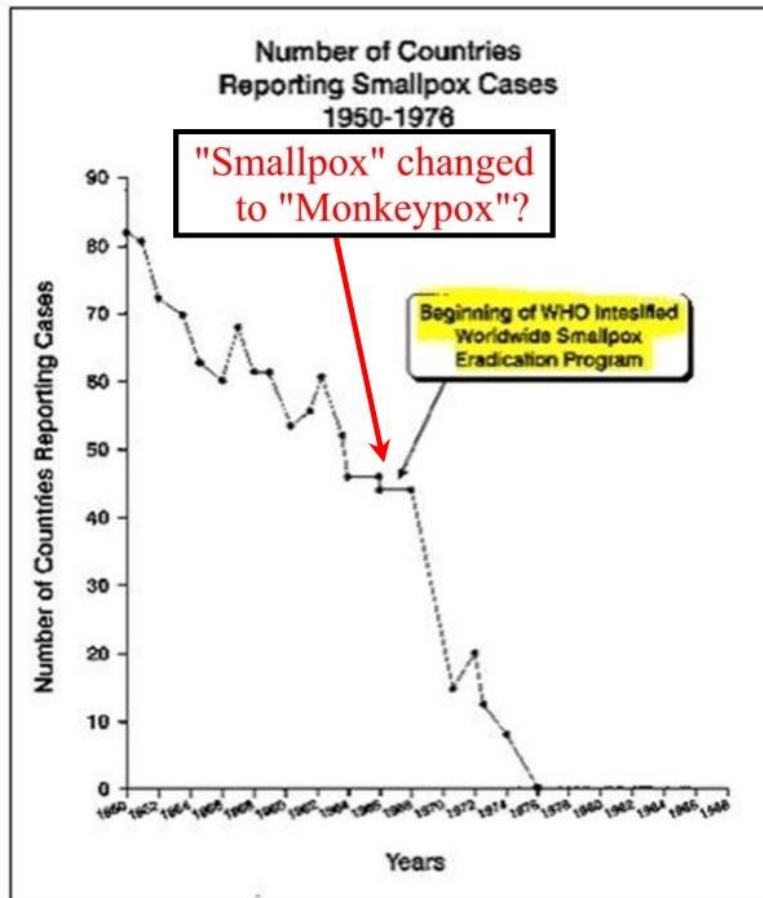
#### Disease Eradication: Do the Stars Still Shine So Bright?

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

<sup>7</sup> <http://www.whale.to/vaccines/decline1.html> loc. cit.



**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.<sup>8</sup> In the following years, reported small pox cases rapidly dropped to zero.**

This graph is quite literally, unbelievable. There is good reason for that: 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....

<sup>8</sup> <http://www.whale.to/vaccines/decline1.html> loc. cit.



Cost and Cost-Effectiveness: The annual cost of the smallpox campaign between 1967-1979 was US\$23 Million.<sup>9</sup> 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>10</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>11</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 do exist in their genomes.<sup>12</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.

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 – REL]<sup>13</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:

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<sup>9</sup> Total cost not adjusted either for inflation or ancillary costs of adverse events, etc., \$2.76 billion in unadjusted US dollars.

<sup>10</sup> <http://www.cgdev.org/page/case-1-eradicating-smallpox>

<sup>11</sup> <http://www.ncbi.nlm.nih.gov/pubmed/10681974>

<sup>12</sup> <http://www.ncbi.nlm.nih.gov/pubmed/11734207>

<sup>13</sup> <http://www.nejm.org/doi/full/10.1056/NEJM199808203390811>



“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. So far in 2015, 1 case has been reported from Pakistan.

On March 27, 2014, Dr. Frieden<sup>14</sup> 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 polio-free areas.

While no 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>15</sup>



Non Polio Acute Flaccid Paralysis (NPAFP) is characterized by weakness, paralysis and sudden onset in children under 15 years of age

The truth, which you 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>16</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

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<sup>14</sup> Current Director of CDC

<sup>15</sup> <http://www.cdc.gov/polio/updates/>

<sup>16</sup> [http://www.naturalnews.com/035588\\_polio\\_vaccine\\_india\\_paralysis.html#](http://www.naturalnews.com/035588_polio_vaccine_india_paralysis.html#)



**NPAFP. Clinically indistinguishable from polio paralysis but twice as deadly, the incidence of NPAFP was directly proportional to doses of oral polio received.**<sup>17</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 programme was primarily designed to prove the fundamental usefulness of eradication as a public health tool by the *Pan American Health Organisation* (PAHO) - the incubator of eradication campaigns<sup>18</sup>

An initial overseas grant of \$20 Million US launched the Indian Polio eradication program ("Pulse Plus") in 1995<sup>19</sup> although public health experts in India felt that polio eradication was not the top priority for the country<sup>20</sup>.

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>21</sup>

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

Having accepted the grant of \$20 million US, India had, by 2012, spent a hundred times as much<sup>22</sup>. What might she have accomplished with this vast sum of money were it wisely spent on meaningful health expenditures?



The oral polio vaccine is so easy to administer, even non-doctors can give it. Bill Gates administering the oral polio vaccine in India. 23

<sup>17</sup> <http://www.issuesinmedicalethics.org/index.php/ijme/article/view/110/1065>

1. <sup>18</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>19</sup> Sathyamala C, Mittal O, Dasgupta R, Priya R. Polio eradication initiative in India: deconstructing the GPEI. *Int J Health Serv*. 2005;35:361-83.

<sup>20</sup> <http://www.issuesinmedicalethics.org/index.php/ijme/article/view/110/1065>

<sup>21</sup> John TJ. India's polio eradication efforts at the crossroads. *Indian Pediatr*. 1998;35:307-10.

<sup>22</sup> <http://www.issuesinmedicalethics.org/index.php/ijme/article/view/110/1065>



**In the 13 months before receiving its “Polio Free” status, 53,563 new cases of NPAFP were documented in India.**<sup>24</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>25, 26</sup>

Polio vaccination coverage is 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>27</sup>

Vaccine manufacturers 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 program provides disease protection to most of those inoculated with a given vaccine according to some fairly rigid, nationally recommended, vaccination schedule.”<sup>28</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>29</sup> which are declared to be safe as required by statute<sup>30</sup> which stipulates “The Secretary shall approve a biologics license application on the basis of a

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<sup>23</sup> <http://healthimpactnews.com/2014/the-vaccine-myth-of-polio-free-status-polio-vaccine-caused-53000-paralysis-victims-in-india-last-year/>

<sup>24</sup> <http://healthimpactnews.com/2014/the-vaccine-myth-of-polio-free-status-polio-vaccine-caused-53000-paralysis-victims-in-india-last-year/>

<sup>25</sup> Puliye J, Vashisht N, Sreenivas V. Trends In Non-polio Acute Flaccid Paralysis Incidence In India. WebmedCentral *plus* PAEDIATRICALS 1970;-39(1):WMCPLS0035

<sup>26</sup> NPAFP increased with the OPV doses used. ( $R^2=32.1\%$ ;  $P2=62.5$ ). 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. Puliye J, Vashisht N, Sreenivas V. Trends In Non-polio Acute Flaccid Paralysis Incidence In India. WebmedCentral *plus* PAEDIATRICALS 1970;-39(1):WMCPLS0035

<sup>27</sup> <http://www.livemint.com/Politics/XS6vPor5jFX3vKkaE7Ri6H/India-to-get-poliofree-status-amid-rise-in-acute-flaccid-pa.html>

<sup>28</sup> [http://dr-king.com/docs/20130501\\_Vaccines\\_The\\_Safest\\_of\\_Medicines\\_or\\_the\\_Biggest\\_Liequstn\\_e\\_b.pdf](http://dr-king.com/docs/20130501_Vaccines_The_Safest_of_Medicines_or_the_Biggest_Liequstn_e_b.pdf)

<sup>29</sup> 42 U.S.C. § 262(j)

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 safety, “... 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>31</sup>

Despite the clear statutory requirement for safety, 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>32</sup>, or viral influenza<sup>33</sup> the policy of policy makers is to add more doses of the ineffective vaccine without regard to any parameters of cost 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>34</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.

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.

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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]

<sup>30</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 ...”

<sup>31</sup> Title 21 of the United States Code of Federal Regulations (see, 21 C.F.R. § 600.3(p))

<sup>32</sup> [http://drking.com/docs/120806\\_PGKDrftRevu\\_Anti\\_vaccineMovementCausesTheWorstWhoopingCoughEpidemicIn70Yrs\\_fnlr2b.pdf](http://drking.com/docs/120806_PGKDrftRevu_Anti_vaccineMovementCausesTheWorstWhoopingCoughEpidemicIn70Yrs_fnlr2b.pdf)

<sup>33</sup> “Influenza Vaccine: Review of Effectiveness of the U.S. Immunization Program, and Policy Considerations” by Geier DA, King PG, Geier MR).

<sup>34</sup> [http://dr-king.com/docs/110128\\_DrftRevuNonCostEffectivenessOfVaxProgrmForN\\_MeningitidisAnd\\_b.pdf](http://dr-king.com/docs/110128_DrftRevuNonCostEffectivenessOfVaxProgrmForN_MeningitidisAnd_b.pdf)





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 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>35</sup>

The CDC's recommendations for people who develop influenza after vaccination is then to take one of 3 dangerous failed or unproven antivirals.<sup>36</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>37</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 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

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<sup>35</sup> <http://www.today.com/video/today/56803874#56803874>

<sup>36</sup> Oseltamivir, zanamivir or peramivir

<sup>37</sup> <http://dr-king.com/> provides a treasure trove of publications detailing aspects of this issue with exquisite



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.”<sup>38, 39</sup>

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”)
- 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>40</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

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<sup>38</sup> [http://dr-king.com/docs/20130501\\_Vaccines\\_The\\_Safest\\_of\\_Medicines\\_or\\_the\\_Biggest\\_Liequstn\\_e\\_b.pdf](http://dr-king.com/docs/20130501_Vaccines_The_Safest_of_Medicines_or_the_Biggest_Liequstn_e_b.pdf)

<sup>39</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

<sup>40</sup> [http://dr-king.com/docs/110128\\_DrftRevuNonCostEffectivenessOfVaxProgrmForN\\_MeningitidisAnd\\_b.pdf](http://dr-king.com/docs/110128_DrftRevuNonCostEffectivenessOfVaxProgrmForN_MeningitidisAnd_b.pdf)



- 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.<sup>41</sup>

The US The 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 as "boosters", courtesy of the.<sup>42</sup>

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

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 recommends 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>43</sup>

Calculations are based on:

- a. Cost per dose, at least \$150<sup>44</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>45</sup>
  - c. Ignore the second shot costs for college students.

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

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<sup>41</sup> Ibid

<sup>42</sup> Ibid

<sup>43</sup> Ibid

<sup>44</sup> This probably underestimates the cost significantly

<sup>45</sup> Ibid



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 of 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>46</sup> [Emphasis added – REL]

Interestingly, however, 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.

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>47</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. meningitidis 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. meningitidis 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

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<sup>46</sup> : [http://www.fiercepharma.com/story/cdcp-panel-backs-additional-vax-doses/2010-10-28?utm\\_medium=nl&utm\\_source=internal](http://www.fiercepharma.com/story/cdcp-panel-backs-additional-vax-doses/2010-10-28?utm_medium=nl&utm_source=internal)

<sup>47</sup> <http://www.cdc.gov/vaccinesafety/Activities/vaers.html>



threatening events, 1,006 hospitalizations, 63 extended hospitalizations and 7,900 emergency room visits”<sup>48</sup> [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.**

I submit to you that his preventable tragedy was brought about through the financial and personal emoluments blandished on regulators and other influential decision-makers leading clinical decision-making to follow the bidding of the highest bidders with public health sacrificed to private gain.

### Conclusions and Recommendations

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

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.

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.

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 my 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.

Our esteemed colleague and Congress Chair, Dr. B M Hegde, MD, is, in fact, well versed in the literature and use of the precise substance and was instrumental in bringing it to India. 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.

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<sup>48</sup> [http://dr-king.com/docs/110128\\_DrftRevuNonCostEffectivenessOfVaxProgrmForN\\_MeningitidisAnd\\_b.pdf](http://dr-king.com/docs/110128_DrftRevuNonCostEffectivenessOfVaxProgrmForN_MeningitidisAnd_b.pdf)



Why not make sure that in addition to clean water and wholesome food, every home in India has a small bottle of Nano Silver 10 PPM which is taken at the very first signs of illness 2-3 times per day, depending on the severity of the symptoms?

What would India save by freeing up the human and economic capital currently wasted on dangerous and highly dubious vaccination programs? How greatly would India benefit if her people no longer suffered the scourge of vaccine failures and vaccine-induced injuries and her children and workers were free of infectious diseases?

Decision-making on the basis of India's needs, not India's corporate (or multinational) needs could bring her, quite literally, a new day of health and prosperity.



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