

Facility Automation Management Engineering (FAME) Systems

33 Hoffman Avenue, Lake Hiawatha, NJ 07034 – Tel. 973263-4843

Wednesday, 21 December 2005

To Whom It May Concern:

The review that follows this introductory letter is a critical assessment of the opinions expressed by Randolph W. Pate, J.D., MPH and Heritage Foundation “visiting fellow” in the Center for Health Policy Studies in a column titled “Vaccine Liability: Congress Should Give Vaccines A Shot In The Arm,” which was electronically published at:

<http://www.heritage.org/Research/HealthCare/wm946.cfm>,

on a page that I visited as a part of my research in this area on Sunday, 18 December 2005.

In general, to clearly differentiate between my assessment comments and those of the author, this reviewer’s remarks are written in a “News Gothic MT” font with the various author’s printed statements indented and quoted in a “Times New Roman” font.

Quotes from general reference articles and documents will be presented in an “Arial” font and federal laws and statutes will be quoted in a “Lydian” font.

Should anyone find any factual misrepresentations in this reviewer’s remarks, then this reviewer requests that the factual error along with the scientifically sound and appropriate documents that prove your point to this reviewer so that this reviewer can learn from you, incorporate that new knowledge into his understanding, and, where indicated, appropriately correct this document.

Respectfully,

A handwritten signature in black ink that reads "Paul G. King". The signature is written in a cursive style with a large initial "P" and "K".

Paul G. King, PhD, MS, BA
Founder, **F.A.M.E. Systems**

Review of “Vaccine Liability: Congress Should Give Vaccines a Shot in the Arm”

“Randolph W. Pate, J.D., MPH,” “Visiting Fellow in the Center for Health Policy Studies at The Heritage Foundation,” begins his “December 16, 2005” opinion piece (“*WebMemo #946*”) for the Heritage Foundation by stating:

“In response to scientists’ warnings about an avian influenza pandemic, President George W. Bush recently called for the creation of a \$7.1 billion influenza preparedness strategy. The cornerstone of his plan is vaccination.[1] As things now stand, however, the country does not have the resources to make this plan a reality: vaccine makers face too many legal obstacles and too much potential liability to make the investments needed to combat avian flu. Congress has dealt with this problem before, with respect to childhood vaccinations, and should respond today similarly. Extending the Vaccine Injury Compensation Program (VICP) to cover more vaccines will give vaccine manufacturers breathing room to innovate and bring their life-saving products to market, to the benefit of all Americans.”

First, this reviewer finds that this obvious apologist’s views here are based on a false fundamental premise.

That false premise is that the vaccine industry knows how to make a *safe* and *effective* vaccine for *any* human *influenza*.

Based on recent articles^{1, 2, 3, 4} and this reviewer’s understanding of the data published by the Center for Disease Control and Prevention (CDC) in its Morbidity and Mortality Weekly Report (MMWR) concerning the effectiveness, not efficacy, of the human influenza vaccines during the past two decades, the human influenza vaccines have not been effective (> 85% protected) in protecting those vaccinated from getting the “flu” nor is there any strong correlation between vaccination rates and either reported flu-related deaths or flu-related hospitalizations.

Thus, the current “flu” vaccines are not truly effective – even in those studies published and referenced by the CDC in the MMWR.

Perhaps this is one reason that the “healthcare establishment” is pushing its Congressional apologists for an “indulgence” to immunize them from all liability for their products.

In addition, because the majority (>95 %) of the vaccine doses approved for the very young (< 4 years of age) and the elderly (> 65 years of age) are “Thimerosal Preserved” (0.01 % [100 parts per million] Thimerosal [56.73% “ethylmercury” by weight]), the current mercury-containing “flu” vaccines mercury

¹ Jefferson T, Smith S, Demicheli V, Harnden A, Rivetti A, Di Pietrantonj C. Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. *Lancet* 2005;365:773-80.

² Jefferson T, Rivetti D, Rivetti A, Rudin M, Di Pietrantonj C, Demicheli V. Efficacy and effectiveness of influenza vaccines in elderly people: A systemic review. *Lancet*. 2005 Sep 22; Early Online Publication.

³ Ritzwoller D P, Bridges C B, Shetterly S, Yamasaki K, Kolczak M and France E K. Effectiveness of the 2003–2004 Influenza Vaccine Among Children 6 Months to 8 Years of Age, With 1 vs 2 Doses. *Pediatrics* 2005;116;153-159; published online as of Oct 3, 2005

⁴ Maeda T, Shintani Y, Nakano K, Terashima and Yamada A. Failure of inactivated influenza A vaccine to protect healthy children aged 6–24 months. *Pediatrics International* (2004) 46;122–125.

poison all that are administered them to some degree, and some to the degree that they exhibit one or more of the symptoms of clinical mercury poisoning.

Thus, the current human influenza vaccines are not truly effective and they are not truly safe.

Given the preceding realities how can anyone except “snake oil salesmen” suggest that any money should be spent in developing a similar ineffective and/or unsafe vaccine?

The author asserts that the “healthcare establishment” and the “vaccine makers face too many legal obstacles and too much potential liability to make the investments needed to combat avian flu.”

Given the current “flu” vaccine track record, any such “avian flu” vaccine would be no more, and probably less, effective than the current human flu vaccines.

Therefore, it makes no sense to spend taxpayer dollars to develop another “flu” vaccine.

Further, while extending “the Vaccine Injury Compensation Program (VICP) to cover more vaccines will give vaccine manufacturers breathing room to innovate and bring their life-saving products to market, to the benefit of all Americans” seems like a good idea on its face, the reality is that, protected from liability for their mistakes, the “vaccine manufacturers” have already knowingly engaged in the continuing manufacture of vaccines that are neither truly safe nor effective in protecting the public from the diseases currently covered by the VICP.

Thus, rather than adding all vaccines to the VICP, manufacturers should be required to prove the long-term safety and effectiveness (not efficacy) of their vaccines to before any VICP coverage should apply and all vaccine components, including mercury compounds, adjuvants extraneous viral impurities, and any other highly toxic or bioactive components or impurities in each covered should either be proven safe with safety margins of 1,000 or higher or removed from the vaccine or, failing both, the vaccine should not be covered by the VICP.

Since the cornerstone of President George W. Bush’s plan “is vaccination.[1]” and, as has been shown, “flu” vaccines are not truly effective, his plan should be abandoned because it is simply another undeserved and unwarranted plan to reward and protect the healthcare establishment at the expense of the health of the public.

Given the financial predictions for the growth in the vaccines business, it seems obvious that the benefit, if any, will be to the “vaccine manufacturers” and their shareholders at the expense (direct and indirect) of “all Americans.”

Until independent studies can prove that the overall benefit to the public health for each vaccine outweighs the costs of the vaccination program for that vaccine; the short-term and long-term harm to those injured by the vaccine; and the damage to the immune system that they inflict, then as some have recommended, the mandatory administration of that vaccine should be stopped.

Further, for those vaccines, which are only partially effective because, *in the case of vaccines for bacterial agents*, they do *not* provide protection for all major

variants, or, *in the case of viral vaccines*, like influenza, they provide a level of effectiveness of less than 75%, this reviewer recommends:

- Those vaccines should *not* be mandated for general use, and
- The limitations for those vaccines should be clearly spelled out in all literature and publications about those vaccines.

Finally, *unless and until*, the government and all other healthcare professionals stop distorting the benefits and the true risks associated with any vaccine, the public should demand that all mandatory vaccine programs be suspended for any vaccine introduced after the VICP was enacted in 1986.

Next, the author states:

“Senate Majority Leader Bill Frist (R-TN) and the House leadership are in final negotiations over a provision to help the vaccine industry meet its challenges. The provision, which is attached to the defense appropriations bill, offers liability protection for a limited number of vaccines deemed critical for responding to an avian influenza pandemic. However, it is unclear what kind of compensation, if any, would be included to cover the small number of people injured by vaccines.[2] While this effort represents a good first step towards shielding the vaccine industry from litigation, Congress will have to revisit the issues of expanding liability protections to more vaccines and improving and extending compensation programs for those injured by vaccines.”

While it is true that “Senate Majority Leader Bill Frist (R-TN) and the House leadership are in final negotiations over a provision to help the vaccine industry” and the “provision, which is attached to the defense appropriations bill, offers liability protection,” this reviewer finds that the provision does much more than merely provide liability protection, it seems to provide **no** compensation to cover the “people injured by vaccines.[2].”

Moreover, the author’s “this effort represents a good first step towards shielding the vaccine industry from litigation” admits that the Congress’ priority is shielding the industry instead of protecting the American public.

Having started with the need for protecting the interests of the “healthcare establishment” with almost no regard for the interests of the American public, the author now addresses “costs” by stating:

“Low Prices, Unlimited Liability

Drug industry experts estimate that it costs nearly \$900 million to bring a new vaccine to market.[3] Despite the increasing costs of research, development, and compliance with Food and Drug Administration regulations, major government programs, such as the Vaccines for Children Program, demand deep discounts that have made many vaccines unprofitable.[4]”

First, the author's reference [3] has been shown to be a gross overestimate of the cost for new drugs other than vaccines and the costs are the unverified self-reported numbers from certain unidentified drug products. Independent estimates of the "cost" to bring a truly new drug to market are less than \$ 210 million and most of these costs are tax deductible.⁵

Second, knowing that "major government programs, such as the Vaccines for Children Program, demand deep discounts," the industry prices its vaccines accordingly so that, after the demanded "deep discounts," the industry still profits.

Thus, this reviewer finds that the author is apparently either unaware of the industry's pricing practices or is aware and has knowingly misrepresented the costing and profit picture.

Third, if the author's picture were valid, why would the companies be investing so heavily in new vaccines and the financial industry protecting growth in the sales and profitability of those firms so engaged?

Because, unlike other drugs, there is limited competition and there are no generic vaccine competitors, the industry has decades to profit from a given vaccine once they succeed in licensing it.

Since major industry players are increasing their efforts in the vaccine area and pushing ever more vaccine products out the door, it would seem that the industry, unlike this author, knows that vaccines are highly profitable and, because of the ease with which they have been able to get Congress to add their vaccines to the VICP and reward them in other ways at the expense of the American public's health, is confident that it is already adequately protected and looks forward to improving profits in the days ahead.

Now, the author attacks the Constitution of the United States of America (which guarantees the right to a civil trial by jury in its Seventh Amendment) by stating:

"Worse, vaccines have fallen prey to the tort monster in America. Unpredictable lawsuits obtain huge verdicts on shaky foundations, stifling the ability of vaccine makers to compete and innovate.[5] Many have criticized the courtroom's ability to weigh the complex scientific and statistical evidence involved in vaccine liability cases.[6] Buffeted by successive waves of courtroom attacks and huge legal expenses over the past three decades, many firms now avoid the potential liability posed by vaccines."

Since most vaccines already fall under the VICP, this reviewer finds that the author's comments lack substance.

Moreover, the quoted references are in opinion pieces authored by persons having strong ties to, financial interests in, and/or involvement in the "healthcare establishment."

In addition, the author's "Many have criticized the courtroom's ability to weigh the complex scientific and statistical evidence involved in vaccine liability cases" references an

⁵ Marcia Angell, "*The Truth About the Drug Companies, How they deceive us and what to do about it*, Revised and updated," pages 37-51, Random House Trade Paperback 2005

opinion piece by a single individual who makes similar unsubstantiated statements as this author and offers examples that, when examined, actually prove that the juries involved were able to “weigh the complex scientific and statistical evidence involved in vaccine liability cases.”

This reviewer has reviewed reference [5] and found that its statements regarding jury trials are not substantiated by factual reality⁶

Contrary to the author’s “Buffeted by successive waves of courtroom attacks and huge legal expenses over the past three decades, many firms now avoid the potential liability posed by vaccines,” some small firms (e.g., MedImmune) and several large multi-national firms (e.g., GlaxoSmithKline, Merck, and sanofi aventis) are expanding their vaccines business by offering new vaccines (e.g., Boostrix, Adacel, Menactra) and buying up smaller firms.

Thus, the author’s words are at odds with factual reality here and should be ignored.

Continuing with his remarks on the American legal system, the author states: “To address vaccine shortages and the resulting dangers to public health, Congress established VICP in 1986. Funded by an excise tax imposed on vaccine doses, VICP was intended to protect the makers of childhood vaccines from legal liability. VICP was designed to be a less adversarial alternative to litigation; victims who can prove that their injuries fall within certain scientifically established boundaries receive full compensation for economic losses without showing fault and without expensive, time-consuming litigation. Furthermore, plaintiffs can decide to opt out of VICP and sue in state or federal court if they choose—though subject to some additional limits.”

This reviewer agrees with the author that the “VICP was intended to protect the makers of childhood vaccines from legal liability” and that, after some period in the VICP,

⁶ “Review of ‘Vaccine history shows need to update VICP law’

...

Having mischaracterized the laws governing the manufacturers of drug, Offit now turns to and attacks the American jury system when he states:

‘Unfortunately, jurors have been poor arbiters of scientific truths. For example, although clearly refuted by epidemiological studies, the courts ruled that silicone-filled breast implants caused connective-tissue diseases (a ruling that resulted in a settlement of \$4.25 billion) and that Bendectin, a drug for morning sickness, caused birth defects (a ruling that drove a safe and effective product off the market).’

This reviewer finds that, contrary to Offit’s views, the jurors in the examples provided have been excellent arbiters of the scientific truths.

In Offit’s first example, the jurors clearly understood that population epidemiological studies cannot be used to prove any outcome and that the direct scientific evidence of the harm caused by the silicone leaking from ruptured silicone-filled breast implants proved the harm caused when they based their verdict on the harm caused especially since the manufacturers had failed to conduct appropriate long-term studies and improperly dismissed the evidence of inflammation seen in some animals in their clinical trials.

Similarly, the direct evidence of a link between those taking Bendectin and then having children with certain birth defects was clear and the jurors made an appropriate finding.

Since the primary use for Bendectin was for treating morning sickness in pregnancy, it was the evidence of birth defects that rendered the product less than ‘safe’ and caused its removal from the market.”

“plaintiffs can decide to opt out of VICP and sue in state or federal court if they choose—though subject to some additional limits.”

However, Congress and the VICP’s administrators have modified the original program so that it now covers all influenza vaccines and some other vaccines for all recipients, not just children.

In addition, changes to the VICP have made it increasingly adversarial, slow and unfair to those damaged by vaccines to the point that less than 10% of all filed cases are settled in the plaintiff’s favor; many cases take several years to settle; the current case backlog is significant; fixed award amounts are not, as they were originally, indexed to inflation; key vaccine-related indications have been removed from the VICP’s table of injury indications; and the government’s “defense” lawyers actions are more adversarial than adjudicative.

Thus, even when a plaintiff is finally successful, the awards are often less than fair and, contrary to the laws in most states, no prior case outcome can be cited in a current case resulting in added expense to all parties by requiring all “administrative” trials to be tried “de novo.”

Finally, after being forced into the VICP by the law, those who opt out may *not* participate in any class action suit and have other limitations.

Continuing with the VICP, the author states:

“Congress Should Give Vaccines a Shot in the Arm

In the VICP, Congress has a model that it can use to provide strong liability protections for vaccine makers while providing fair and prompt compensation to those injured by vaccines. While other “no-fault” compensation systems can become prohibitively expensive, the concept works well for vaccines because there are few injuries.”

All that this reviewer can agree with is “Congress has a model that it can use to provide strong liability protections for vaccine makers.”

Factually, today’s VICP provides neither “fair” nor “prompt compensation to those injured by vaccines” because most claims, though there are injured children, are dismissed because they are not covered by the VICP’s altered table of indications.

Moreover, today’s, *contrary to the author’s views*, VICP “works well for vaccines because there are” few cases that succeed.

In addition, the VICP is not a “‘no-fault’ compensation” system, as the author attempts to portray it because the plaintiff is required to prove by having experts testify that the injury is vaccine related in each instance even when the evidence is clear that the injury was caused by the vaccine and the government attorneys often contest the amounts awarded in the few cases that are decided in favor of the plaintiffs.

Finally, the author is mistaken when he states, “there are few injuries.”

Factually, there are thousands of injuries each year but most plaintiffs’ cases are dismissed after some time in the system because the injuries claimed do *not* fall within those defined in the VICP’s table of compensable indications.

Having distorted the nature of the VICP, the author now states:

“A re-vamped VICP has the potential to create a legal atmosphere for vaccine manufacturers similar to that which existed during the ‘golden age’ of vaccines. Because VICP is funded with excise taxes on vaccine doses and provides relatively hassle-free compensation, it can also approximate the kind of insurance that consumers might purchase for themselves on the private market. To achieve these objectives, Congress should take the following steps:”

Since the VICP exists and vaccines are already being routinely added to it (see the author’s reference [7], the author seems to be confused when he states “legal atmosphere for vaccine manufacturers similar to that which existed during the ‘golden age’ of vaccines.”

At least the author’s “VICP is funded with excise taxes on vaccine doses” does reveal that the consumer pays for the vaccine manufacturer to be protected from being sued – hardly the “kind of insurance that consumers might purchase for themselves on the private market.”

Moreover, today’s VICP does *not* provide “relatively hassle-free compensation” since, *for most filed cases*, it provides no compensation at all.

Before taking any steps to expand the current VICP, this reviewer knows that the VICP first needs to be reformed so that it does provide fast and fair compensation to all of those who are directly or indirectly injured by a vaccine.

To that end, this reviewer has proposed and submitted to several members of Congress a draft titled, “The National Vaccine Program Improvement Act of 2005.

Until and unless the reforms outlined there are enacted so that the program puts compensating the public for the harm caused by government recommended vaccines, this reviewer must recommend that none of the proposed VICP changes be considered.

Moreover, since the Congress is elected by the people to serve the people’s interests and not those of the “healthcare establishment,” this reviewer must recommend replacing any United States Senator or Representative who supports enacting the liability protections currently being proposed by Senator Frist and his colleagues or those being proposed by this author.

That having been said, the author first states:

“Expand VICP to cover most or all vaccines. Liability protection for more vaccines will prevent a single lawsuit from destroying an entire company. Congress has already recognized this principle by extending VICP coverage to common influenza vaccines.[7] Covering more vaccines is important when, as in the case of influenza, only one company supplies the vaccine, putting that vaccine at high risk. Liability protection will also speed progress in creating vaccines to treat different ailments, because manufacturers will know the protection will be there. Moreover, increased diversity in vaccines can also help to cross-fertilize ideas from one kind of vaccine to another, improving existing vaccines”

Since four (4) vaccine makers (sanofi aventis, GlaxosmithKline, Chiron [currently being merged into Novartis], and MedImmune) currently provide the influenza vaccine to the U.S., the author’s “Covering more vaccines is important when, as

in the case of influenza, only one company supplies the vaccine, putting that vaccine at high risk” seems to be a knowing misstatement of the facts.

With respect to the author’s “Liability protection will also speed progress in creating vaccines to treat different ailments, because manufacturers will know the protection will be there,” this reviewer must note that the current VICP protections have seemingly led the industry to be less concerned about both the safety and the effectiveness of the vaccines they market, contributed to the industry’s failure to remove Thimerosal from all U.S.-licensed childhood vaccines in late 1980s and early 1990s when the European countries began removing it from theirs, and is the main reason, the manufacturer’s did *not* recall all “Thimerosal Preserved” in November of 1999 as they should have when in the closed-to-the-public October 1999 “Lister Hill” meeting clearly revealed that Thimerosal (56.7% “ethylmercury”) was toxic to humans at levels well below the 0.003% to 0.01% in “Thimerosal Preserved” being marketed at that time.

Had the firms been liable for the damage done by “Thimerosal Preserved” vaccines in 1991 as they were in the late 1930s for Calomel-laced teething powders, then, at the first sign of proven toxicity in 1991, they would have rapidly switched to other preservatives (e.g., 2-phenoxyethanol).

Instead, protected by the VICP, they continued to market “Thimerosal Preserved” vaccines into the 2000s and only began “phasing out its use in 1999.

Because of the vaccine industry’s craven actions, children continued to be mercury poisoned for at least a decade longer than they would have been if the vaccine manufacturers had not been protected by the VICP.

Thus, though it protected the industry, the VICP has unnecessarily harmed the public by additionally mercury poisoning 100-million-plus children to some degree, and, through the “Thimerosal Preserved” influenza vaccine, mercury poisoning millions of adults to some degree.

Rather than talking about extending the VICP, the author should be talking about some mechanism for holding the industry responsible for the knowing harm that these “Thimerosal Preserved” vaccines have caused.

The author next states:

“Make VICP the exclusive remedy for participants. One of the most important elements of liability protection is certainty, something that is in short supply in today’s unpredictable legal environment. If, after choosing to participate in VICP, claimants are free to sue in court to obtain a higher judgment, liability protection will mean little. Congress should discourage claimants from “gaming” the system by requiring those receiving vaccines to decide up front whether or not they will participate in the VICP protection. If they choose not to participate in the program, Congress could require claimants to bring their cases in federal court under strict compensation standards. Congress might also choose to indemnify vaccine makers from the expenses of the resulting lawsuits.”

Again, without any consideration for the rights of the public under the Constitution and with little consideration for other than protecting the vaccine makers from all liability – even when their knowing actions lead to the harm, the

author mischaracterizes the VICP by stating, “If, after choosing to participate in VICP, claimants are free to sue in court to obtain a higher judgment, liability protection will mean little.”

Currently, participation in the VICP process is mandated for all possible injuries for any covered vaccine.

In addition, “claimants” are not “free to sue in court to obtain a higher judgment.”

Next, portraying claimants as some sort of thief, the author states, “Congress should discourage claimants from ‘gaming’ the system by requiring those receiving vaccines to decide up front whether or not they will participate in the VICP protection.”

Since the VICP currently provides no such optional participation and the VICP provides no protection to the individuals, this reviewer is at a loss to understand the purpose of the author’s statement here other than to proverbially “muddy the water” about the nature of the VICP.

Finally, because the author’s proposals would even reward vaccine makers who make bad vaccines, this reviewer is opposed to such broad indemnifications for the vaccine makers.

Next, the author attempts to expand the VICP from vaccines to their “components, including preservatives and other ingredients” by stating:

“Ensure liability protection for the whole vaccine. As has been seen with thimerosal, a vaccine preservative that has been the subject of several lawsuits despite that the lack of evidence linking it with vaccine injuries, trial lawyers will find any way possible to thwart the intent of Congress and circumvent VICP’s protections. Congress should provide that VICP prospectively applies to all vaccine components, including preservatives and other ingredients.”

First, the author confuses a component, Thimerosal, with its use as a vaccine preservative and ignores the fact that Thimerosal has been illegally used as a preservative because its use as a preservative has never been proven to be safe, as required by 21 CFR 610.15(a), by appropriate toxicological safety studies and, based on the literature dating back into the 1940s⁷, Thimerosal is an *ineffective preservative* at levels of up to 0.01% and *toxic* to human tissues at levels below 0.00002%.

Moreover, contrary to the author’s *unsubstantiated* views, there is a body of evidence that clearly shows that Thimerosal is a bioaccumulative highly toxic poison at levels from 0.01% to 0.00002%⁸.

Thus, any proposed change to include any vaccine component in the definition of a vaccine should explicitly require that that component be proven *in appropriate long-term chronic toxicity studies in the most susceptible primate species*

⁷ To be effective as a preservative, the component must be bactericidal at the concentration of use. Factually, at concentrations up to 0.01%, Thimerosal is only bacterostatic and not bactericidal at 0.01% and below and toxic to human tissue at levels below 0.00002%. See Morton H E, North L L and Frank D. Engley F D. “THE BACTERIOSTATIC AND BACTERIOCIDAL ACTIONS OF SOME MERCURIAL COMPOUNDS ON HEMOLYTIC STREPTOCOCCI In Vivo and in Vitro Studies,” JAMA 136(1);36-41 1948.

⁸ See references in http://www.mercury-freedrugs.org/docs/Thimerosal_Causes_Mercury_Poisoning.pdf/ and the other documents posted in <http://www.mercury-freedrugs.org/docs/> that address the issue of the toxicity of injected Thimerosal and its metabolites ethylmercurihydroxide and bound “inorganic mercury.”

and the most susceptible other mammalian animal species to be safe at levels at least 100 times the highest level proposed for the vaccine formulation.

As to the author's "trial lawyers will find any way possible to thwart the intent of Congress and circumvent VICP's protections," this reviewer finds that, as the Fifth Circuit Court of Appeals correctly ruled, a component of a vaccine is no more a vaccine than a piston is an engine and, if plaintiffs can prove that a component of a vaccine caused the harm observed, then those plaintiffs are entitled to compensation for the harm done by that component.

Since the author is a lawyer, he should understand the laws governing vaccine components require proof of safety before use (see 21 CFR 610.15(a) and thus knows, as this reviewer, that the industry has failed to prove that Thimerosal is safe using the appropriate toxicological studies required to do so.

Thus, the author's statements here seemingly seek to indemnify vaccine makers who have, and are, knowingly violating the laws governing drugs, in general, and vaccine components, in specific.

Therefore, any such extended liability protection should be contingent upon the vaccine makers' providing proof that:

- The vaccine lot in question was made in full compliance with all applicable statutes and regulations governing the production of drugs and vaccines especially those governing safety and effectiveness, and
- The components, *other than the vaccine's active ingredients*, used in each formulation have been proven in independently audited scientifically sound long-term chronic toxicological studies in the most susceptible primate species to be safe (without any adverse effects) at levels at least 100 times the highest level permitted in the formulation for that vaccine.

Thus, in each instance where the vaccine failed to meet the proofs required, the vaccine manufacture should lose all liability protections for their actions and also be appropriately prosecuted for knowingly introducing adulterated drugs into commerce as provided in The Federal, Food, Drug, and Cosmetic Act as amended with firms who are found to have a pattern of so operating being prosecuted under the appropriate Racketeering, Influencing and Corrupt Organization (RICO) statutes.

Recognizing that, *contrary to his earlier statements*, the current VICP system is adversarial, the author now states:

"Make VICP less adversarial. While Congress originally intended VICP to be an "expeditious, less adversarial, and fair system," it still retains many of the trappings of litigation.[8] For the small number of VICP claims that require hearings, Congress might provide for court-retained expert witnesses to offer unbiased testimony about causation reflecting the current state of scientific knowledge. By providing strong liability protections to vaccine makers, this could also encourage the companies themselves to help claimants determine the cause of their injuries. Similar results have been achieved in Scandinavian countries that have adopted "no-fault" compensation schemes for medical errors: doctors and nurses there (the would-be defendants in medical malpractice lawsuits)

now help injured patients fill out their claim forms and share relevant information surrounding their cases.[9]”

Though this reviewer finds that the author’s suggestions have some merit, the plaintiffs would be better served if the findings in previous cases could be used as precedents in their case and all VICP proceedings limited to compensating those who have been harmed by injuries that could be vaccine related without having to prove to the court’s satisfaction that the injury was, in fact, caused by the vaccine and, to facilitate this, adding all of the *possible* vaccine-related indications to the VICP’s table for the vaccines with allowable latency periods appropriate to the diagnostic ability of medicine instead of the current restricted indications and arbitrary time periods.

Finally, the author suggests:

“Waive the excise tax for low-income or high-priority participants. Because VICP is funded with excise taxes imposed on vaccine doses, it is more like an insurance program than a litigation-based system. And, unlike the regressive “tort tax” that everyone pays regardless of their income, an excise tax on vaccines could be waived, raised, or lowered by the government. This could prove useful for encouraging low-income individuals and high-priority populations (such as the elderly or health care workers) to participate in vaccination programs.”

Not content with improving the liability portion of the VICP, the author includes a proposed incentive for “encouraging low-income individuals and high-priority populations (such as the elderly or health care workers) to participate in vaccination programs.”

While this reviewer sees nothing wrong per se with encouraging vaccination programs, this reviewer notes that there are better ways than starving the VICP’s revenue source to achieve that end.

For example, the government could simply provide vaccines free of charge to the poor and at nominal co-pay amounts to the high-priority populations.

Having finished outlining his plan, the author of this article closes with:

“Conclusion

Keeping in mind the dual objectives of promoting a robust vaccine industry and encouraging public confidence in vaccines, Congress should take the steps needed to bring about a second “golden age” of vaccines that will benefit all Americans. Of the solutions available, a retooled and expanded VICP, or some similar program, is the best opportunity to protect vaccine makers from lawsuits while quickly and fairly compensating injured parties. While the vaccine provision currently pending before Congress would be a good first step towards offering the vaccine industry the liability protection it needs, Congress will have to revisit the issues of extending the number of vaccines protected and providing fair and just compensation to those injured by vaccines.”

Though the author begins with, “Keeping in mind the dual objectives of promoting a robust vaccine industry and encouraging public confidence in vaccines,” this reviewer sees nothing in this article that would “encourage public confidence in vaccines.”

If vaccines are as “safe” as the “healthcare establishment” and this author attempts to portray them, then why do the vaccine maker’s need virtually absolute liability protection?

If vaccine makers truly require virtually absolute liability protection, then it should be clear to the public that these vaccines are neither as safe nor as effective as the public is being told that they are.

Looking at the projected and observed smallpox vaccine in the about 38,000 “first providers” inoculated where the adverse events and death rates were orders of magnitude larger than projected by the government and the industry or the anthrax vaccine experience where the Department of Defense hid more than 20,000 adverse events from Congress, it should be clear that vaccines are not as safe as they are represented to be.

Until the truth about vaccine safety and effectiveness is revealed to the American public, Congress should pass no legislation granting any liability protection to the vaccine makers.

Furthermore, until each vaccine is proven to provide a cost-effective net long-term benefit to overall public health, the federal government should stop recommending that vaccine for inclusion into the government’s list of recommended vaccines.

Since it has been established that the government agencies cannot be relied upon to tell the truth about the rates for adverse effects and the true long-term net benefits of a given vaccine versus an aggressive hygiene program coupled with aggressive supportive therapies for those who contract a given disease, an independent panel of scientists with no ties to the drug industry or the CDC should be convened and, considering all costs, benefits, and risks, asked to:

- Determine whether, or not, the vaccine is a net long-term benefit, and
- Set the administration schedule for each net beneficial vaccine so that, *based on the schedules used in the U.S and other developed countries where the same diseases are treated by recommended vaccination,*⁹ the recommended schedule minimizes the risk of adverse events and, for those that are nursing, postpones the first recommended vaccinations until after nursing stops or the child is at least two (2) years of age, *whichever is greater.*

Finally, all of the current financial “incentives” to doctors for promoting vaccination should be coupled with appropriate penalties for the failure of the doctors to report all possible adverse vaccination effects observed to VAERS within 5 business days of the first observance.

⁹ Vaccines that are not generally mandated in developed countries that have the same, similar, or lower disease incidence rates than the U.S. should, in general, be removed from the U.S. recommended list and the other programs, if any, that ensure low incidence introduced into the American healthcare system to the extent that such introductions are possible with minimal disruption of the current American system.

From the pen of Paul G. King, PhD, MS, BA

“Randolph W. Pate, J.D., MPH, is Visiting Fellow in the Center for Health Policy Studies at The Heritage Foundation.”

About This Reviewer, Dr. King

In addition to the information available on his web page [<http://www.dr-king.com/>], this reviewer is the New Jersey Representative of the Coalition for Mercury-Free Drugs (CoMeD) [<http://www.mercury-freedrugs.org/>], current District 33 Democratic Committeeman for Township of Parsippany-Troy Hills, Morris County, NJ, Taoist philosopher and servant of Elohim.

As a scientist and student of the federal regulations and statutes governing drugs, Dr. King led CoMeD in the drafting and submission of a Citizen Petition, posted in the FDA Public Docket 2004P-0349 and wrote and filed CoMeD’s response to the FDA’s 180-day response letter.

In addition, Dr. King has drafted the “Mercury-free Drugs Act of 2005,” the “Federal Drug Safety Act of 2005,” and a comprehensive substitute for Congressman Burton’s H.R. 1297, titled, “The `National Vaccine Injury Compensation Program Improvement Act of 2005,” which Dr. King re-titled, “The National Vaccine Program Improvement Act of 2005.”

Article's References:

“

-
- [1] See President George W. Bush, 'President Outlines Pandemic Influenza Preparations and Response,' November 1, 2005, at <http://www.whitehouse.gov/news/releases/2005/11/20051101.html>.
 - [2] Rebecca Adams, 'Vaccine Makers Seek Inoculation From Suits,' CQ Weekly, December 5, 2005, p. 3248.
 - [3] 'Total Cost to Develop a New Prescription Drug, Including Cost of Post-Approval Research, is \$897 million,' Tufts Center for the Study of Drug Development, May 13, 2003, at <http://csdd.tufts.edu/NewsEvents/RecentNews.asp?newsid=29>.
 - [4] See Robert Goldberg, 'Destroying vaccine development,' The Washington Times, October 21, 2005, at <http://www.washingtontimes.com/op-ed/20051020-092128-7162r.htm>.
 - [5] See Michael Kinsley, 'Taking Vioxx—For Plenty,' The Washington Post, August 28, 2005, p. B07, at <http://www.washingtonpost.com/wp-dyn/content/article/2005/08/26/AR2005082601489.html>. See also Phillip K. Howard, "Legal Malpractice," The Wall Street Journal, January 27, 2003, at <http://cgood.org/healthcare-reading-cgpubs-opeds-20.html>.
 - [6] Paul Offit, 'Vaccine history shows need to update VICP law,' The Hill, November 15, 2005 at <http://hillnews.com/thehill/export/TheHill/News/Frontpage/111505/offit.html>.
 - [7] American Jobs Creation Act of 2004, Pub. L. No. 108-357, 118 Stat. 1644.
 - [8] Wendy K. Mariner, "The National Vaccine Injury Compensation Program," Health Affairs, Spring 1992 Update, p. 258.
 - [9] See Carl Espersson, "The Swedish Patient Injury Act," presentation delivered on October 31, 2005, at http://cgood.org/assets/attachments/Carl_Espersson_USA.pdf; Martin Erichsen, "The Danish Patient Insurance Scheme," presentation delivered on October 31, 2005, at: http://cgood.org/assets/attachments/Martin_Erichsen_USA.pdf.