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Friday, 30 May 2008

To All:

The text following this page is a draft review of the excerpted text from an article by Paul A. Offit, MD that apparently appeared as an "**PERSPECTIVE**" article in the "**may 15, 2008**" issue of "***The NEW ENGLAND JOURNAL of MEDICINE***."

The excerpted text of this "**PERSPECTIVE**" article, titled, "**Vaccines and Autism Revisited — The Hannah Poling Case**," was located and then downloaded on 23 May 2008 from:

http://www.nejm.org

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The formal review, which is titled "**A Review of: 'Vaccines and Autism Revisited - The Hannah Poling Case'**" begins on the next page.

Introductory Remarks

First, *to simplify this review*, the statements in the article by the author, Paul A. Offit, will be quoted in a "Times New Roman" font.

Second, remarks by this reviewer, Paul G. King, PhD, will be presented in indented text following each of the writer's quoted remarks.

In addition, this reviewer's remarks will be in a dark blue "News Gothic MT" font except, when he quotes: **a)** from or refers to any federal statute or regulation, the text will be in a "Lydian" font or **b)** from other sources, the quotations will be in an "Arial Narrow" font.

When this reviewer quotes from statements made in the author's article, this reviewer will use an *italicized* "*Times New Roman*" font.

Finally, should anyone find any significant factual error for which they have published substantiating documents, please submit that information to this reviewer so that he can improve his understanding of factual reality and appropriately revise his views and the final review.

Respectfully,

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A Review of: "Vaccines and Autism Revisited - The Hannah Poling Case"

[An article by "Paul A. Offit, M.D." ***NEJM*** 2008 May 15; **358**: 20]

"On April 11, 2008, the National Vaccine Advisory Committee took an unusual step: in the name of transparency, trust, and collaboration, it asked members of the public to help set its vaccine-safety research agenda for the next 5 years."

> While in the author's view, the action of the National Vaccine Advisory Committee (NVAC) was "*an unusual step*," this reviewer finds that this step was both warranted and long overdue because of the public's increasing realization that the "vaccine insiders" (industry, research, academic and governmental) have knowingly avoided the Congressional mandate to safen vaccines [1] and increasingly failed to ensure that vaccines are: a) safe to the standard "**sufficiently nontoxic** …" [2] and b) in-use effective (e.g., ineffective influenza vaccines [3] and less-than-effective rotavirus vaccines [4]).

"Several parents, given this opportunity, expressed concern that vaccines might cause autism — a fear that had recently been fueled by extensive media coverage of a press conference involving a 9-year-old girl named Hannah Poling."

> Here, the author seems conflicted by his own pro-vaccine zeal because he fails to mention that these "*parents*" are medical professionals and researchers who have been studying the various in-use links between an ever-increasing vaccination schedule and the rise in incidence of various childhood diseases that, before the 1970s, were unknown as childhood diseases (e.g., type 2 diabetes and ADHD) or occurred at incidence rates of 1 in 10,000 or less (e.g., neurodevelopmental conditions characterized as autism spectrum disorders [ASDs]).
>
> In addition, while the author begins by correctly characterizing one aspect of the public's testimony as a "*concern that vaccines might cause autism*," he then mis-characterizes this "*concern*" as "*a fear*" even though it is clear that this concern is evidence based.

"When she was 19 months old, Hannah, the daughter of Jon and Terry Poling, received five vaccines — diphtheria–tetanus–acellular pertussis, *Haemophilus influenzae* type b (Hib), measles–mumps–rubella (MMR), varicella, and inactivated polio."

> Here the author's statement is both somewhat misleading and woefully incomplete.
>
> First, the five (5) vaccinations introduced nine (9) vaccine actives, four (4: measles, mumps, rubella and varicella) of which were man-made live-viruses that infected Hannah Poling to some degree.
>
> Second, she received an additional 50 micrograms of mercury (100 micrograms of Thimerosal) from vaccination with the diphtheria–tetanus–acellular pertussis (DTaP) and Haemophilus influenzae type b (Hib) vaccines.
>
> Finally, these vaccines also contained various amounts of albumin (from various sources including recombinant human cells and chicken embryos), sorbitol, sodium phosphate, sucrose, sodium chloride, hydrolyzed gelatin, fetal bovine serum, other buffer and media ingredients, a 50-ppm level of the antibiotic neomycin, formaldehyde, glutaraldehyde, and aluminum compounds as well as trace impurities from the purification of the vaccine actives.

"At the time, Hannah was interactive, playful, and communicative. Two days later, she was lethargic, irritable, and febrile. Ten days after vaccination, she developed a rash consistent with vaccine-induced varicella."

This reviewer finds that, *while the author's cursory account glosses over the seriousness of the vaccine reactions*, his account is factually accurate.

"Months later, with delays in neurologic and psychological development, Hannah was diagnosed with encephalopathy caused by a mitochondrial enzyme deficit."

This reviewer finds that the author's account is at odds with the case history because the child was first diagnosed with regressive autism, a symptom-based neurodevelopmental disorder before the underlying outcome contributors and/or causes of Hannah's autism diagnosis were identified.

"Hannah's signs included problems with language, communication, and behavior — all features of autism spectrum disorder."

Here, the author essentially admits that Hannah had the symptoms ("*features of autism spectrum disorder*") that are used to diagnose autism.

"Although it is not unusual for children with mitochondrial enzyme deficiencies to develop neurologic signs between their first and second years of life, Hannah's parents believed that vaccines had triggered her encephalopathy."

First, with respect to the author's "*Although it is not unusual for children with mitochondrial enzyme deficiencies to develop neurologic signs between their first and second years of life*," this reviewer notes:

1. There is no published evidence that Hannah Poling had any mitochondrial issues prior to her 19-month vaccinations,
2. There is no evidence that the mitochrondrial dysfunction observed in Hannah Poling was caused by "*enzyme deficiencies*," and
3. It appears that, *if anything*, Hannah's mitochondrial dysfunction is related to her being significantly mercury poisoned by the nominal 100-microgram dose of Thimerosal (50 micrograms of mercury) in her 19-month vaccinations.

Second, *based on the facts made public*, it is clear that Hannah's parents, medical professionals, and Dr. Andrew Zimmerman, one of Hannah's physicians and a testifying expert, found that Hannah's regressive autism symptoms began to develop shortly after her 19-month vaccinations.

Thus, contrary to the author's representations, Hannah's parents and her direct healthcare diagnosticians and providers knew and had strong supporting scientific evidence that "*vaccines had triggered her encephalopathy*."

"They sued the Department of Health and Human Services (DHHS) for compensation under the Vaccine Injury Compensation Program (VICP) and won."

Again, the author is misrepresenting reality because Hannah's parents did not sue the DHHS.

Factually, they petitioned the administrative Vaccine Injury Compensation Program in 2002 on behalf of Hannah and:

- *In late 2007*, medical professionals in the DHHS (Department of Health and Human Services), *after reviewing Hannah's medical records and her parents' affidavits*, conceded that Hannah's 19-month vaccinations had caused her neurodevelopmental regression (diagnosed as regressive autism).
- *In early 2008, apparently upon reviewing the expert reports that had been filed by Drs. Mark R. Geier and Dr. Andrew Zimmerman after the DHHS' November 2007 concession*, medical professionals in the DHHS also conceded that the 19-month vaccinations were a causal factor in the seizure disorder that Hannah Poling developed several years after her 19-month vaccinations.

"On March 6, 2008, the Polings took their case to the public. Standing before a bank of microphones from several major news organizations, Jon Poling said that 'the results in this case may well signify a landmark decision with children developing autism following vaccinations.'[1]"

Since the DHHS had already conceded the Polings' case, the author again mischaracterizes the Polings' actions.

Based on the quotation, "*the results in this case may well signify a landmark decision with children developing autism following vaccinations*," cited by the author, the Polings actions were to publicly communicate the reality that the government had conceded that some children can develop regressive autism "*following vaccinations*."

"For years, federal health agencies and professional organizations had reassured the public that vaccines didn't cause autism."

Although the author's statement is factually accurate, it conceals the reality that these same groups have failed to conduct the studies required to exonerate vaccines, conducted intentionally flawed epidemiological studies that cannot prove the absence of a causal link between vaccinations and autism, and suppressed and attacked the ever-growing body of independent studies (epidemiological, case-study, and toxicological) that clearly indicate a causal link between some component of a vaccine (e.g., Thimerosal) and/or some vaccine (e.g., MMR) and the development of the set of neurological symptoms used to diagnose autism.

"Now, with DHHS making this concession in a federal claims court, the government appeared to be saying exactly the opposite.

First, since, *before any hearing was held on the Poling petition*, medical professionals in the DHHS conceded that Hannah Poling's disorders were linked to her vaccinations, the DHHS' concessions were made outside of the court.

Thus, based on the medical evidence, it is clear that the medical professionals in the DHHS found that vaccinations were a causal factor in Hannah Poling's regression into autism.

Therefore, it is clear that, *in the Poling case*, the federal medical professionals found, and should find in any similar vaccine injury case, that Hannah's 19-month vaccinations caused the neurodevelopmental symptoms used to diagnose Hannah's autism.

"Caught in the middle, clinicians were at a loss to explain the reasoning behind the VICP's decision."

Again, the author, purportedly a medical clinician, misrepresents the facts because

the decision was made by medical professionals in the DHHS before any hearing was conducted by the VICP court.

What the author apparently finds disconcerting is the fact that federal medical professionals outside the "*federal health agencies*" (i.e., the Center for Disease Control and Prevention [CDC], the Food and Drug Administration [FDA] and the National Institutes of Health [NIH]) and "*professional organizations*" (e.g., the American Medical Association [AMA] and American Academy of Pediatrics [AAP]) found, "**by the preponderance of the evidence**," that Hannah's 19-month vaccinations caused her medical conditions.

"The Poling case is best understood in the context of the decision-making process of this unusual vaccine court. In the late 1970s and early 1980s, American lawyers successfully sued pharmaceutical companies claiming that vaccines caused a variety of illnesses, including unexplained coma, sudden infant death syndrome, Reye's syndrome, transverse myelitis, mental retardation, and epilepsy. By 1986, all but one manufacturer of the diphtheria–tetanus–pertussis vaccine had left the market. The federal government stepped in, passing the National Childhood Vaccine Injury Act, which included the creation of the VICP. Funded by a federal excise tax on each dose of vaccine, the VICP compiled a list of compensable injuries. If scientific studies supported the notion that vaccines caused an adverse event — such as thrombocytopenia after receipt of measles-containing vaccine or paralysis after receipt of oral polio vaccine — children and their families were compensated quickly, generously, and fairly. The number of lawsuits against vaccine makers decreased dramatically."

Since the Poling case was "decided" by federal medical professionals on the basis of concrete medical evidence before any hearing in the VICP court, except to present the author's obviously jaundiced views of the creation of the VICP, the reviewer sees no need for this paragraph in an article purportedly offering "perspective on" (insight into) the Poling case.

"Unfortunately, in recent years the VICP seems to have turned its back on science."

If, as the author implies, the original compensable injuries alluded to in the author's "*If scientific studies supported the notion that vaccines caused an adverse event ... children and their families were compensated quickly, generously, and fairly*," were valid, then the VICP turned its back on science in the 1990s when, *without any hearings*, it administratively removed many of these previously compensable injuries from the compiled list of compensable injuries.

"In 2005, Margaret Althen successfully claimed that a tetanus vaccine had caused her optic neuritis. Although there was no evidence to support her claim, the VICP ruled that if a petitioner proposed a biologically plausible mechanism by which a vaccine could cause harm, as well as a logical sequence of cause and effect, an award should be granted. The door opened by this and other rulings allowed petitioners to claim successfully that the MMR vaccine caused fibromyalgia and epilepsy, the hepatitis B vaccine caused Guillain–Barré syndrome and chronic demyelinating polyneuropathy, and the Hib vaccine caused transverse myelitis."

Lacking access to all of the evidence in these cases, this reviewer can only note that, in the cases where such awards were made, the Special Masters appointed to hear these cases found that the scientific and medical evidence indicated that the harm caused to the child was related to vaccination by the preponderance of the evidence.

"No case, however, represented a greater deviation from the VICP's original standards than that of Dorothy Werderitsh, who in 2006 successfully claimed that a hepatitis B vaccine had caused her multiple sclerosis. By the time of the ruling, several studies had shown that hepatitis B vaccine neither caused nor exacerbated the disease, and the Institute of Medicine had concluded that "evidence favors rejection of a causal relationship between hepatitis B vaccine and multiple sclerosis."[2] But the VICP was less impressed with the scientific literature than it was with an expert's proposal of a mechanism by which hepatitis B vaccine could induce autoimmunity (an ironic conclusion, given that Dorothy Werderitsh never had a detectable immune response to the vaccine)."

Given the early 2008 disclosure of formal investigations in France into "two managers from drugs groups GlaxoSmithKline (GSK.L: Quote, Profile, Research) and Sanofi Pasteur over a vaccination campaign in the 1990s" based on "allegations that the companies failed to fully disclose side effects from an anti-hepatitis B vaccine used in a vaccination campaign between 1994 and 1998" [5], a 2002 Reuters medical report [6], and the 2007 disclosures of a link between vaccination with hepatitis B and a rise in MS cases 4 years after the vaccination campaign was started in a recent peer-reviewed journal [7], it appears that: **a)** the VICP's decision is supported by the scientific current evidence and **b)** the cited Institute of Medicine (IOM) report was wrong – perhaps because it was based on studies that failed to track outcomes for a sufficient period of time (e.g., for more than 4 years, based on the findings in France).

"Like the Werderitsh decision, the VICP's concession to Hannah Poling was poorly reasoned."

Lacking access to all the evidence in the Werderitsh decision, given that the recent evidence supports the validity of that decision, and having access to the public information in the Poling case, this reviewer must conclude that, *like in the Werderitsh decision*, the medical professionals properly conceded Poling.

Thus, the author's assertion, "*the VICP's concession to Hannah Poling was poorly reasoned*," is: **a)** apparently the author's own wishful thinking and **b)** <u>not</u> supported by the available evidence.

"First, whereas it is clear that natural infections can exacerbate symptoms of encephalopathy in patients with mitochondrial enzyme deficiencies, no clear evidence exists that vaccines cause similar exacerbations. Indeed, because children with such deficiencies are particularly susceptible to infections, it is recommended that they receive all vaccines."

Here, this reviewer finds that the author's remarks should be ignored because the Poling case and others like it are clear evidence that, *in some instances*, vaccinations can cause mitochondrial dysfunction and/or encephalopathies that can lead to the set of neurological symptoms used to diagnose autism.

"Second, the belief that the administration of multiple vaccines can overwhelm or weaken the immune system of a susceptible child is at variance with the number of immunologic components contained in modern vaccines."

Here, the author begins with a "*belief*" statement that is clearly at odds with the facts of the Poling case.

"A century ago, children received one vaccine, smallpox, which contained about 200 structural and nonstructural viral proteins. Today, thanks to advances in protein purification and recombinant

DNA technology, the 14 vaccines given to young children contain a total of about 150 immunologic components.[3]"

First, the author's remarks ignore the reality that the "smallpox" vaccine, a live-virus cowpox vaccine, clearly overwhelmed or weaken the immune system of children who had a severe adverse reaction to it and, just as in the recent "first responders" program, they died from being infected by the cowpox vaccine.

Second, the author conveniently ignores the following realities:

- It is the nature of the "*immunologic components*" and their interaction with the children's immune systems that are critical to the impact on said immune systems.
- Some of the other components in vaccines may exacerbate the vaccine's harm to children's immune systems.

Based on the preceding realities, the author's remarks here should be ignored.

"Third, although experts testifying on behalf of the Polings could reasonably argue that development of fever and a varicella-vaccine rash after the administration of nine vaccines was enough to stress a child with mitochondrial enzyme deficiency, Hannah had other immunologic challenges that were not related to vaccines."

First, the author's remarks are knowingly misleading because no experts testified on behalf of the Polings.

Factually, medical professionals in the DHHS conceded the Poling case before the Polings' experts even filed their reports and, *based on their concession*, the vaccine court removed this scheduled Autism Omnibus test case for the theory "Thimerosal in vaccines is a causal factor in autism" from the court's Autism Omnibus docket.

In addition, there was no evidence in Hannah's disclosed medical records or the Polings' public remarks that Hannah had any pre-existing "*mitochondrial enzyme deficiency*."

Further, with respect to the author's, "*Hannah had other immunologic challenges that were not related to vaccines*," this reviewer finds that some vaccines (e.g., Thimerosal-preserved hepatitis B at birth and 1 month; and Thimerosal-preserved Hib and Thimerosal-preserved DTaP vaccines at 2.5, 4 and 6 months) were administered to Hannah before any of the immunologic challenges subsequently mentioned by the author began to occur.

"She had frequent episodes of fever and otitis media, eventually necessitating placement of bilateral polyethylene tubes."

Based on Hannah's available public medical records, the cited episodes of otitis media and fever began when Hannah was seven months of age and continued until she was beyond 15 months of age – causing her mother to decline Hannah's 12-month and 15-month vaccinations.

While it is clear to this reviewer that Hannah's "*frequent episodes of fever and otitis media, eventually necessitating placement of bilateral polyethylene tubes*" were related to the vaccinations she received prior to seven months of age, this reviewer again notes that, *according to her public medical records*, she consistently met her developmental milestones through her 19-month pre-vaccination check-up.

"Nor is such a medical history unusual. Children typically have four to six febrile illnesses each year during their first few years of life[4]; vaccines are a minuscule contributor to this antigenic challenge."

Absent large-scale comparative studies between matched populations of never-vaccinated children with fully vaccinated, this reviewer first notes that there is no substantiation for the author's belief (medically and/or scientifically unsubstantiated claim) that *"vaccines are a minuscule contributor to this antigenic challenge."*

Moreover, based on his early childhood medical history and that of his siblings and friends (in the late 1940s and early 1950s) and that of his daughter and her friends (in the late 1970s), the claim of *"four to six febrile illnesses each year during their first few years of life,"* while not at odds with both sets of experiences, ignores the Hannah's recurrent bouts of otitis media (ear infection) which were not common in the earlier periods.

"Fourth, without data that clearly exonerate vaccines, it could be argued that children with mitochondrial enzyme deficiencies might have a lower risk of exacerbations if vaccines were withheld, delayed, or separated. But such changes would come at a price. Even spacing out vaccinations would increase the period during which children were susceptible to natural infections, giving a theoretical risk from vaccines priority over a known risk from vaccine-preventable diseases."

First, the author ignores the findings of a recent study of DTP vaccination [8] that reported:

"Among 11,531 children who received at least 4 doses of DPT, the risk of asthma was reduced to (1/2) in children whose first dose of DPT was delayed by more than 2 months."

Thus, *in an apparently normal population of babies*, delaying the onset of vaccination by at least two months apparently has a significant lifetime health benefit that far outweighs the present-day minimal risk that healthy babies will contract diphtheria, pertussis or be infected by tetanus.

Moreover, a large Chicago pediatric practice, Homefirst® Health Services [9], which does not press their parents to vaccinate, has reported only one case of asthma among its never vaccinated breastfed children while, in the vaccinated children in Chicago, the asthma rate exceeds 10%.

Based on the preceding, trading today's low risk of contracting a communicable short-term childhood disease (typically, less than 1 in 1,000) by not vaccinating for a greater than 1-in-10 risk for chronic childhood asthma and other chronic childhood medical conditions (e.g., childhood type 2 diabetes and autism spectrum disorders and other neurodevelopmental disorders) associated with vaccination seems to be a rational choice.

Further, the risks from vaccines, as stated in their package inserts or documented elsewhere, are anything but theoretical.

Based on the preceding realities alone, it is obvious, *to other than vaccine apologists like the author*, that the current vaccination program is not medically cost effective nor as safe as possible, and is in need of major revisions, including delay of the start of vaccination and, *in some instances*, pruning.

Finally, this reviewer notes that the price of revising the national program to only offer vaccines that are safe and medically cost-effective and to allow delay of vaccination until after the child's immune system has developed to the point that maternal

antibodies and immune-support factors are no longer expected (after 21 – 24 months of age when weaning naturally occurs) would result in the loss of revenue to the vaccine makers, vaccine patent holders, and pediatricians as well as the loss of prestige and face that vaccine apologists like the author would suffer – no wonder the author continues to ignore the problems with the current national vaccination program and to argue for maintaining the status quo.

"These diseases aren't merely historical: pneumococcus, varicella, and pertussis are still common in the United States. Recent measles outbreaks in California, Arizona, and Wisconsin among children whose parents had chosen not to vaccinate them show the real risks of public distrust of immunization."

Apparently, the author and this reviewer live in different Americas, if not different universes.

In the author's America, vaccination is a panacea; only those who do not get vaccinated are at risk of getting and/or transmitting pneumococcus, varicella, pertussis, and measles; the adverse effects of vaccination are localized to the injection site; and vaccination provides long-term immunity.

In this reviewer's America, the vaccines licensed for use in the U.S. range from lifesaving (e.g., the rabies vaccine after disease exposure) to probably medically cost-effective (e.g., the measles vaccine) to less-than-effective and/or not even societally cost-effective (e.g., the human influenza vaccines, the rotavirus vaccines, the HPV vaccines, and the varicella vaccines, to name a few).

While the author speaks of the most recent isolated measles outbreaks totaling less than 100 individuals in a country of 300 million (3.3 per 10 million), he failed to note that about 20% of the cases were too young to be vaccinated, some of those who contracted measles were fully vaccinated, only a few required any hospitalization and none died or were reported to have suffered long-term harm since supplementation with large doses of Cod liver oil renders the disease benign in most all cases.

Moreover, *based on the well-studied 2005 Indiana measles outbreak*, the most seriously ill patient can be a vaccinated individual.

Based on all of the preceding and appropriate supportive care, *including curative doses of the proper dietary supplements in most cases*, a national program that focuses on increasing hygiene, sanitation, and nutritional supplementation is clearly more medically cost-effective than a medically non-cost-effective vaccination program it would replace (e.g., replacing the annual influenza vaccination program, *which provides only limited protection against some strains of the influenza virus*, with an appropriate vitamin D-3 supplementation program, *which provides near universal protection against all strains of the influenza virus and, with higher doses, is curative in those who contract influenza* [10]).

"After the Polings' press conference, Julie Gerberding, director of the Centers for Disease Control and Prevention, responded to their claims that vaccines had caused their daughter's autism.

'Let me be very clear that the government has made absolutely no statement ... indicating that vaccines are a cause of autism,' she said.[5]"

Here, the reviewer notes Dr. Gerberding's cited remark cleverly uses the wording, "*the government has made absolutely no statement ... indicating that vaccines are a cause of autism*" rather than the government's concession wording (with underlining added for emphasis):

"In sum, DVIC has concluded that the facts of this case meet the statutory criteria for demonstrating that the vaccinations Hannah received on July 19, 2000, significantly aggravated an underlying mitochondrial disorder, which predisposed her to deficits in cellular energy metabolism, and manifested as a regressive encephalopathy with features of autism spectrum disorder. Therefore, respondent recommends that compensation be awarded to petitioners in accordance with 42 U.S.C. § 300aa-11(c)(1)(C)(ii)."

Since autism is diagnosed by its symptoms (the governments "features of autism spectrum disorder"), DVIC (Division of Vaccine Injury Compensation, Department of Health and Human Services) medical personnel essentially concluded that Hannah's 19-month vaccinations are a causal factor in Hannah's autism since autism is diagnosed solely by one's having the "*features of autism spectrum disorder*" or, *using Dr. Gerberding's wording*, Hannah's vaccinations are a cause of Hannah's autism, or, generalizing, vaccinations are a cause of autism.

Thus, it is clear to this reviewer that Dr. Gerberding's clever statement might be true if multiple vaccines were never administered on the same day or immunologically close to each other.

Since multiple vaccines were and are routinely administered on the same day, the truth about the Gerberding statement cited by the author is that it is an intentional hair-splitting attempt to mislead the uninformed reader.

"Gerberding's biggest challenge was defining the term "autism." Because autism is a clinical diagnosis, children are labeled as autistic on the basis of a collection of clinical features."

Here, the author begins by misrepresenting reality because "*the term 'autism'*" has been rigorously defined in the psychiatrists' Diagnostic and Statistical Manual of Mental Disorders (DSM) for decades.

Thus, *contrary to the author's assertion*, Gerberding, who is not a psychiatrist, has no such challenge.

Finally, *revealing his lack of emphathy for the children harmed*, the author declares, "*children are labeled as autistic on the basis of a collection of clinical features*," instead of "children who have a certain set of neurological symptoms are diagnosed with an autism spectrum disorder."

"Hannah Poling clearly had difficulties with language, speech, and communication. But those features of her condition considered autistic were part of a global encephalopathy caused by a mitochondrial enzyme deficit."

Apparently, the author, *without examining Hannah, reviewing all her medical records and/or reading the experts reports*, is ignoring the conceded cause of Hannah's "*global encephalopathy*," her 19-month vaccinations, and invoking "*a mitochondrial enzyme deficit*" for which there is no supporting evidence (and much normal developmental evidence to the contrary) prior to Hannah Poling's 19-month vaccinations and, *based on the available evidence*, her mitochondrial dysfunction was caused by her vaccinations.

Perhaps, *after reviewing Hannah's published medical information*, the author will correct his unsupported assertions.

Otherwise, this reviewer suggests that, *after reviewing all of the data when the "Vaccine Court" publishes all of the information filed in the Poling case as her parents have formally asked*, the medical boards in the states in which the author is licensed to practice medicine should consider censuring the author for his knowingly misleading remarks.

"Rett's syndrome, tuberous sclerosis, fragile X syndrome, and Down's syndrome in children can also have autistic features. Indeed, features reminiscent of autism are evident in all children with profound impairments in cognition; but these similarities are superficial, and their causal mechanisms and genetic influences are different from those of classic autism."

While the author's remarks are almost accurate in that other medical conditions can also have some autistic features and are correct with regard to "*these similarities are superficial, and their causal mechanisms and genetic influences are different from those of classic autism*," this reviewer must note that these remarks should be ignored because one of Hannah Poling's diagnoses was regressive autism induced by her 19-month vaccinations — and not the author's "*classic autism*."

"Going forward, the VICP should more rigorously define the criteria by which it determines that a vaccine has caused harm."

Here, the author ignores not only the statutory standard ("**preponderance of the evidence**" [11]) by which the VICP must determine "*that a vaccine has caused harm*" but also the reality that, *since these are administrative civil actions in lieu of judicial civil trials*, such actions would be a violation of **Amendment VII of the Constitution of the United States of America**, governing civil lawsuits, as any such change would implicitly deviate from the "… **according to the rules of common law**" requirement that is set forth in **Amendment VII** because the VICP's administrative proceedings are provided in lieu of civil lawsuits ("**Suits at common law, where the value in controversy shall exceed twenty dollars** …").

"Otherwise, the message that the program inadvertently sends to the public will further erode confidence in vaccines and hurt those whom it is charged with protecting."

First, because the governmental agencies, the vaccine makers, and certain professional societies have attempted, and are still trying, to hide the VICP from the general public and because the actions of the VICP take place out of the public eye, the program sends no message to the public.

What the author and other vaccine apologists seem to fear is the greater public disclosure, *by the Polings and others*, of the harm caused to thousands of children by vaccinations.

Since, because of the short statute of limitations for filing under the VICP (currently, administratively set at three years from the date of the first recorded symptom), the reluctance of the VICP to consider harm that starts years after vaccination, and the lack of government advertising of the program's availability, only a small portion of the cases of vaccination harm are filed with the VICP.

Moreover, *because of the program's filing time limit of three years from the first recorded symptom*, many of the filed cases are dismissed by the "Vaccine Court" on the grounds that, *based on the program's view of the date of the first symptom in the child's medical records*, the cases were not filed within that time window.

Therefore, the thousands of filed cases only represent the visible tip of the ever-increasing mass of children (and adults) harmed by vaccinations.

Given the government's 2004 uncorrected "**Autism A.L.A.R.M.**" estimate that "**1 out of 6 children are diagnosed with a developmental and/or behavioral problem**" [12], the reality may be that more than 20% of American children have some vaccination-induced deficit (developmental or behavioral problem).

Thus, the failure of the federal, state and local governments, the vaccine makers, and the healthcare establishment to safen vaccines as well as their failure to only recommend, mandate and/or offer vaccinations that are truly safe and long-term medically cost-effective have combined to erode the informed public's confidence in the current national vaccination program.

If the author were truly concerned about improving the public's confidence in our national vaccination program, then he would: have stopped misrepresenting the facts about the problems with the current national vaccination program and be supporting the public in its efforts to reduce our national vaccination program to only those vaccines that are truly proven to be: **a)** sufficiently nontoxic by appropriate acute, reproductive, and long-term (20-year) comparative toxicity studies against a saline placebo and **b)** medically cost-effective!

"Dr. Offit reports being a co-inventor and co-holder of a patent on the rotavirus vaccine RotaTeq, from which he and his institution receive royalties, as well as serving on a scientific advisory board for Merck. No other potential conflict of interest relevant to this article was reported.

Dr. Offit is chief of infectious diseases at the Children's Hospital of Philadelphia and professor of pediatrics at the University of Pennsylvania School of Medicine — both in Philadelphia."

Dr. King is a PhD Analytical Chemist and a vaccine-safety advocate. He has no financial conflicts of interest and has no child, grandchild, nephew or niece who has been significantly harmed by vaccination. His background, interests, credentials and publications can be found on his website, http://www.dr-king.com and many of his recent vaccination-related publications can be found in the "Document" section of http://www.mercury-freedrugs.org. As a pro-vaccine advocate, he is involved in legal actions that some might perceive as a potential conflict of interest.

"1. CNN. American Morning. March 6, 2008 (television broadcast).
2. Stratton K, Almario DA, McCormick MC, eds. Immunization safety review: hepatitis B vaccine and demyelinating neurological disorders. Washington, DC: National Academies Press, 2002.
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References

1. **42 U.S.C. Sec. 300aa-27 Mandate for safer childhood vaccines.**
2. **21 C.F.R. Sec. 610.15(a) Constituent materials.**
3. Geier DA, King PG, Geier, MR. Influenza Vaccine: Review of Effectiveness of the U.S. Immunization Program, and Policy Considerations. ***J Am Phys Surg*** 2006 Fall; **11**(3): 69-74.
4. Geier DA, King PG, Sykes LK, Geier MR. RotaTeq vaccine adverse events and policy considerations ***Med Sci Monit***. 2008 Mar; **14**(3): PH9-PH16.
5. http://www.reuters.com/article/rbssHealthcareNews/idUSL0173467120080201
6. Reuters Medical News. Reports criticizes French Hepatitis Vaccination Campaign. Medscape, Nov. 2002.
7. Girard M. When evidence-based medicine (EBM) fuels confusion: multiple sclerosis after hepatitis B vaccine as a case in point. ***Med Veritas*** 2007 Nov.; **4**(2): 1436–1451.
8. McDonald KL, Huq SI, Lix LM, Becker AB, Kozyrskyj AL. Delay in diphtheria, pertussis, tetanus vaccination is associated with a reduced risk of childhood asthma. ***J Allergy Clin Immunol***. 2008 Mar; **121**(3): 626-631. [Epub 2008 Jan 17 ahead of print]
9. http://www.homefirst.com/ with underlining added for emphasis:

"Homefirst® Health Services, under the leadership of founder and Medical Director Mayer Eisenstein, M.D., J.D., M.P.H., provides a full range of services in family health care in the greater Chicago metropolitan area with four medical centers. Our doctors, dedicate themselves to providing the

highest quality of health care standards while maintaining personalized care for each patient and family. We encourage patient involvement in the many decisions made regarding their health care.

Since 1973 the Homefirst® doctors have delivered over 15,000 babies at home, served over 75,000 parents, children and now grandparents. They apply the principles of minimal pharmaceuticals to adult medicine with emphasis on Natural substitutes to control chronic illnesses such as: high blood pressure, high Cholesterol, muscle and joint pain, IBS Irritable Bowel Syndrome, GERD, heartburn, acid reflux and other medical conditions. The Homefirst® doctors promote an integrative evidence based approach to managing illness. The majority of health problems are resolved by our medical staff. Homefirst® offers complimentary seminars featuring Dr. Mayer Eisenstein, on Natural pharmaceutical alternatives, vaccine law (Dr. Eisenstein is also an attorney) and physician-attended natural childbirth in the home.

Homefirst® also sponsors "The Dr. Mayer Eisenstein Radio Show" heard live coast-to-coast on XM satellite radio channel 170 every Saturday from 9 a.m. to 10 a.m. central time and live in the Chicagoland area on AM1160 10 a.m. to 11 a.m.

The goal of Homefirst® is to introduce you to the world of natural treatments and as such increase your quality as well as quantity of life. We want you to use all of the available resources: books, internet, pharmacists and medical practitioners. We follow the principles of Hippocrates, the father of modern medicine, of Primum Non Nocere (Above All Do No Harm)."

10. Cannell JJ, Vieth R, Umhau JC, Holick MF, Grant WB, Mandronich S, Garland CF, Giovannucci E. REVIEW ARTICLE Epidemic influenza and vitamin D. ***Epidemiol Infect***. 2006 Dec; **134**(6): 1129-1140 [Epub 2006 Sep 7] as well as the applicable references therein.

11. **42 U.S.C. Sec. 300aa-13 Determination of eligibility and compensation**

"(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole -

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition. The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine" -

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death."

12. AUTISM A.L.A.R.M., issued by the HHS, CDC, American Academy of Pediatrics, and others in January of 2004 and available through *http://www.aap.org/healthtopics/autism.cfm*. [**Note:** When that web page displays, click on the "**Autism A.L.A.R.M. (Fact Sheet)**" entry (the 2nd reference) to load the two-page ".pdf" file.]