Justification for a Federal Injunction to suspend all vaccine licenses based on unreasonable health risks and causal links to chronic disease pandemics

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Abstract

Saluting our unsung independent research heroes, this prototype action plan posits that the quality and quantity of new independent research now warrants a U.S. Federal District Court injunction order that suspends the licenses of all vaccines listed on the National Vaccine Program's (NVP) and Centers for Disease Control's (CDC) schedule, as the Federal District Court is a normally unbiased judicial court, unlike the National Vaccine Injury Compensation Program (NVICP) or Secretary of Health and Human Services (SHHS) forums that appear tainted.

Viewed through a Civil Suit "42 USC § 300aa-31" lens with its "more likely than not" evidentiary burden and its *Daubert*, infra, prohibition against expert opinion reliance upon poor quality and flawed data, the surviving good quality data shows the SHHS was statutorily required to suspend the National Vaccine Program (NVP) since it "more likely than not" caused numerous neurological and immune system pandemics (e.g., autism, neurological disorders, autoimmune disorders, etc). Since the SHHS knew of this linking data and intentionally exposed the public to these serous risks of harm, while attempting to hide/alter the data that showed the harm, the SHHS also violated the 14th Amendment's "Constitutional Safety Guarantees." Under these egregious and horrifying circumstances, both Sec. 300aa-31 and a 28 USC § 1331 "Bivens Action" would authorize injunctive relief, and where warranted damages. (Ref. 34)

Unlike the formerly attempted Congressional, IOM, FDA, CDC and U.S. Federal Claims Court forums, the § 300aa-31 and "*Bivens* Action Court" processes ban all flawed data, accept high quality biological data over poor quality epidemiological data, and place all quality evidence of harm before a hopefully unbiased Federal Judge who is not influenced by politics or the pharmaceutical industry. Most importantly, these Judges have the authority to remedy the problem and are accustomed to restraining the conduct of Federal Executive/Legislative branch agencies that jeopardize the public safety rights. Here quality data triumphs over politics, as these Courts routinely protect our federal civil rights.

The NVP is an umbrella for the vaccination activities of the Centers for Disease Control (CDC), National Institute of Health (NIH), Advisory Committee for Immunization Practice (ACIP) and the Food and Drug Agency (FDA) among others.

Keywords: 42 USC § 300aa-31, QER/EBM, NVP/NVICP, pandemic, autism

1. Introduction

Since the 1970s the incidence rates for numerous chronic gastrointestinal, neurological, immune and autoimmune disorders have exploded into pandemics that now affect about one third of all school-aged children. [H.E. Buttram, Medical Veritas, 2008 5:1820-1827. (Ref. 1-2)]

Over the last twenty years, independent research scientists have massed a tsunami of good quality biological data and temporal data, which, if graded under QER (quality of evidence ratings) and EBM (evidence-based medicine) standards, would show the evidence of vaccine dangers far more sound than the evidence compiled by the Secretary of Health and Human Services (SHHS) to promote vaccine safety. [Ref. 5-7, 35]

Indeed, if assessed collectively, this independent research shows that these pandemic-inducing vaccine dangers from the National Vaccine Program (NVP) and indirectly the National Vaccine Injury Compensation Program (NVICP) are "more likely than not" [in re Winship, 397 U.S. 358, 371, 90 S.Ct. 1068 (1970) ("Simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence")], the primary causes for the above pandemics. The NVP is an umbrella for the vaccination activities of the Centers for Disease Control (CDC), National Institute of Health (NIH), Advisory Committee for Immunization Practice (ACIP) and the Food and Drug Agency (FDA) among others.

Horrified by the portion of the research that linked the current autism pandemic to the vaccines that contained mercury poisoning to increase pharmaceutical industry profits, suffering parents teamed up with heroic researchers such as Paul G. King, PhD (CoMeD, Inc., Lake Hiawatha, NJ) and numerous others, presented high quality biological data showing the harm mercury was causing to our children to members of Congress, the FDA, the CDC, and several IOM committees. [SEE: David Kirby's *Evidence of Harm*. Published by St. Martins Press, New York, 2005. (Ref. 3)]

It was all to no avail. These government agencies rejected all the high quality data that linked mercury to autism in favor of poor quality data, which supported their hypothesis that mercury-poisoning vaccines were safe, even though the agencies knew their data was fraudulently based on altered data. [SEE: Kirby at p. 382, supra. (Ref. 3) and R.L. Blaylock, Medical Veritas, 2008 Apr.; 5(1):1714-1726. (Ref. 4).]

Recognizing all of these unsung heroes, the profound pain that millions of affected families suffer, the profound professional courage of the unnamed researchers, and the correctly petitioned Congressional Hearings (U.S. Congressional Hearings on Vaccine Safety, 1999-Dec., 2004),

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that refused to take corrective action when presented with data that showed a clear and present danger (Ref. 3), this proposal touches upon the tsunami of independent research that has ensued following the U.S. Congressional Hearings, and in large measure because of the hearings, that indisputably link the NVP/NVICP to the current global pandemic crisis.

In addition, this proposal contrasts the higher quality of this new evidence with the statutory duties and obligations of the SHHS to be aware of such new evidence and to take it into account in their policies. (42 USC § 300aa-2 and § 300aa-26)

Next, the proposal outlines the SHHS' Statutory Safety duties to assure that every aspect of vaccine research, development, testing, licensing, and warning processes assure a safe product, and that the licenses for vaccines that are subsequently proven to be unreasonably dangerous are suspended and revoked. These noble statutory duties are then contrasted with examples of reckless misconduct wherein the SHHS-managed agencies deliberately disregarded nearly all of these statutorily mandated protections and safeguards for seemingly nefarious reasons. (42 USC §§ 300aa–26 and 300aa–27)

Applying the principles of Ockham's Razor through a legal lens, the proposal then advocates rejection of any and all of the potential solutions to the safety crisis proposed by the CDC, FDA, and IOM because these well-intended forums are overly complicated by politics and pharmaceutical industry financial interests, which have so infected these forums as to make them incapable of protecting the American public, or performing their statutory duties.

Since the current safety statutes governing both vaccine safety and the SHHS conduct are more than adequate to protect citizens from unsafe and unreasonably dangerous vaccines, this proposal suggests filing suit under 42 USC § 300aa–31 to enforce the statutorily mandated duties of 42 USC §§ 300aa–25 though 300aa–27, that have been knowingly disregarded for more than 20 years by the SHHS. Enforcing current laws under professional standards would protect all concerned individuals. Since all CDC schedule vaccines are unreasonably dangerous under independent professional standards, an injunction could be obtained to suspend all unsafe vaccine licenses since this is something the SHHS should have done but failed to do. Moreover, since all vaccines are known by the SHHS to be unreasonably dangerous to the public, this conduct is reckless, shocks the conscience and allows protective relief under due process protections of a 28 USC § 1331 "*Bivens* Action".

Unlike IOM forums, the federal judiciary court can act unilaterally to ban products based on flawed methodology and data; it should accept quality biological studies over scientifically unsound population surveys; should not be influenced by the pharmaceutical industry or politicians; routinely restrains government agencies, and should not hesitate to suspend the NVP if warranted by the evidence. In sum, the Federal District Court should protect the public from the SHHS.

2. SHHS knows of all high quality data linking NVP as cause of multiple pandemics and knows high quality trumps lower quality data

Pursuant to his or her statutory legal obligations, the SHHS is required to stay abreast of all non-governmental vaccine research and to share this data with his or her governmental agencies. If the independent research uncovers dangers to the public, then this information must be shared with all medical doctors who administer the vaccines or groups of vaccines. [SEE: 42 USC 300aa–2(a)(8) ("The director…shall…provide for the exchange of information between federal agencies…and non-governmental entities engaged in…vaccine research…"); and 42 USC § 300aa–26(c): ("The information in such materials shall be based on available data and information.")]

While the SHHS may claim his above-duties do not extend to knowledge of non-published data generated by independent research scientists, no such claim could ethically be made for published-peer-reviewed data, as such material is a fundamental component of "good science," [*Daubert v. Merrell Dow Pharmaceuticals, Inc*, 509 U.S. 579, 113 S.Ct 2786, 2797 (1993): "Publication and peer review, while not necessarily depositive of hypothesis, are basic components of 'good science'"].

Moreover, published data momentarily aside, the SHHS should also be cognizant of all vaccine-related injuries or deaths that are reported to VAERS (Vaccine Adverse Event Reporting System), or that come to his or her attention via NVICP petitions, [42 USC 300aa–11(d)(1): "…initiated by service upon the Secretary…" and § 300aa–25: (establishment of VAERS)] wherein the SHHS admitted that vaccines caused autism or autism-like symptoms, such as: Poling, Kleinert, Underwood, Sanford, Basian, Lassiter, Suel, Freeman, Noel, and Banks. [SEE: http://neurodiversity.com/weblog/article/148.htm, for example (for a listing, see Ref. 21).]

However, the SHHS is bathed in an ocean of studies and is held to the same professional evidence evaluation standards as the independent expert is. Under these "Evidence-Based Medicine" (EBM) and Quality of Evidence Ratings (QER) standards, the SHHS must first grade the quality of the study before relying on it to validate or falsify any given hypothesis or theory. Under EBM standards he must base his decisions on the highest quality evidence that is available. Under QER standards, the highest quality evidence is graded as QER-I and QER-II evidence, while the lowest quality is graded as QER-III-IV evidence. [Greenhalgh, BMJ, 1997. (Ref. 5, 7, 35, 36)]

Therefore, the SHHS would know that under professional norms, higher quality data on the EBM/QER tiers would always trump lower quality or flawed data in the medical decision-making process. When assessing the quality of data, the SHHS would know that "repeated opinions based on poor quality data cannot improve the quality of evidence" [M. Donohoe (2003), p. 241, paper on Shaken Baby Syndrome, (Ref. 5-7)] and, under QER, "independent" data trumps other data.

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To make the higher tier grades (I-II), the study must employ "rigorous methodologies," have proper controls, and, if epidemiologic, it must have "the inclusion of representative patient samples"…"with sufficient statistical power." [Donohoe, 2003 (Ref.7, 35)]

"Proper 'rigorous methodologies' in hypothesis testing include but are not limited to: eliminating all forms of bias and error, careful and sound data collection and analysis, utilizing proper controls, the inclusion of multiple independent studies and designs founded upon accepted scientific principles. Experimental studies with proper controls and experimental designs can also be a part of this evolving process". [Foster, MIT Press, 1997. (Ref. 37)]

When evaluating vaccine-safety-hypotheses, like all other hypotheses, the SHHS cannot accept the hypothesis as proven nor upgrade it to scientific theory, until said hypothesis is submitted to vigorous scientific testing and until all attempts at falsification have failed. [Foster, 1997 and *Daubert*, infra.]

Assessing all the clinical trial and epidemiological studies that are available to support the "vaccines-are-safe" hypothesis, the SHHS would recognize that each one of these studies have flaws that would prevent them from earning QER I or QER II ratings. 21-day clinical trials that lack proper controls cannot support long-term safety claims. Every SHHS population study failed to either apply proper methodology/design or represent the proper population group. Other population studies, such as the secret VSD studies, though published, could not be classified as valid science since their methodologies and data sets were not disclosed. A hypothesis that cannot be examined or tested is not science but rather a faith-based belief system:

> "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified: indeed, this methodology is what distinguishes science from other fields of human inquiry." [*Daubert*, (id), 509 U.S. at 11]

For example, if the SHHS initially graded the Fombonne 2001 paper that found no MMR-autistic link, the study could earn no higher grade than QER III, since the study was not "independent", as required by QER I and QER II. By comparison, the "independent" Goldman/Yazbak 2004 epidemiological study would qualify for a QER I grade. Thus, if faced with both population studies, the SHHS would be required, under the EBM mandate to base his decision on the higher quality 2004 study. Moreover, when the 2005 independent peer-review by Cochran detected significantly flawed methodology in the 2001 Fombonne study, then the paper became ungradable for QER and EBM decision-making purposes. [Ref. 8, 10, 35, 38]

This same end result would hold true for the 2004 Ip P, Wong V, *et al.* population study used to support the safety hypothesis. Since the 2007 peer review by DeSoto and Hitlan found significant data methodology flaws, which the 2004 authors conceded, the 2004 study could not be graded under QER standards, nor used for EBM decisions. (Ref. 39-40)

As one further example, the SHHS could not give any weight to the VSD secret studies for a variety of reasons, foremost of which is the fact that the secret studies cannot be classified as "scientific." A scientific hypothesis must be testable. No epidemiological study can be tested in the scientific sense unless its underlying design, methodology, and data sets are disclosed. Since the authors of all VSD studies have concealed or "lost" their data, these studies cannot be peer-reviewed and are not "science" even though published. Secondly, since they are not capable of review and employ unsound methodology (concealed data), they cannot earn a QER rating [*Daubert*, (id)], period.

In sum then, the SHHS must know of all published vaccine safety data and must always base his decisions on the best quality data that is available via peer review or publication. Quality data should always trump flawed data, and higher quality data should always supersede lower quality data in his or her decision-making process. At least this is how the process is supposed to work under the Secretary's statutorily mandated duties and the academia's EBM/QER Standards that bind him or her.

Under these standards, the SHHS would know that temporal data has shown that today's outbreak of numerous neurological, immunological, gastrointestinal, respiratory, and other chronic disease pandemics coincide with the NVP's mercury-containing vaccines and its ever increasing numbers of recommended vaccines (38 by school-age at last count, with more in the wings). [H Buttram, MVI, 2008. (Ref. 1-2); and E.F. Yazbak, Red Flags Daily.com, "Regressive Autism and MMR Vaccination," 2004 Editorial (Ref. 11)] Since the outbreaks of autism, ADHD, asthma, gastrointestinal, and autoimmune disease have sharply risen in the last 30 years and permeate large geographical areas, they are properly identified as pandemics rather than epidemics.

Supporting this temporal data is a massive amount of high and good quality data which supports the hypothesis that the NVP is "more likely than not" the cause of these pandemics.

Dr. R. Blaylock's microglial and astrocyte model (immune cells of the brain and nervous system) presents strong and high quality data from a wide range of disciplines. His hypothesis posits that the NVP schedule results in excessive and repeated overstimulation of the brain's microglia and astrocytes for prolonged periods of time, resulting in vaccine-induced encephalitis (brain inflammation), which can be very destructive, leading to complications such as autism, ADHD (Attention Deficit Hyperactive Disorder), Parkinson's Disease, and Gulf War Syndrome. Dr. Blaylock consistently cites the highest quality data available in his references. [SEE: e.g., Vargas *et al.*, 2005 (Ref. 12); Russell L. Blaylock, Medical Veritas, 2008 Apr.; 5(1):1727-1741, "The danger of excessive vaccination during brain development: the case for a link to Autism Spectrum Disorders." (Ref. 13); and Russell L. Blaylock, VRAN Newsletter, Spring 2008, "Vaccines, Depression and Neuro-degeneration after age 50: Another Reason to Avoid Vaccines" (Ref. 14).]

Under Dr. Blaylock's model, numerous studies from the neurosciences indicate that this overstimulation is caused by live viruses, intoxicants and adjuvants such as mercury and highly insoluble aluminum, and increasing combinations of simultaneous vaccines, which may cause exponential increases in immunosuppressive and/or toxicity effects; that is, two vaccines together may increase immunosuppression and/or toxicities 10-fold, three vaccines together may cause 100-fold

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increases. As stated by Dr. Buttram (Ref. 2), it is with confidence we declare that Dr. Blaylock's papers, as cited here, represent the most comprehensive publications to date on the pathophysiology of adverse vaccine reactions. [Refs. 13-17]

Paul G. King, Ph.D. has also conducted an extensive review of the data which support his Thimerosal/mercury-poisoning model. Like Blaylock's model, King finds the Thimerosal used in vaccines unreasonably dangerous. Relying on high and good quality data from multiple scientific disciplines, King finds mercury an "all-systems" poison that harms the neurological and immunological systems, at the same time acting as a teratogen, mutagen, and carcinogen. His independent research on Thimerosal (which consists of 49.6 weight-percent mercury) has found the poison to be a causal factor for the foregoing pandemics. [SEE: Paul G. King, Medical Veritas, 2008 Nov., 5(2):1816-1819, "Thimerosal in vaccines: Inconvenient Reality." (Ref. 18); and "A review of doublespeak in vaccines and autism: myths and misconceptions". (Ref. 20).] After submitting the preceding manuscript on March 31, 2008, King's hypothesis was strongly validated by Geier *et al.*, in a study that found significantly decreased plasma levels of reduced glutathione (GSH), cysteine, taurine, and sulfate in autistic children as compared with controls. [These are all sulfur-based compounds, one of the body's primary means of detoxification. [SEE: "A prospective study of transsulfuration biomarkers in autistic disorders," Neurochemical Research, by Geier DA, *et al.*, in press July 2008). (Ref. 19).]

In what may be one of the most penetrating studies to date into the scope of adverse vaccine reactions, in a prepublication release of a macaque study involving the Universities of Pittsburgh, California, Kentucky, the Washington National Primate Center and 13 professional contributors, 13 macaques were treated with the recommended vaccines for children during the 1994-1999 time period, when vaccines contained as much as 100 times the safe dose of mercury according to current EPA and FDA standards. Doses were adjusted for developmental age, size, and weight of the macaques. Three (3) unvaccinated macaques served as controls in the studies:

> "**Results:** Compared with unexposed animals, significant neuro-developmental deficits were evident for exposed animals in survival reflexes tests, tests for color discrimination, learning sets, and aberrant social and nonsocial behaviors mimicking behaviors seen in autism. Brain MRIs showed an attenuation of amygdala growth, an important center for memory. Following necroscopy, severe chronic inflammation was found on tissue exams of the gastrointestinal tracts of vaccinated animals but not in controls. In gene expression comparisons between the vaccinated and unvaccinated groups, there were 120 genes differentially expressed at 10 weeks following vaccines, 450 genes differentially expressed at 14 weeks, and 324 differentially expressed between the two groups at necropsy" …
>
> "**Conclusions:** This animal model, which for the first time examined behavioral, functional, and neuromophometric consequences of the childhood vaccine regimen during the 1990s, mimics certain neurological abnormalities of (childhood) autism." [Also a first is the finding of significant numbers of altered genes following vaccines, highly suggestive that there may be major disruptive effects on the genetic system which, even if not immediately evident, may manifest in later generations.] (http://www.age ofautism.com/2008/05/pediatric-vacci .html)

As reviewed by Buttram (Ref. 2), in a careful cataloguing of more recent vaccine safety studies meeting high EBM/QER standards, there is a consistent pattern indicating potential harm, including, for example, Vargas, 2005 (Ref. 12), Pourcyrous *et al.*, 2007 (Ref. 22), Sajdel *et al.*, 2008 (Ref. 23), and X Ming *et al.*, 2008 (Ref. 24).

The reports of Blaylock, King, and Buttram are cited merely for representative purposes as indicative of a much larger body of high quality evidence indicating that NVP is likely responsible for the pandemics that affect one third of our children.

Indeed, when this scientifically sound evidence is contrasted with the fact that the SHHS has no scientifically sound data to dispute this evidence, then the decision-making process under the EBM standards becomes clear in that no vaccines should be administered. [SEE: Congressional report from the U.S. Congressional Hearings on Issues of Vaccine Safety (1999-Dec., 2004), reporting that the CDC epidemiologic studies all significantly flawed, as released in 2008. (Ref. 25)]

In support of this conclusion, it is posited to all members of the scientific community that each tier of the QER standards demands or assumes proper scientific methodology in any given study: For example, QER I-II "rigorous methodology;" QER III-I: "2 or more well designed and controlled studies performed by a single group;" QER III-4: "Conflicting evidence obtained from 2 or more well-designed and controlled studies." [See: Donohoe 2003 (Ref. 35) for a complete listing of ratings.]

Non-peer-reviewable and significantly flawed studies are all that support the SHHS vaccine-safety-hypothesis. As such, these studies are not scientifically sound enough to earn QER grades or to refute the hypothesis that all vaccines are unreasonably dangerous to the public. Thus, for EBM purposes, the decision maker cannot compare studies with significant flaws, such as inadequate or improper controls, bias, or suppressed data, to scientifically sound studies that qualify for QER I – II reliability grades, because the flawed studies carry no evidentiary weight. [*Daubert* (Ref. 7)]

Indeed, if one uses other evidence grading scales such as the USA-Canadian Task Force System, these points are accepted and similar conclusions are found (Ref. 45)

Accordingly, it is fair to assert that, since the SHHS knows of all the better quality data showing that: a) the NVP is unreasonably dangerous to the public, b) the NVP likely causes multiple pandemics, and c) no scientifically sound data contradict these findings, it follows that the SHHS knows the NVP should be suspended. [SEE, for example: Kirby (2005), supra; J. Roberts, Medical Veritas, 5(2008): 1897-1905, "The dangerous impurities of vaccines" (Ref. 26); Blaylock, Medical Veritas, supra; King, Medical Veritas, supra; Goldman and Yazbak, Medical Veritas, supra; and Buttram, Medical Veritas, supra.]

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Thus, the SHHS is legally mandated to know all the foregoing data and would be held to the same professional conduct standards as an independent expert for his decision-making purposes. Moreover, the established standards for evidence require SHHS decisions to be based on best quality data and not on data that is of poor quality or lacks any provable quality.

3. SHHS subverts statutory vaccine safety duties with tainted committees that disregard high quality data linking NVP to pandemics in favor of corrupted data that supports vaccine licenses.

Contrary to some common beliefs, the NVP/VICP Statutes demand a high level of safety protection in the development, testing, production, and safe administration of vaccines. Incorporated within this comprehensive body of statutes is the authorization of several committees whose task is to constantly monitor and improve the effectiveness and safety of the NVP. However, after summarizing the implicit SHHS safety duties that the statues mandate, the author will posit why these committees should not be utilized or petitioned to remedy the NVP's dangerous actions.

Our NVP legality basis consists of 42 USC § 300aa–1 through § 300aa–6, while the NVICP (National Vaccine Injury Compensation Program) continues with 42 USC § 300aa–10 through § 300aa–34. Under the NVP, the SHHS is required to provide direction in research, safety, development, testing, need, effectiveness, and adverse reactions to vaccines. In pursuit of this goal he or she must implement a plan that results in "safe and effective" vaccines through establishment of priorities in research, testing, licensing, and effective use that is revised yearly. Along with the creation of a committee that recommends research that could enhance the safety of vaccines. [42 USC § 300aa–2, § 300aa–3.]

Under the NVICP, even more emphasis is placed on the SHHS safety duties. This act creates another committee to better advise the SHHS on how he or she can implement his or her section 300aa–27 (infra) safety duties that result in fewer adverse reactions, that advises how to better gather adverse reactions data, how to better use credible data related to the frequency and severity of adverse reactions, and how to better research vaccine caused injuries [42 USC § 300aa–19]. The NVICP set up a mandatory vaccine adverse reaction reporting system (VAERS) [Section 300aa–25] and established a very comprehensive warning system that requires the SHHS to consider "all available data and information" and then provide to all end-users a "concise description of the risks associated with the vaccine" [Sec 300aa–26]. Thus, if credible data linked a specific vaccine with any chronic condition, the treating physician who administered the vaccine would be aware of this danger (e.g., MMR-brain damage).

Assuring the public safety should always come first. The NVICP requires the SHHS to invoke and use all his FDA/CDC powers and "other pertinent laws under the jurisdiction of the Secretary" to assure the safety of vaccines. Specifically, under this law the SHHS shall "promote the development of … less serious adverse reactions … assure improvements … and otherwise use the authority of the Secretary with respect to the licensing … testing … warning … use … instructions … and research … in order to reduce the risks of adverse reactions" [see 42 USC § 300aa–27]. It is proposed that a qualified expert who was held to the standards of his profession and who implemented his duties under these noble statutes would immediately suspend all the CDC Scheduled Vaccine licenses until such time as their safe use can be proven. (Ref. 41)

Therefore, with the exception of the requirement that the SHHS "encourage public acceptance" of vaccines, these extensive statutes are intended to "ensure … safe and effective vaccines" (Sec 300aa–2), a noble and well-intended goal. Indeed, if these laws were being implemented by the SHHS, few complaints over the NVP would exist.

Yet, however noble these laws may be, the SHHS, a political appointee, has knowingly disregarded these duties. Before discussing the clear solution to this safety problem, this action plan will first explain why presenting the evidence of harm to any Congressional Forum or SHHS Committee would appear to be futile. While the examples that follow do not include all efforts to remedy the safety issue, this sampling will suffice for the purpose of showing why the solution does not lie in this direction.

In 1991 the IOM (Institute of Medicine) sent shock waves throughout the scientific community when they issued a statement that allowed pharmaceutical companies to conduct trials without proper control groups. Rather than using "never-vaccinated" groups as controls, the industry was told they could use a group that received an "alternative vaccine" as their control. In 1993, Mrs. Sandy Gottstein testified before the IOM and asked if the NIH ever intended to do a proper vaccine safety study that utilized a proper "never-vaccinated" control group. The NIH conceded that no such study had been done, and the point was taken under advisement. To the best of this author's knowledge, no such government or pharmaceutical study has yet to be done. [SEE: VRAN, Spring, 2008, p. 7-8. (Ref. 27)] This IOM decision and the decision of the vaccine makers to follow it effectively precludes all such "safety" studies from earning QER grades.

In 1992, the WHO (World Health Organization) took this a step further by advising that control groups, vaccine additives (e.g. mercury), and up to 20% of noted deaths, be removed from MMR preclinical neurotoxicity safety studies. (Ref. 44, p. 1918)

In 1998 and 1999, the NIH (National Institute of Health) met with top government regulatory scientists, members of WHO, and the leading vaccine manufacturers. At these meetings, it was disclosed that the manufacturing process was unsafe as the vaccines could not be "purified," could not meet the lowered government standards, and that foreign DNA/RNA could be causing cancers and autoimmune diseases. [J. Roberts, Medical Veritas, 5 (2008) 1897-1905. (Ref. 28)] To this author's knowledge, no remedial action has been taken to address these safety issues.

On July 9, 1999, representatives of the American Academy of Pediatrics (AAP) and vaccine manufacturers agreed that mercury-poison should be removed from all vaccines. In a joint U.S. Public Health Service and AAP statement it was declared that: "Thimerosal-containing vaccines should be removed as

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soon as possible." [Morbidity, Mortality Weekly Report, 1999, July 09, 48(26): 563-566. (Ref. 29)]

By August 24, 2007, mercury was still widely used in vaccines, so on this date Paul G. King, Lisa K. Sykes and CoMeD tried to remove the poisons by filing with the FDA a "Citizen's Petition To Ban Use of Mercury in Medicine…" (FDA docket # 2007p-0331). By August 3, 2008, 17 mercury-containing vaccines were still being licensed and sold. [King, Medical Veritas, 2008 Nov.; 5(2):1816-1819, "Thimerosal in vaccines, an inconvenient reality". (Ref. 18)]

Furthermore, under the CDC's current 2009 vaccine schedule, a child's cumulative mercury exposure would exceed pre-1999 levels with the annually recommended influenza vaccine which, if coming from multidose vials, contains 25 mcgs mercury per 0.5 mL, the recommended dose for those 3 years of age and older. [King, (Ref. 18)]

On December 17, 1999, Dr. T. Verstraeten with the CDC compiled his report on the affects of vaccines with mercury on children's developing neurological system. Relying upon an extensive HMO (Health Maintenance Organization) data base that is not available to independent researchers, his analysis showed a bold statistically significant increase in the incidence rates for autism, sleep disorders, night terrors, ADD (attention deficit disorders) with and without hyperactivity. It consisted of three separate studies of the CDC (Centers for Disease Control and Prevention). Previously, on November 29, 1999, Dr. Verstraeten had his data peer-reviewed in the biased hope that other government statisticians could detect "major flaws" in his work. No known flaws were disclosed. [Kirby, p. 380-382, supra. (Ref. 3)]

On June 7-8, 2000 a "secret" conference was held by 51 government scientists and representatives of both the pharmaceutical industry and the WHO. Both the public and the news media were illegally excluded. In this meeting, the government representatives discussed various methods of altering the secret December 17, 1999 study that linked autism to mercury-containing vaccines, so that the public would not know of the dangers. Years later, Dr. Verstraeten published his 1999 studies, which, having been altered, no longer showed a statistical link between autism and mercury-containing vaccines. [Blaylock, Medical Veritas, 2008 Apr.; 5(1):1714-1726. (Ref. 4)] On June 15, 2000, the U.S. House of Representatives Committee on Government Reform held hearings and determined that the FDA's "Vaccine and Related Biological Products Advisory Committee" and the CDC's "Advisory Committee on Immunization Practices" were both biased and overly influenced by the pharmaceutical industry. [These are the committees that determine licensing and shot-scheduling matters.] About half of these committees' members had financial conflicts, as they owned vaccine patents, pharmaceutical stock, were paid as pharmaceutical company advisors, or had some other vested interest. [Burton, Medical Veritas, 2008 Apr.; 5(1):1670-1696). (Ref. 30)] To this author's knowledge, no corrective action has been taken to remedy these FDA/CDC conflicting financial interests.

During the 1999-2004 Congressional Hearings on Vaccine Safety, Congress learned that there had been no vaccine safety tests that would meet current scientific standards. [Kirby D, Evidence of Harm, New York, St. Martin Press, 2005, page 186). (Ref. 3)] To this author's knowledge, Congress took no binding actions that would assure that proper safety studies took place after making this shocking discovery. In 2001, the IOM issued a report concluding that Thimerosal was not causally related to autism. However, Walter O. Spitzer, MD, Professor Emeritus in Epidemiology at McGill University and 15-year member of IOM found the MMR report so flawed that he asked the IOM president to retract it, stating, "I am embarrassed by the process". In 2004, the IOM again looked into the MMR autism link. At the onset of these hearings, Congressman Dr. Weldon complained that the process was "heavily biased" against independent research and moved to expand the hearing beyond "one hour" to hear evidence – a request which was denied. After the IOM found no link between vaccines and autism, Dr. Weldon criticized the report for favoring significantly flawed epidemiological studies over high quality biological data. [FE Yazbak, May 11, 2005, written letter to IOM President requesting flawed 2004 report be retracted. (Ref. 31)]

On February 21, 2008, the SHHS admitted that Hannah Poling's July 19, 2000 vaccine shots (which contained mercury) caused her to suffer "a seizure disorder as sequela of her vaccine injury". [*Hannah Poling v. SHHS*, No. 02-1466V. E-mail order filed 3-6-08.] Since this admission, no safety corrective action has been taken by the SHHS, even though this was the tenth such case. [Ref. 21, page 1617.]

On January 14, 2009, the Interagency Autism Coordinating Committee (IACC) removed vaccine safety research that had been previously approved from the "Strategic Plan for Autism Research Objectives." The committee action was in direct opposition to the majority of its public members and, furthermore, was a violation of the Congressionally mandated directive of the "Combating Autism Act of 2006" which specifically called for research into "potential links between vaccines, vaccine components, and autism spectrum disorder." IACC Chair and HIMH Director Tom Insel implied that vaccine research by the NIH would constitute a conflict since the SHHS was defending vaccines in the NVICP claims court. SEE: [Age of Autism.com/2009/01national-autism-association-on-IACC-removal-of-vaccine-safety-research.]

On February 5, 2009, investigative news reporter Bert Wallace-Wells published the results of his investigation into Eli Lilly's new atypical antipsychotic drugs. This investigation covered the clinical trials, development, testing, and marketing of drugs, and subsequent lawsuits representing a $16-billion product. This largely centered around federal lawsuits that were won by citizens and the State of Texas against Ely Lilly. The investigation also showed that Lilly had misrepresented the safety data of their trials, had suppressed their data which linked the drugs to unreasonable risks of death and diabetes, knowingly had marketed the drug "off-label" (for uses not licensed). In sum, they knew the drugs were unreasonably dangerous and repeatedly misrepresented safety data to the FDA, obviously for profits. While not a vaccine, these court records and the investigation into 1991-2005 events pose a horrible and chilling reflection on the vaccine safety issue. Since this history is relevant to the motive behind the NVP, it is included herein. All concerned citizens are encouraged to read this well-written article. [Wallace-Wells, 2009. (Ref. 42)]

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These brief snapshots cover only the smallest fraction of the efforts that were made by many to bring safety into the NVP process, Kirby, 2005 (Ref. 3), and are not intended to represent all the efforts which were made to bring the evidence of dangers to light.

However, it will suffice to support the proposition that our IOM/CDC/FDA/Congress safety mechanisms are dysfunctional to the point where they should no longer be used. Under Ockham's Razor, these forums are overly complicated by politics and the influences of both the scientists who built their careers around the need for vaccines and the pharmaceutical industry. Due to the random affects of these influences, a more analytical and unbiased forum should be utilized, one that adheres to sound scientific principles and professional data-review standards.

4. Evidence compels injunction to suspend vaccine licenses of NVP via overlooked 42 USC § 300aa–31 and 28 USC § 1331 Citizen Protection Process

While David Kirby did not draw any conclusions from his extensive FDA/CDC/IOM/Congress research on vaccine safety in his Evidence of Harm, it would take little effort to convince a rational and unbiased mind that said evidence proves collusion amongst the FDA/CDC/IOM experts to significantly alter their data and hide the unacceptably dangerous NVP that is being implemented and mandated in much of the USA. [See Evidence of Harm, 168-173, 380-383. (Ref. 3)] Sadly, this suggests that those agencies will take no affirmative action to assure vaccines are safe [see: Blaylock (Ref. 4)] or to protect our children from this ever-growing national emergency.

Moreover, while the efforts of all independent researchers and courageous parents should be applauded and honored for attempting to affect change in the NVP, this author posits that those efforts now prove that no government agency within the executive or legislative branches can be depended on to protect our children. Consequently we must look to other avenues, the most appropriate being the U.S. Federal District Court for the District of Columbia.

(a) SHHS Violates Statutory Safety Duties

Under the plain language of 42 USC § 300aa–31, any citizen may file suit in any federal district court based on the grounds that the SHHS failed to uphold his statutory safety duties under the NVICP. As discussed previously, these safety duties are extensive. For example, if these duties were upheld, no vaccine would remain licensed unless a proper safety test/trial had been conducted that used proper scientific methodology. This means biological testing in the manner discussed by Dr. Buttram [H. Buttram, Medical Veritas, 2008 Nov.; 5(2):1821. (Ref. 2)] with proper control groups (never vaccinated), and trials that go far beyond the 7 to 21 day window (Ref. 27). If these were being done properly, adding poisons to increase the pharmaceutical industry profits would never be tolerated (Ref. 18-21); nor would the more recent vaccine-incriminating biological studies be ignored, as has been the case until the present.

In sum the NVICP safety statutes are designed to address every valid complaint that any researcher or parent has ever lodged and require the SHHS to implement these duties. When he fails to do so, Sec. 300aa–31 allows any citizen to file suit with the U.S. federal courts and compel corrective action. Pursuant to a legal data base search under the "Westlaw" and "Lexis" systems performed in 2008, no citizen has ever filed suit under Sec. 300aa–31, as their focus has been on the different NVICP forum.

This process has nothing in common with the US Federal Claims Court or the FDA/CDC, IOM Congressional forums. The US judicial courts for the District of Columbia are the courts that routinely protect the public from dangerous government actions and junk science. Here the pharmaceutical industry has no influence, and here the legal discovery process would include any data potentially relevant to the question of whether or not the SHHS was negligent in the SHHS' safety-licensing duties (e.g., Ref. 25 and 42).

Unlike the IOM past hearings, the rules of evidence for the Federal District Court do not allow medical hypotheses that are founded upon flawed data or hypotheses that were tested and falsified.

For example, if the CDC put forth a hypothesis that the MMR vaccine was safe and could not cause autism and based this opinion on the Madsen Denmark population study which in turn had used a significantly flawed scientific methodology [see: "An Investigation of Association between MMR vaccination and Autism in Denmark," by G.S. Goldman, F.E. Yazbak, Journal of the American Physicians and Surgeons, 2004; 9(3):70-75. (Ref. 10), finding temporal association between MMR and a statistically significant rise in autism prior to the change in enrollments and classification], then the Federal Court should find that *Daubert v. Merrell Dow Pharmaceutical Inc*, 509 US 579, 113 S.Ct 2786 (1993) would prohibit testimony which relied upon the CDC Madsen study (Ref. 32).

Daubert is the Federal Court test which governs the admissibility of expert testimony and scientific evidence. It "entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid." Another "pertinent consideration is … peer-review and publication … because it increases the likelihood that substantive flaws in methodology will be detected …" Consideration is also given to a scientific technique "known or potential rate of error … and the existence and maintenance of standards controlling the technique's operation … the focus, of course, must be solely on principles and methodology, not on the conclusions that they generate." Id, 505 US, at 592-595.

Since the Madsen study example did not utilize valid scientific methodology and had significant flaws, it would not meet the *Daubert* test and the CDC could not rely on it. It should also be noted, by contrast, that to qualify for the highest QER Tier, the epidemiological study must be "independent," as was the case of the Goldman/Yazbak study. [Ref. 10]

For another safety-obligation example, if the licensing process of the rubella vaccine claimed it was safe for children based on clinical trials that extended for only 21 days and that used improper controls, as all such trials do, then this flawed safety hypothesis would be falsified by independent testing such as but not limited to the 2003 Pukhalsky *et al.*, a study which tested for immunosuppression evidence 30 days after the rubella shot and found profound depression of interferon

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gamma. [Ref. 33] Therefore, even if the clinical trial did test for immunosuppressive effects, and even if it used a proper never-vaccinated control, the 21-day results would be trumped and outweighed by the 30-day results which indicated safety dangers. "Scientific methodology today is based on generating hypotheses and testing them to see if they can be falsified. Indeed, this methodology is what distinguishes science from other fields of human inquiry." [*Daubert*, 113 S.Ct, at 2796, supra.]

This contrasting of "good quality" versus "poor quality" data is unlike any of the former IOM hearings whereat the government agency rejected high quality biological data in favor of knowingly flawed population surveys, such as Dr. Verstaeten's VSD data. [Ref. 3] Such a decision-making process contradicts the EBM standards that mandate reliance upon the "highest quality evidence," and should not be tolerated by a U.S. Federal District Court.

Thus, a citizen petition filed under Sec. 300aa–31 would entail a new experience for concerned citizens and research scientists. This would be a forum where quality research holds rein over pseudo-science, where proper scientific standards and methodology triumph over improperly generated data, and with a "focus on principles and methodology, not on the conclusions they generate". Unbiased scientific scrutiny is the fear and bane of the vaccine-apologists.

It is the author's medico-legal opinion that all the alleged safety studies wielded by the pharmaceutical industry and the SHHS-managed agencies cannot rebut the overwhelming biological evidence of harm from the NVP, especially since most of their evidence did not have proper controls (never vaccinated), did not test for chronic affects on the neurological, respiratory, GI, immune, reproductive systems, or genetics; or that consisted of population studies which had significant flaws/bias. These fundamental shortcomings should prohibit most of this alleged science from passing the *Daubert* test and should not rebut the independent research that undermines the entire NVP.

The SHHS is also required (statutorily under Sec. 300aa–26) to provide adequate warnings that include "a concise description of the risks associated with the vaccine…" which shall be based on available data and information." [42 USC § 300aa–26] Accordingly, under this statutory requirement the SHHS would need to warn of ***all*** the risks – period, as the statute is not confined to short-term risks, but would include chronic risks.

This duty to inform is not restricted to the risks government scientists agree upon but extends to all credible risks uncovered by independent research. It would necessarily have to list all the associated neurological, immune system, and other disorders that are plausibly caused by the vaccines. Failing to warn of foreseeable vaccine dangers has long been viewed by Federal Courts as valid grounds to find the vaccine unfit or unreasonably dangerous. [*Alman Bros Farms and Feed Mill Inc v. Diamond Lab Inc*, 437 F.2d. 1295 (CA5) (1971)]. This duty was codified into Sec. 300aa–26 and rests squarely upon the shoulders of the SHHS. As an initial draft proposal, this paper is only intended to list a few examples of the SHHS and his NVICP safety duties and indicate how the SHHS has failed in these duties. It is beyond the scope of this broad outline to discuss the thousands of biological studies that show the entire NVP to be unreasonably dangerous.

It should be illuminated once more for the reader that a 42 USC § 300aa–31 petition filed before a U.S. Federal District Court Judge for the District of Columbia for injustice relief, has nothing in common with petitions filed before the FDA, petitions filed with a U.S. Federal Claims Courts, petitions filed against the pharmaceutical industries, or hearings before the IOM and Congress.

This action pivots solely on the statutory duties of the office of the SHHS, held to the standards of an expert in the field and what said expert knew or should have known about the safety of vaccines in all contexts; i.e., development, safety testing, manufacturing, acute and chronic adverse reactions, warnings, and licensing; and what actions the SHHS should have taken to protect the public after assessing the scientific evidence through the lens of *Daubert*, and the scientific community's quality of evidence standards.

Indeed, under this unbiased and analytical analysis, the Federal Court would assume the SHHS knows of all the independent research, assume he or she rejected all research that had fundamental flaws or could not be peer-reviewed, assume he or she graded the quality of the remaining data under EBM/QER or other recognized standards; and then based his or her Sec. 300aa–26-27 decisions on the best quality research. If this negligence analysis showed the SHHS should have suspended vaccine licenses but failed to do so, then Sec. 300aa–31 action would be won and the SHHS would be ordered to implement this previously ignored duty.

This would be the very first time that all the evidence of harm was assessed by a neutral unbiased forum that was accustomed to evaluating the quality of scientific data, accustomed to protecting the public from unwarranted government action, accustomed to rejecting flawed data, and that had the power to suspend any and all FDA vaccine licenses that posed an unreasonable danger to the public, via the issuance of an emergency restraining order or injunction under Rule 65, Federal Rules of Civil Procedure.

While a 42 USC 300aa–31 petition is the easiest solution, as it need only focus on what the independent research should have required of the SHHS under Sec. 300aa–26-27 duties, any 42 USC § 300aa–31 statutory duties complaint should be accompanied by a 14th amendment "substantive" due process complaint under 28 USC § 1331 that alleges the NVP is unreasonably dangerous and should be suspended. The reasons for this are as follows:

(b) SHHS Violates 14th Amendment Safety Guarantees

While the 14th Amendment of the U.S. Constitution offers numerous protections to the public, its "substantive" and perhaps "procedural" due process protections are the subject of this article. A 28 USC § 1331 "*Bivens* Action" allows suits against Federal Government officials whose official actions violate a citizen's constitutional rights.

U.S. Constitutional due process violations under the 14th amendment can be "substantive" or "procedural." A 'substantive' violation occurs when government conduct "shocks the conscience." *Rochin v. California*, 342 U.S. 165,

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172, 72 S Ct. 205, 209 (1952), or "Interferes with rights implicit in the concept of orderly liberty," *Pulko v. Connecticut*, 302 U.S. 319, 325-326, 58 S Ct 142, 152 (1937).

Government statues that comply with "substantive" due process must still be applied in a "fair manner," e.g., *Mathews v. Eldridge*, 424 U.S. 319, 335, 96 S Ct. 893, 903 (1976), "So as not to violate any recognized principle of fundamental fairness," and *Medina v. Calif.* 505 U.S. 437, 112 S Ct. 2572, 2578 (1992), otherwise known as "procedural" due process.

An example of government conduct that would "Shock the Conscience" under *Rochin*, supra, would be having police strand a woman in a knowingly dangerous neighborhood where she was subsequently raped, *Wood v. Ostrander*, 879 F.zd 583, 588, 596 (9th Cir.)(1979).

To violate the *Rochin* standard, the government conduct must have been done with "reckless intent" that was "conscience shocking." ' Reckless intent' would be government action or lack of action that recognizes or should recognize an unreasonable danger to the public and yet intend to expose the public without regard to the danger. To violate the 'conscience shocking' standard, the act or conduct must be so egregious, outrageous, and fraught with unreasonable risk that it shocks the conscience. Adopting a common sense principle, courts will find conduct which poses an imminent risk of serious harm, and which was motivated by an improper purpose, to be unquestionably more likely to 'shock the conscience.' [SEE: *Williams v. Denver City and County of*, 99 F.3d 1009 (10th Cir)(1997)(En Bmc)(In depth discussion of "Shock the Conscience" test).]

For example, a vaccine will be deemed unreasonably dangerous and unsafe if it fails to provide warnings of all potential dangers to health that can arise from its use, [see: *Williams v. Lederle Lab., Div. of American Cyanamid Co.*, 591 F. Supp. 381(SD Ohio)(1984), "even if said vaccine is potentially beneficial" (id)], and this requirement is now codified in Sec. 300a**a-2**6.

Placing this in context, the SHHS must implement his or her Sec. 300aa–26-27 safety duties in a manner that is not reckless and does not violate our 'Shocks-the-conscience' due process constitutional protections.

This places all of his or her statutory duties under a Constitutional lens rather than a Sec. 300aa–31 statutory negligence lens. While this legal test is more complex than a Sec. 300aa-31 claim, it has two distinct advantages. First, Congress lacks the power to foreclose suits under the 14th amendment or alter the Constitution; and Congress could not get away with altering the 28 USC § 1331 Statutes.

Secondly, while the Sec. 300aa–31 process may not provide horrified parents with monetary relief, the 28 USC § 1331 process leaves open all forms of relief, to include monetary relief for compensatory and punitive damages if the vaccine is linked to a specific injury.

For all the same reasons that the SHHS was negligent under Sec 300aa–31, his or her conduct violated substantive due process under *Rochin*, Supra.

In civil court the moving party must prove their claims by a "preponderance of the evidence" which by years of judicial interpretation means: "more likely than not." Moreover, it is reasonable to assume that the SHHS should be held to the same standards as a manufacturer of vaccines, which are judged as vaccine experts. (*Williams vs. Lederle Labs*, supra.)

Indeed, when 12 jurors are shown that one third of all this nation's children were given chronic lifelong ills by our very own SHHS for no reason other than private industry profits, there should be no doubt in any rational mind that said jurors would find such reckless conduct to be "conscience shocking." For if these actions did not meet the legal test, it could be fairly said that the nation has no conscience – something this author cannot envision.

Accordingly, if independent high quality data proved that no proper studies had been conducted on chronic adverse reactions, and that sound scientific evidence showed it "more likely than not" that vaccines were the cause of multiple pandemics, then the vaccine would be deemed "unreasonably dangerous." (*Lederle Lab*, supra), since no warnings were given for these adverse reactions.

Moreover, if the transcripts from secret CDC meetings showed it "more likely than not" (i.e., 50+ %) that the government knew of linking data (for example) that indicated neurological disorders could be caused by Thimerosal additives in vaccines, [R.L. Blaylock, 2008 (Ref. 4)], and were knowingly concealing this evidence or trying to hide the data "signal" by improperly tampering with the concealed study, [SEE: David Kirby citation (Ref. 3, p. 382)], or knowingly accepted flawed survey data and rejected high quality biological data to hide the signal, then the jury would more likely than not find this "conduct" which poses an imminent risk of serious harm and which was motivated by an improper purpose to be unquestionably more likely than not to 'shock the conscience.' (*Denver City and County*, supra)

(c) Preliminary NVP/NVICP injunctions to suspend all vaccine licenses

Once the 28 USC § 1331 "*Bivens* Action" is initiated, the court can be petitioned to issue a preliminary "emergency" injunction which directs the SHHS to suspend the licenses of all vaccines that are unreasonably dangerous to the public and ban their sale/use, while prohibiting the FDA from issuing any new licenses unless the product is first tested under proper scientific standards and deemed reasonably safe.

While some experts may advocate that only live-virus and mercury/aluminum- containing vaccines should be quarantined under reasoning that the bulk of the evidence points to these links, the author feels this view is inadequate, as it lacks modifications based on R. Blaylock's model, that the increasing numbers of vaccines with their adjuvants, given without adequate spacing, overstimulate the brain's immune cells (microglia and astrocytes) for prolonged periods of time, which "can be very destructive to the brain." Since no proper safety tests have been conducted on any vaccine, all should be retracted until proven safe.

Preliminary injunctions are granted to prevent a party from suffering "irreparable harm" while she (or he) awaits the court's decision on her or his suit and request for a permanent injunction. Hearings on these requests should take place promptly, typically within 2 to 12 weeks of the filing [e.g., *Diamontiney v. Borg*, 918 F.2d 739, 795. (9th Cir. 1990)].

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To qualify for this relief, the parties must show that no other remedy at law would protect them from the potential harm and that each is at risk of future harm unless the court takes immediate action. The "party" could be a child or a class action that sought protection for all of today's and future children.

Autism would be an example of a "harm" that cannot be fixed by some other legal remedy such as monetary relief, as once this potential damage takes place, the injury can be lifelong. Courts typically find such a potential risk of harm or potential violation of the 14th Amendment sufficient to meet the "irreparable harm" test. [*Elrod v. Burns*, 427 U.S. 347. (1976)].

It must also be shown under the "balance of hardships" that you will suffer more than the SHHS/manufacturers unless the injunction is granted [e.g., *Doran v. Anaya*, 642 F. Supp. 510, 527 (D.N.M. 1986) (holding that prisoners' interests in safety and medical care outweighed government interest in saving money).] Courts will have no trouble finding that the safety of children outweighs the potential drop in pharmaceutical industry profits or stock prices.

Finally, it must be proven that you have a high likelihood of success in your suit, that it would be in the public interest to grant the injunction, and that you can't afford to post a security bond required by Rule 65 (c). Fed. Rules of Civil Procedure.

Considering the growing tsunami of high quality data which links vaccines to neurological and immune system pandemics, proving a high likelihood of success and that the injunction would be in the public interest should not be overly difficult.

Security bonds are intended to protect your opponents' potential monetary loss in the event an injunction is erroneously granted initially but later correctly reversed. However, this rule is not applied when it would prevent a party from seeking an appropriate injunction, or when the party seeking the injunction is impoverished. [E.g., *Orantes – Hernandez v. Smith*, 541 F. Supp. 351, 385. Fn. 30(C.D. Cal. (1982) (excusing "impecunious class of plaintiffs" from posting bond)].

These are the nutshell requirements for obtaining emergency preliminary injunctive relief. This process is commonly used by environmentalists who seek protection from governmental action, (e.g., recent injunction banning navy from sonar use that beached whales), or nongovernmental actions (e.g. oil drilling that threatens irreparable harm to the environment, and prisoners that face unsafe and dangerous prison conditions.)

When an unbiased and objective analysis is applied to the independent vaccine safety research and then contrasted with the lack of biological data from the SHHS to prove safety, it appears "more likely than not" that the vaccine program poses a serious risk of harm to the public and should be halted – now (*In Re Winship*, supra).

Faith-based safety opinions have no place in a U.S. Federal District Court, and the preliminary injunction process should be invoked by interested parties, who wish to exercise their civil rights under 42 USC § 300aa–31 and 28 USC § 1331.

(d) Administrative Exhaustion, Limitations and Capacities

Any government official whose actions violate the U.S. Constitution may be sued under *Bivens* in their "Official Capacity" for injunctive relief or in their "individual capacity" for monetary damages. Before filing suit under *Bivens* or Sec. 300aa–31, the party must attempt to resolve the matter via any appropriate administrative remedies. For Sec. 300aa–31 negligence suits, this requirement is met by giving notice to the SHHS 60 days prior to filing suit.

For Bivens suits, there would need to be an administrative process that determined if the SHHS and other persons who did work for the government, (e.g., IOM President, FDA/CDC scientists) had or had not violated the U.S. Constitution and could be held responsible for the violations. If no such process is available, then the party is relieved of their obligation to first exhaust administrative remedies. [*McCarthy v. Madigan*, 112 S.Ct. 1088 (1992); *John Poll v. Thornburgh*, 898 F.2d 849, 851 (2nd Cir.), cert.dnd., 111 S.Ct. 63 (1990).] Moreover, no party should be required to file with the NVICP administrative court as a prerequisite to filing a *Bivens* action, since the SHHS, IOM, CDC employees and contractors are not a "Vaccine Administrator or Manufacturer." [42 USC 300aa–11(a)(2)(A).]

Federal Courts will uphold the Defendant-State's "general or residual statute of limitations for personal injury actions," [*Owens v. Okure*, 488 U.S. 235, 243-250 (1989)] and apply the statute to the *Bivens* action. [*Kreines v. U.S.*, 959 F. 2d 834, 836-837 (9th Cir.)(1992)] The time will start running from the time the party knows of the grounds for the suit or should have known. Unless the government defendant concealed or misrepresented the essential evidence, which would toll the clock until you discovered the fact. [*Bell v. City of Milwaukee*, 746 F. 2d 1205, 1229-1231 (7th Cir.)(1984)]

In light of all the government agencies' permeating misrepresentations to the public and the inferences of concealed data, this tolling of the statute of limitations point is a very important one that should be fully investigated by all families and their lawyers. Examples of misrepresentation would be the IOM President's report of 2004 and the news release which declared no link between mercury poison and autism. [SEE: (Ref. 44)] Examples of concealed evidence would include the generation zero Vaccine Safety Data (VSD) studies and secret meetings that took place in 2000. (SEE Ref. 44)

Before filing any suit, the party should consult with a lawyer to determine what administrative remedies, if any, must be used; and to determine which statute of limitations will apply to the suit, as these answers will vary on a case-by-case basis.

5. Action Plan Discussion

"In this article, the quality of evidence rather than the predominance of findings is being assessed. The issue of evidence…appears analogous to an inverted pyramid, with a small database (most of it poor-quality original research, retrospective in nature, and without appropriate control groups) spreading to a broad body of somewhat divergent opinions. One may need reminding that repeated opinions based on poor-quality data cannot improve the quality of the evidence." [Donohoe, 2005, at p. 241) (Ref. 7)]

While Donohoe bespoke of the SBS (Shaken Baby Syndrome) evidence, the same point could be made for the SHHS safe-vaccines hypothesis, which consists of clinical trials that did not have valid control groups, and which tested only for acute adverse reactions. The acute reactions (1-21 day) evidence is then combined with fundamentally flawed

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population studies to put forth the hypothesis that vaccines do not cause pandemics or even epidemics. Nonsense!

Our government agencies and the SHHS are bound by the very same scientific methodology and evidentiary review standards as the independent scientist. Under these EBM/QER standards and the *Daubert* (supra) legal test, good quality data is always given more evidentiary weight than significantly flawed data.

Indeed, while the EBM/QER standards can rate population surveys high on the "weight of evidence" scales with transparent and rigorous methodology, and with sufficient numbers of test patients and controls to be statistically significant. This QER I and QER II high quality grade can only be achieved by "independent" studies from independent research scientists", the very type of data that was rejected by the 2004 IOM hearing in favor of flawed SHHS studies that cannot be graded. [Donohoe, 2003, (Ref. 35) and Blaylock, Medical Veritas, 2008, at p. 1727, EBM criticism) (Ref. 13)] These scientific and medical decision making standards assume proper scientific methodology and give far more weight to "independent" (QER 1-2) studies than biased studies. (Ref. 45)

Accordingly, these standards which rate non-flawed studies support the independent researcher. Flawed methodology cannot generate reliable data, and this type of study can no more earn an EBM/QER rating than a significantly tainted or contaminated tissue sample could generate reliable DNA data if tested.

Once the discussion focuses on sound scientific data that is assessed under EBM/QER standards, the evidence overwhelmingly falsifies and invalidates the SHHS hypothesis that vaccines are safe. Moreover, while the scientist is properly restrained by terms such as "statistically significant," "causal link," "association," or "correlation," when describing data in support of a theory or hypothesis, no such restraints exists for the average juror.

A civil jury would look at all the evidence and determine if the preponderance of evidence makes it more likely than not that the vaccines are the cause of the pandemics and that the SHHS was negligent in his or her duties. In making their assessment, the jury would not consider significantly flawed population studies as overly flawed evidence would be banned under *Daubert*, supra. Once the flawed circumstantial (epidemiological) evidence is removed from the safe-vaccines hypothesis, what is left? Clinical trials with improper controls that did not test for chronic conditions? Even if this direct evidence were scientifically sound (which it was not), it could not rebut tests and data confirming ensuing chronic illnesses related to the vaccines.

Simply put, chronic illness data invalidates acute signs data for safe-vaccine hypothesis purposes. Sound conflicting data invalidates a hypothesis founded upon flawed data. Moreover, high quality data generated by independent research, will always invalidate lower quality data generated by a biased researcher who tries to create data in support of his unfounded hypothesis.

While future research may validate a specific manufacturing process that addresses the safety concerns expressed by Dr. Buttram [Buttram, 2008 (Ref. 2)] and Mrs. Roberts [Roberts, 2008 (Ref. 28)]; while harmful adjuvants may one day be removed from all vaccines; and while a non-harmful/reduced shot schedules may come into existence and be proven safe, that day is not here yet. Moreover, this action plan is a "call to arms" for all persons who wish to protect our children from this horror, by exercising their Federal Civil Rights. The community of vaccine researchers and terrified families have never yet had their day in court, as their courageous and heroic efforts were blocked by the very government agencies that were originally designed to protect the public. Quality of data and scientifically recognized grading standards should be the focus of all discussions.

Under the 42 USC § 300aa–31 process it is not necessary to prove that any specific vaccine caused any specific injury as is required by the vaccine court to obtain injunctive relief. It is enough to prove that the SHHS was negligent and that the vaccines pose an imminent risk of harm and are unreasonably dangerous to some. This injunction relief point remains true for the *Bivens* action that no specific case injury must be proven, just reckless conduct which "shocks the conscience" and poses an imminent risk of harm. These do not appear to be difficult burdens in light of overwhelming biological data.

This action plan has not discussed the constitutionality of the NVP/NVICP, as this was not its purpose. However, any person who contemplates a 42 USC § 300aa–31/*Bivens* action should be cognizant of the fact that the entire NVP/NVICP statues may be unconstitutional. Statues must be capable of being applied or interpreted in a legal manner. The problem with 42 USC § 300aa–1 through § 300aa–30 is that the statutes assume vaccines are safe. If no vaccine is safe, then the NVP/NVICP would violate *Rochin*, supra ("Shock the Conscience"). While such a claim is not yet suggested, it may warrant further legal investigation and bear fruit at a later and more favorable time.

For too many years, horrified parents and researchers alike have had their sound data rejected in favor of flawed data that would support the pharmaceutical industries' profits. These **nefarious** decisions violated all our objective standards for reviewing evidence.

Since our vaccine statues have noble safety protections built into them, why not enforce these laws? The time to act is now.

6. Conclusion

Tristfully, after completing this manuscript and during its editing phase, the February 13, 2009 news media advised the public that the 3 NVICP court test cases had been denied by the Tax Law Special Master. Pursuant to CNN's February 13, 2009 report by Dr. Gupta, the Special Master relied upon studies that have been noted herein as being low quality or too flawed to be graded by the international scientific standards of the QER. The families, who are the victims of that decision and the CDC mercury-poison shot schedule, have the author's sympathy and condolences.

However, the purpose of this article is to advise these families, their lawyers, our heroic independent researchers, and the public at large of their civil rights under 42 USC § 300aa–31 and 28 USC § 1331, which will protect us from unreasonably dangerous National Vaccine Programs that may be lethal or disabling to members of the public. All persons who wish to exercise these safety protection rights should seek out

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professional legal and scientific advice to assist with the preparation of such a long overdue suit.

Such suits would not be a battle of the experts but rather a battle of proper vs. improper scientific methodologies and scientific quality standards. Once all relevant safety studies are graded under recognized scientific standards, the flawed data will be removed from the courtroom. The remaining high-quality data will be sufficient to convince 12 jurors that the National Vaccine Program has caused numerous pandemics. Questions and comments will be welcomed, and this author will help in any feasible manner such as evidence presentation tactics..

Author's Note: K.R. Holcomb has no conflicts or competing interests. He has been performing paralegal work for over 16 years and recently conducted a medico-legal investigation of Shaken Baby Syndrome (SBS) in Arizona. The results of that investigation were published in the November, 2008 issue of Medical Veritas and are the primary subject matter of the nation's very first Federal Court "Actual Innocence" Evidentiary Hearing for SBS/SIS in an old SBS-conviction case of *Stern v. Schriro*, CV-06-16-TUC-DCB, that should be set for June, 2009. The investigation of this case proved the SBS diagnosis is a myth. Numerous other SBS cases are now being reopened or dismissed because of that *Medical Veritas* article (Ref. 43).

The assumption that vaccines are safe appears to be another medical myth that has no sound underlying science to support it. When this evidence is properly presented to the courts, there can be little doubt that the safe-vaccine-hypothesis will be rejected. I invite all questions and comments.

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QER I: Consistent evidence obtained from more than 2 independent, randomized, and controlled studies or from 2 independent, population-based epidemiologic studies. Studies included here are characterized by sufficient statistical power, rigorous methodologies, and inclusion of representative patient samples. Meta-analysis of smaller, well-characterized studies may support key findings.

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