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Thursday, 18 October 2007

To All:

This article is a review of a *Washington Post* column by Paul Howard included as a special “to washingtonpost.com's **Think Tank Town**, Friday, October 12, 2007; 12:00 AM, titled, “**On Vaccines, Immune to Reason**,” which was located and then downloaded on 12 October 2007 at about 9:30 AM from:

<http://www.washingtonpost.com/wp-dyn/content/article/2007/10/11/AR2007101101597.html?nav=hcmodule>

After some introductory remarks, the formal review, titled “**Mercury Poisoning by Thimerosal in Vaccines — A Rebuttal to the Doublespeak in: On Vaccines, Immune to Reason**,” begins on the next page.

Introductory Remarks

First, *to simplify this review*, the comments by the writer, Paul Howard, 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 mentions, or quotes from, a federal statute or regulation; these items will be in a “Lydian” font.

Finally, when this reviewer quotes from statements made in the writer’s column, an *italicized* “Times New Roman” font will be used.

With these things in mind, this review of “**On Vaccines, Immune to Reason**,” begins on the next page.

Respectfully,

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Mercury Poisoning by Thimerosal in Vaccines

A Rebuttal to the Doublespeak¹ in: “On Vaccines, Immune to Reason”

By Paul G. King, PhD in Analytical Chemistry, MS in Inorganic Chemistry, ACS-certified BA in Chemistry

“Recently, when visiting family in Philadelphia, my wife and I had the pleasure of seeing friends of ours and their baby daughter, Iona. While the proud papa and I swapped complaints about health care -- his as a father, mine as a policy wonk -- the topic of vaccines came up. Why, he asked, had companies ever put a mercury-based preservative (thimerosal) in vaccines and why did doctors administer those ‘dangerous’ vaccines to children?”

- Why is it that vaccine apologist, Paul Howard, never addresses the simple questions posed by his friend?
- Why, without the required proof of safety, do the vaccine makers continue to distribute Thimerosal-containing vaccines?
- Why do doctors keep giving these vaccines to pregnant women and children without the required toxicological proofs of safety?

“My friend is highly educated, very intelligent, and he naturally worries about anything that could affect the health of his daughter. But while many studies have failed to link thimerosal (phased-out of childhood vaccines by 2001) with developmental disorders like autism, he either hadn't heard of them or else just didn't trust them.”

- Why is it that Paul Howard continues to lie about the removal of Thimerosal from “*childhood vaccines by 2001*”?

Factually:

1. Without the required toxicological proofs of safety, starting in 2002, Thimerosal-preserved and then, in 2004, Thimerosal-containing inactivated influenza vaccines have been recommended for administration to pregnant women and children from 6 months to now 5 years of age (or, in 2007, up to 9 years of age in many cases),
2. Several other Thimerosal-containing vaccines that are approved for children are still being distributed²,
3. The FDA has continued to license and approve Thimerosal-preserved human influenza vaccines³,
4. The unexpired childhood Thimerosal-preserved vaccines were not recalled and destroyed in 2001,
5. *In some cases*, the Thimerosal-preserved childhood vaccines continued to be distributed long after the FDA approved the trace-Thimerosal formulations,

¹ *Doublespeak* is defined as: “evasive, ambiguous, high-flown language intended to deceive or confuse.” <http://www.damronplanet.com/doublespeak/whatisdoublespeak.htm> (last visited 18 October 2007)

² <http://www.fda.gov/cber/vaccine/thimerosal.htm#t3>, (last visited 12 October 2007)

³ FluLaval, 5 October 2006, licensed ID Biomedical Corporation of Quebec, Canada (IDB), License No. 1739; and Afluria, 28 September 2007, licensed to CSL Limited of Australia, License No. 1764 (from 12 Oct. 2007 searches of: <http://www.fda.gov/cber/index.html>)

6. Some of these Thimerosal-preserved childhood-vaccine doses did not expire until from late 2004 to early 2005,
7. The U.S. FDA has not revoked the approvals and licenses for the Thimerosal-preserved vaccines when the trace-Thimerosal vaccine formulations were approved,
8. The FDA has also not revoked the approvals and licenses for the trace-Thimerosal vaccines when the “no Thimerosal” vaccine formulations were approved,
9. Federal and state officials, medical groups, and industry-supported groups have lobbied, and are lobbying, state legislators to block state laws seeking to protect pregnant women and young children from being mercury poisoned by Thimerosal-preserved and/or by Thimerosal containing vaccines, and
10. Last flu season, state health officials declared “availability” (California) or “cost” (Illinois) “emergencies” in order to circumvent the state protections for pregnant women and young children – protections that banned giving them a Thimerosal-preserved influenza vaccine shot unless there was an emergency.

Given the preceding factual realities and the fact that influenza vaccines have been proven (in published studies⁴) not to protect almost all inoculated young children and pregnant women from getting influenza, it is obvious that not only have Thimerosal-containing vaccines not been “*phased-out of childhood vaccines by 2001*” but our governmental and the healthcare establishment have also *knowingly* colluded to maintain and increase the mercury-poisoning risk from vaccines by adding the ineffective inactivated influenza vaccines, most doses of which still contain 2- to 100-ppm levels of Thimerosal⁵, to the recommended vaccination schedules for pregnant women and young children.

- Why is it that, *more than eight years after a 1999 pledge by government, the healthcare establishment, and the vaccine makers to remove Thimerosal from vaccines as soon as possible*, new Thimerosal-preserved vaccine formulations are still being licensed and approved?
- Why is it that Paul Howard and other vaccine apologists fail to mention the ever-growing number of published studies, *including case studies*⁶, linking Thimerosal to neurodevelopmental and other disorders, and/or correctly identifying the underlying causative factor, mercury poisoning?

⁴ [1] Jefferson T. Influenza vaccination: Policy versus evidence. *BMJ* (British Medical Journal) 2006 October **28**; 333: 912-915.

[2] Geier DA, King PG, Geier MR. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. *JAPS* (Journal of American Physicians and Surgeons) 2006 Fall; **11**(3): 69-74.
and the pertinent references that these authors cite.

⁵ Thimerosal levels that exceed 1-ppm have been shown to be toxic in reproductive and other toxicity studies.

⁶ [1] Geier DA, Geier MR. A Prospective Study of Mercury Toxicity Biomarkers in Autistic Spectrum Disorders. *J Toxicology and Environmental Health, Part A* 2007; **70**: 1723-1730, 2007.
[2] Nataf R, et al. Porphyrinuria in childhood autistic disorder: implications for environmental toxicity. *Toxicol Appl Pharmacol* 2006; **214**: 99-108.
[3] Geier DA, Geier MR. A prospective assessment of porphyrins in autistic disorders: a potential marker for heavy metal exposure *Neurotox Res* 2006; **10**: 57-64.

Possibly, as the article being reviewed exemplifies, the mainstream media has apparently been co-opted by the advertising dollars lavished upon it by the pharmaceutical industry and is knowingly colluding with said industry to mislead the public.

Perhaps, the author's "highly educated, very intelligent" friend is smart enough to see through the vaccine propaganda, such as Paul Howard's article, and the Orwellian doublespeak where the truths:

- a. Theoretical protection from disease is provided by vaccines,
- b. Actual risks are associated with each vaccine, and
- c. Most vaccines lack both intermediate-term and long-term proofs of safety

have been "transformed" into the following Orwellian doublespeak phrases:

1. "the protection from disease afforded by vaccines,"
2. "theoretical risks of harm," and
3. "vaccines, the safest of medicines."

"Sadly, too many parents have lost faith in vaccines."

Given the compulsive state mandates, the vaccination rates for most of the vaccines "recommended" for nationwide administration exceed 90%, this statement is an obvious twisting of reality on several counts:

1. Vaccines are not supposed to be a religion, where "faith in vaccines" is required.
2. In our democracy, parents are supposed to be given the facts and allowed to make an informed consent decision as to whether or not they vaccinate, when they vaccinate, and with which vaccines they allow their children and themselves to be vaccinated.
3. Thus, those who speak of "lost faith in vaccines" apparently have raised vaccines to the status of gods, which are to be blindly worshipped, rather than medicines to be rationally considered.

"Partly, this is because of a 'generation gap.' In 1940, U.S. infant mortality rates stood at 40 deaths per 1,000 live births. Tens of thousands more children would go on to be killed or maimed by measles, polio and chicken pox."

Here, using a common vaccine-apologist's ploy, the author changes the subject from the issue of Thimerosal⁷ in vaccines to the subject of the additional harm that might have occurred if it weren't for the live-virus vaccines for measles, polio and chicken pox.

This ploy is especially duplicitous because: **a)** according to official federal government publications, Thimerosal has never been used in the manufacture of the licensed live-virus vaccines for measles, polio, or chickenpox, **b)** chicken pox has never caused even hundreds of deaths annually⁸, **c)** most of those who have died are the elderly who succumb from the complications from chicken pox, and **d)** the current number

⁷ Thimerosal (49.55% mercury by weight) is a highly toxic teratogen, mutagen, carcinogen, immune-system disruptor, and systemic poison at levels below 1 part-per million.

⁸ "We examined varicella deaths in the United States during the 25 years before vaccine licensure and identified 2262 people who died with varicella as the underlying cause of death."

http://www.ncbi.nlm.nih.gov/sites/entrez?cmd=Retrieve&db=PubMed&dopt=AbstractPlus&list_uids=10915066 (12 Oct. 2007)

of deaths from varicella, *still mostly deaths in the elderly*, is about 90 deaths annually⁹ in the U.S.

Examining our infant mortality rates and vaccines in perspective, this reviewer found:

Published U.S. Infant Mortality Data

Year	Deaths per 1,000 live births ¹	Change in Death rate	% of change	Significant Event
1920	86 [-----]	-----	-----	1923 Diphtheria 1926 Pertussis 1927 Tuberculosis (BCG) 1927 Tetanus
1930	65 [65]	21	- 24.4	1935 Yellow Fever
1940	47 ["49"]	18	- 27.7	1940s DTP 1945 First influenza vaccines (flu) began being used. late 1940s Penicillins for the public.
1950	29.2 ["37"]	17.8	- 37.9	1955 Inactivated polio vaccine licensed (IPV). Tetanus & diphtheria toxoids, adsorbed (adult use, Td)
1960	26.0 ["28"]	3.2	- 12.3	1961 Monovalent oral polio vaccine licensed. 1963 Trivalent oral polio vaccine licensed (OPV). 1963 The first measles vaccine licensed. 1967 Mumps vaccine licensed. 1969 Rubella vaccine licensed
1970	20.0 ["21"]	6.0	- 30.0	1971 Measles, Mumps, Rubella licensed (MMR). 1976 Ill-fated swine flu vaccine 1978 Fluzone, current flu vaccine made by Sanofi pasteur, licensed.
1980	12.6 ["16"]	7.4	- 37.0	1981 Meningococcal polysaccharide vaccine, groups A, C, Y, W135 combined (Menomune) 1982 Hepatitis B vaccine becomes available. 1983 Pneumococcal vaccine, 23 valent 1989-91 Major resurgence of measles in the U.S. - 55,000 cases vs. low of 1,497 cases in 1983; 2nd MMR dose is added.
1990	9.0 ["12"]	3.6	- 28.6	1990 Haemophilus influenzae type B (Hib) polysaccharide - conjugate licensed for infants. 1990 Typhoid vaccine (oral) 1991 Hepatitis B recommended for all infants. 1991 Acellular pertussis (DTaP) licensed for use in children aged 15 months to six years old. 1993 Japanese encephalitis vaccine
1995	7.6 ["10.5"]	1.4	- 15.6	1995 Varicella vaccine licensed. 1995 Hepatitis A vaccine licensed. 1996 Acellular pertussis (DTaP) licensed for young infants. 1998 First rotavirus vaccine licensed. 1999 Rotavirus vaccine withdrawn -- serious adverse events/deaths. 1999 Lyme disease vaccine approved. 1999 FDA recommends removing mercury from all products, including vaccines.
2000	6.9 ["9"]	0.7	- 9.2	2000 Prevnar recommended for all young children.
2005	6.3 ["7.9"]	0.6	- 8.7	2002 Lyme disease vaccine withdrawn 2003 First live flu vaccine licensed for 5 to 49 year olds
2010"	----- ["6.8"]	-----	----	2004 A combined DTaP, IPV, Hep B vaccines is approved 2005 Tdap vaccines, are approved for teens. Menactra, meningococcal vaccine for ages 11 to 55. 2006 RotaTeq is a new rotavirus vaccine from Merck. ProQuad a combined MMR & Varivax vaccine approved. Zostavax for shingles in the elderly Gardasil, the first HPV vaccine is approved.

¹ The numbers in brackets are a projection based on a constant 24.4% decline in infant mortality each decade in the absence of vaccines, antibiotics, and other drugs introduced after 1920.

⁹ "The risk of contracting and dying from chickenpox was little more than the risk of being struck and killed by lightning (about 89 cases per year in the U.S). (this figure reflected a population of 295,734,134 in 2005, according to the United States Census Bureau)" <http://ufaq.com/wiki/en/ch/Chickenpox.htm> (12 Oct 2007) [Note: Based on this reference, in 2005, the annual mortality from "chicken pox" has not changed significantly from what it was, on average [about 93], before Merck introduced the chickenpox vaccine.]

Based on the tabulated infant mortality data^{10,11}, vaccines do not appear to have made a contribution to reducing infant mortality that is greater than that of antibiotics.

Moreover, today, the direct and indirect harm from the universal vaccination program using Merck's Varivax vaccine clearly outweighs the harm caused by chicken pox before the vaccine.

This is the case because the chickenpox vaccine's immunity is both incomplete and less effective than the natural immunity provided through exposure to the native (wild) chicken pox virus.

Because the vaccine's immunity is incomplete, nursing mothers are unable to effectively pass on their immunity to their offspring.

Furthermore, repeated exposures to the native chickenpox virus boost cell-mediated immunity (exogenous boosting), which helps to postpone or suppress shingles in those children and adults who have had these periodic natural exposures.

Finally, *though understated* (the actual infant mortality rate in U.S. children was about 47 per 1,000 in 1940), the author's assertion that:

"Tens of thousands more children would go on to be killed or maimed by measles, polio and chicken pox"

is correct but incomplete because it fails to address the reality that penicillin antibiotics were not available to the public in 1940¹².

"Today, infant mortality averages about 7 deaths per 1,000 live births, and those other diseases have been largely vanquished by vaccines."

Actually, the current U.S. infant mortality rate is about 6.3 deaths per 1,000 live births; but the infant mortality rate in Japan (3.2 deaths per 1,000 live births) is about half of the U.S. infant mortality rate.

Thus, whatever the "positive" effects of the U.S. vaccination program, we currently lag far behind Japan in reducing infant mortality.

If by "*those other diseases*," the author means measles, polio and chicken pox, none of these diseases were "*largely vanquished by vaccines*" – vaccines simply displaced a significant portion of the wild viral strains so that:

- a. In the case of polio, today all clinical polio cases are some vaccine strain or a mutation of some vaccine strain of polio,
- b. In the case of measles, most of the "wild" strains exist in areas outside of the U.S, and
- c. In the case of chickenpox, the "wild" strains seem only to have been moderately displaced because a large portion of the population carries and, in many cases, can still shed the "wild" strains, which can easily infect many of those who have

¹⁰ http://www.mste.uiuc.edu/malcz/DATA/SOCIALSCIENCE/mortality_rates.html (last visited 12 Oct 2007)

¹¹ *Health, United States, 2001, Table 23* (reviewed 12 October 2007)

¹² <http://www.biology.buffalo.edu/courses/bio531/lecture10.html> (last visited 15 October 2007).

been vaccinated.

Since, in the case of measles, polio and chicken pox, children receive doses of a weakened virus, most have contracted a mild case of each of these diseases that:

1. “Immunized” most of them against the more virulent “wild” strains of these viruses for some period of time, and
2. Displaced the native (wild) strains of these diseases with the vaccine and vaccine-related strains of these diseases.

Finally, as the recent outbreak of measles in a “fully” vaccinated school (where only 10 were not immunized against measles [and apparently none of those children contracted the disease]) shows, the protection provided to those who were fully vaccinated was not complete since all who contracted measles had been vaccinated.

Since the primary case was a vaccinated child who contracted wild measles in another country and the other people affected were also vaccinated, it is obvious that the measles vaccination does not protect all those who are vaccinated.

Moreover, though the writer did not mention it, the current measles, mumps and rubella vaccine, Merck’s MMR-II, has a significant risk of side effects including ones that can cause irreversible neurological damage in children with “below-normal” levels of vitamin A and/or compromised immune systems.

Worse still, the “bankrupt” national vaccination program for chicken pox has not been stopped even though it is clear that it is causing more harm and the emergence of an increasing number of “breakthrough chickenpox” and “childhood shingles,” disease cases that:

1. Were virtually unknown before the national vaccination program was started,
2. Cause those that have them worse discomfort and much worse discomfort, respectively, and
3. In the case of shingles, require the use of antiviral drugs, which have their own risks, to treat the disease.

Thus, the national vaccination for chicken pox, *approved on the basis of the manufacturer’s estimated cost savings*, is a boondoggle that apparently only directly benefits the vaccine makers and the healthcare establishment while, through breakthrough chickenpox and childhood shingles, costs the public much more than the costs prior to the implementation of a “universal” chickenpox vaccination program and, *with the recent recommendation for a second dose*, the direct costs will at least double with almost no increased benefit to those inoculated or their parents.

“A childhood free of serious illness is now taken for granted.”

Here, this reviewer asks: “What alternate universe is this author living in?”

Factually, more than 15 percent of American children now have one or more chronic disease condition(s) that require constant medication to treat and/or mitigate.

In addition, today more than 10 percent of our children have asthma and/or chronic obstructive pulmonary disease (COPD).

In addition, allergies to gluten, casein, soy, and nuts have reached epidemic levels so that as many as one child in six has a serious allergy to one or more of these foods as well as to other foods and food additives.

The rates of both types of diabetes, childhood obesity, certain childhood leukemias, neurodevelopmental disorders, childhood intestinal disorders, childhood idiopathic dilated cardiomyopathy (IDCM), and general childhood immune-system dysfunction (allergies, immune-system compromise, and autoimmune disease), to name a few that seem to be linked to mercury poisoning in children by Thimerosal, are all at epidemic levels.

In our schools, more than 15 % of the children in some grade schools have written alternative instruction plans and, *in some instances*, the percentage of these children exceeds 25 % of the enrollment.

Thus, the stark reality is that many of today's children have one or more serious illnesses and a "*childhood free of serious illness is now*" becoming *increasingly rare*.

"When mysterious disorders like autism strike seemingly healthy children -- at about the same age when childhood vaccines are typically administered -- frustrated parents lash out at doctors and pharmaceutical companies. And today's vaccine inventors must contend with a powerful force that had yet to arise when Jonas Salk created his revolutionary polio vaccine -- mass litigation."

First, there is nothing mysterious to this reviewer about the neurodevelopmental disorders, like autism, or the other disorders that have symptoms like those observed for sub-acute mercury poisoning – if you inject Thimerosal into pregnant mothers and young children, all such children are mercury poisoned to some degree and some are mercury poisoned to the degree they exhibit the symptoms used to diagnose neurodevelopmental disorders, including autism.

Again, this reviewer finds that this author seems to be living in his own world.

In his world, *unlike ours*:

- a. Parents have been educated to accept vaccines are not the "safest medicines"¹³,
- b. Vaccine makers have no absolute, non-dischargeable duty to ensure that each of their vaccine lots are safe¹⁴ prior to distributing them,
- c. No toxicity studies are required for compounds used as preservatives¹⁵,
- d. No effectiveness studies are required,
- e. Clinical trials are not required to have a true placebo (sterile saline) in the control

¹³ In America, *the universe in which we actually live*, we are repeatedly reminded that vaccines are "the safest medicines" – no wonder we react negatively when our healthy children are obviously damaged by a vaccine that is touted as one of the "safest medicines."

¹⁴ The U.S. Supreme Court has decisively ruled that the vaccine makers have an absolute non-dischargeable duty to ensure their drug products, including vaccines, are safe to the CGMP [current good manufacturing practice] minimums set forth: 1) by statute [in Title 21 or Title 42 of the U.S. Code], 2) in a legally binding administrative regulation [in Title 21 of the U.S. Code of Federal Regulations], or 3) in an official policy.

¹⁵ A violative practice that the FDA is illegally ignoring in the case where Thimerosal is used as a preservative or as a process sterilant when the process leaves any residual level of Thimerosal in a vaccine.

arm of any pre-approval Phase III clinical trial¹⁶,

- f. No short-term (up to a year) post-injection population studies are required to establish what the in-use short-term side effects truly are and their approximate incidence rates¹⁷, and
- g. No long-term (30-year), post-approval studies are required to establish that vaccines are free of any significant long-term health risks¹⁸.

Since none of the preceding views (“a.” – “g.”) in this author’s “world” is supposed to be a reality in today’s America, U.S. parents understandably have the expectation that vaccines are the “safest medicines,” medicines whose safety and effectiveness (not efficacy) has been proven and whose serious adverse reaction risks are almost non-existent.

As to “*mass litigation*,” if an industry is responsible for *knowingly* injuring tens of thousands of individuals annually and is *knowingly* concealing the risks of harm from the masses, that industry is rightly liable to “*mass litigation*” – as the tobacco and asbestos industries have learned.

Thus, the federal government, vaccine makers and the healthcare establishment (and not the parents) have generated the need for “*mass litigation*” by *knowingly*:

- Allowing or participating in the mass distribution of vaccine doses that are harmful and/or adulterated and
- Concealing the risks, the evidence of the harm, and the adulteration of their vaccines from those who were harmed, parents, and the public at large.

“The birth of ‘liability without fault’ in pharmaceutical litigation in 1958 -- captured in Dr. Paul Offit’s riveting book The Cutter Incident -- set the dangerous precedent that vaccine companies would be held liable for side effects even when their products were made using the best available science and according to government regulations.”

As Dr. Offit did, this author ignores the reality that if one knowingly uses the best available science to produce any drug product that contains an unnecessary¹⁹ poison, Thimerosal, which, to varying degrees, mercury poisons all who are given it, then that “person” is obviously liable for the harm caused to each person harmed, whether the number harmed is a few or, *in the case of Thimerosal*, in the millions.

Moreover, *contrary to the author’s views*, vaccines that contain Thimerosal at a level of 0.01% to 0.001% (a “preservative” level) or use Thimerosal as a process sterilant and

¹⁶ A questionable practice that the FDA has recently started allowing [e.g., the HPV vaccine] in clinical trials on order to mask the incidence of adverse reactions.

¹⁷ Here, conditions in our universe are similar – efficacy studies extend to 3 years and beyond; adverse effect studies rarely extend beyond a few months)

¹⁸ Except for the chickenpox vaccine, this reviewer is not aware of any government-run long-term (>3-year) post-approval “adverse effects” studies being conducted even though, in other countries, significant long-term disease risks have been linked to certain vaccines [e.g., in France, hepatitis B was linked to a large increase in the incidence of MS at about 4 years after the last dose of hepatitis B was administered to middle-school-age children])

¹⁹ The use of Thimerosal has always been unnecessary because: **a)** no preservative is required for any vaccine packaged in a unit-dose container and **b)** there are and have been other less toxic and non-bio-accumulative compounds that are or could have been used as a preservative instead of Thimerosal.

leave any level of Thimerosal-derived mercury in the final product have not been manufactured “*according to government regulations*” since 1960 for all drugs (see 21 U.S.C. Sec. 351(a)(2)(B)) or, *at the latest*, since 1973 for vaccine formulations that contain preservative levels of Thimerosal (see 21 C.F.R. Sec. 610.15(a)).

Given the preceding facts, Paul Howard is again speaking of the manufacture of Thimerosal-containing vaccines in some “alternative world” where Thimerosal is a “vitamin” required to ensure a child’s health instead of the highly poisonous bioaccumulative all-systems poison as well as a teratogen, carcinogen, mutagen, and immune- and endocrine- system disruptor, which Thimerosal is at subppm levels in today’s America.

“Vaccine litigation exploded in the 1980s. In 1983, Lederle estimated that its diphtheria, tetanus, and pertussis (DTP) vaccine sales were ‘dwarfed by [legal] claims by 200 to 1.’ In 1984, the first-ever million dollar vaccine jury verdict came down against a DTP vaccine manufacturer, later followed by a \$10 million verdict against a polio vaccine manufacturer. Litigation took a deadly toll on vaccines; in 1957, there were 26 vaccine makers but, by the mid-1980s, there were just four.”

Contrary to the simplistic word picture painted by the author, much of the reduction in the number of vaccine makers in the 1980s was caused by the merger of drug companies and the decision of most states to cease being in the vaccine making business.

Moreover, the first major vaccine maker to exit the vaccines market was Eli Lilly and Company who *apparently* exited the vaccines business in the mid-1970s because:

- a. All of Lilly’s vaccines were “Thimerosal preserved” with a 100-ppm level of Thimerosal and
- b. Internal research (reported in a 1971 memo), *conducted in response to the new CGMP “sufficiently nontoxic ...” requirement set forth in what is now 21 C.F.R. Sec. 610.15(a)*, had established toxicity at 1 ppm (100 times lower than the level in Lilly’s licensed vaccines).

Finally, today, a dozen (12) vaccine makers are currently approved to distribute vaccines in America – something else the author forgot to mention.

“In 1986, Congress intervened to create the Vaccine Injury Compensation Program (VICP), which substituted a science-based, administrative compensation system for injuries suffered from childhood vaccines (other vaccines have since been added) on place of ... The program has brought the industry back from the brink, but thimerosal litigation is threatening to sink it yet again.”

More than bringing the vaccine industry back from the brink, the protections afforded by the National Vaccine Injury Compensation Program (“NVICP”)²⁰ have encouraged the vaccine makers to submit increasingly less-than-safe vaccines for licensing and approval.

Further, *through the influence that the vaccine makers wield through the various advisory committees and otherwise*, the reality is these more-risky vaccines have been licensed

²⁰ The proper name of and the proper acronym for this government program (see 42 U.S.C. Sec. 300aa-10(a)) and not “*the Vaccine Injury Compensation Program (VICP)*”,

and, *in some cases*, approved for universal use before, or at the same time as, they were licensed for sale.²¹

However, the immediate reality is the harm caused by Thimerosal-containing vaccines that were *knowingly not* produced “*according to government regulations*” is “*threatening*” to cost the government and vaccine makers more than they want to pay.

Thus, the government officials who *knowingly* allow adulterated vaccine doses to be manufactured, distributed and used, and the vaccine makers who keep *knowingly* making and distributing adulterated vaccines are the ones complaining about the true costs of the harm that these adulterated vaccines have caused and are causing.

“Since 2001, about 5,000 families have filed thimerosal-autism claims against VICP, forcing the program to lower its standards for evaluating claims. According to Newsweek, ‘autism plaintiffs are no longer required to file medical records with their claims, because VICP clerk’s office does not have the space to accommodate such massive amounts of paper.’”

Apparently, the author is confusing a change in the requirements for filing a claim, where “*autism plaintiffs are no longer required to file medical records with their claims,*” with the “*standards for evaluating claims,*” which, *for the most part*, can only be lowered by either legislative or judicial action.

Since, *by statute*, each claim must be administered in a *de novo* manner, and the vaccine court can only administer about 50 cases a year (implying the need for more than 100 years for the current Thimerosal-autism claims to be evaluated), there is obviously plenty of time for the clerks to request the needed medical records for the next year’s fifty cases at the beginning of the current year as per 42 U.S.C. 300aa-11(e)²².

However, the governmental barriers to administering each case has been lowered by judges, who have repeatedly held that government attorneys have been overzealous in opposing claims where there was clear evidence of possible harm by a vaccine.

Finally, though the Secretary of Health and Human Services is required by statute²³ make “**reasonable efforts to inform the public of the availability of the Program,**” this reviewer notes this author has not addressed the knowing failure of the Secretary, in specific, and the federal government, in general, to publicize the availability of the Program in, *at a minimum*, every pediatrician’s office with a requirement to post the notices provided

²¹ The vaccines highlighted in orange in the “**Published U.S. Infant Mortality Data**” table in this review are vaccines that, based on the in-use evidence:

- a. Are not truly cost effective, and/or
- b. Do not provide the implied protection from disease as claimed by the vaccine maker, and/or
- c. Have much higher and more dangerous adverse reaction rates than the vaccine maker’s literature indicates, and/or
- d. May actually do more long-term harm to the recipient than the disease they are claimed to prevent.]

²² 42 U.S.C. Sec. 300aa-11(e) Schedule

“The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.”

²³ 42 U.S.C. 300aa-10(c) Publicity

“The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.”

prominently in order to receive any government payments.

Lacking the required publicity, many of the parents whose children are, *in their parent's view*, damaged by a vaccine, *Thimerosal-containing or not, only* find out about the "Program" after its statutory filing limits have passed.

This omission plainly indicates:

- The author apparently has no interest in the rights of those who have been harmed by a vaccine to be appropriately compensated in the supposedly non-adversarial NVICP, but rather, *based on his statements*,
- The author is focused on protecting the vaccine makers and the healthcare establishment from being held financially accountable for the harm that they have *knowingly* inflicted.

"VICP claims have been consolidated into a handful of test cases before the U.S. Court of Federal Claims. In these "vaccine courts" claimants just have to meet a civil claims standard of 'preponderance of evidence,' showing that causation is 'more likely than not.'" If the plaintiffs win, the VICP program -- with only \$2.5 billion in reserves -- could be bankrupted."

Again, the author is plainly mistaken because, by statute²⁴, each petition filed must be separately administered ("tried") in a *de novo* fashion where no prior finding or decision can be used in the current petition being administered.

Thus, no matter what the outcomes of the "*handful of test cases before the U.S. Court of Federal Claims*," *an administrative court (not an adjudicatory court) that usurps the injured parties constitutionally guaranteed right of trial by jury*, could not hear and settle (in the plaintiffs' favor) more than about 50 cases annually [since other claims need to be tried], given the current statutes, the average length of each administrative hearing, the staffing level of the current administrative system, even if the expedited hearings were mandated.

Since the tax on each disease in each dose of vaccines is currently \$ 0.75 and, *given all of the vaccines covered, including all of the now 100-plus-million doses of the vaccines for influenza*, the current tax on vaccines generates between \$ 360 million and \$ 600 million annually and, *after its overhead and typical annual payouts*, there is an annual net revenue increase that exceeds \$240 million, the Program should have no funding problem.

Moreover, the interest on the current surplus, though only about 3 %, is more than the current annual pay out for claims.

Finally, were the payout to exceed the interest on the surplus, the government would simply raise this hidden tax on all vaccine doses.

²⁴ 42 U.S.C. Sec. 300aa-23. Trial at paragraph (e) (with underlining added for emphasis):

"(e) Evidence

(1) In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible."

Given the preceding realities, there is no current danger that the National Vaccine Injury Compensation Program “-- with only \$2.5 billion in reserves -- could be bankrupted.”

“Even if the claimants fail there, they can opt-out of the program and sue in civil court. According to UCLA law professor Stephen Sugarman, writing in the New England Journal of Medicine, VICP may not be much of a firewall against thimerosal litigation: ‘Not only do families with autistic children have support groups and organized lawyers behind them, but they also have the backing of several prominent senators and congressional representatives.’”

Since the current statute:

a. Only provides for opting out after some significant period of time has elapsed (supposedly at “240 days” or “420 days”²⁵ but typically, *in effect*, no less than about two years in the 240-day instance and no less than about 5 years in the 420-day instance) and

b. Bars class-action lawsuits,

only those parents with significant financial resources above those required to care for their injured child can afford to opt out of the NVICP – leaving more than 95% of the parents with no viable option other than to remain in the program even though it may take decades for their case to be heard.

Further, to date, most of the federal “Thimerosal” civil suits have had the plaintiffs’ causation experts disqualified on some pretext in the required “Daubert” hearings and, *lacking “qualified” causation experts*, the judges have then dismissed the cases or, *in some cases*, these federal cases have been dismissed with prejudice on other legal technicalities or the plaintiff’s have failed to meet the burden of proof of harm from mercury poisoning by Thimerosal-containing drugs that is required to sustain a Thimerosal-injury civil case.

Furthermore, in the recent Maryland state case, *where the general allegation of harm by mercury from Thimerosal or power plants has yet to be adjudicated*, the “jury” is still out as to whether or not the judge will let the plaintiffs’ experts testify.

Thus, by succeeding in making the judge the decider on whether or not experts are permitted to testify and packing the courts, state and federal, with industry-friendly judges, the industry has tilted the “playing field” in its favor – making it difficult for a “Thimerosal injury” civil lawsuit to reach trial.

Finally, cognizant of its knowing culpability in the harm caused by Thimerosal in vaccines, the pharmaceutical industry has joined with other industries, *including the*

²⁵ 42 U.S.C. Sec. 300aa-12. Court jurisdiction at paragraph (e):

“(g) Notice

If -

- (1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) of this section (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section), or
- (2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D) of this section, and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C) of this section) after the date on which the petition was filed, the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa-21(b) of this title or the petitioner may choose under section 300aa-21(b) of this title to have the petition .

healthcare and insurance industries, in seeking protection from the knowing harm they inflict on their customers, and acted to get low-value punitive damages caps enacted in both the state and the federal courts without, *in many cases*, any automatic cost-of-living adjusters.

“The debate over vaccine litigation has thus shifted from a presumption of innocence to a presumption of guilt. While the number of major studies that have failed to find any substantive link between vaccines and developmental disorders or autism is now in the double-digits (including a September 27th CDC study in the New England Journal), critics are effectively demanding that scientists prove that thimerosal does not cause illness -- an impossible standard.”

Here, the author:

- Knowingly miscasts the debate as a “*debate over vaccine litigation*” with “*a presumption of guilt*”,
- Relies on for-the-most-part-unidentified epidemiological studies, the author’s “*number of major studies that have failed to find any substantive link between vaccines and developmental disorders or autism is now in the double-digits (including a September 27th CDC study in the New England Journal)*,” that cannot be used to prove safety,
- Knowingly misstates what critics are demanding, the author’s “*critics are effectively demanding that scientists prove that thimerosal does not cause illness*,” and
- Cleverly casts the demand he has created as if it were “*an impossible standard*.”

Given his own words, it is clear that the author knows that the real “Thimerosal-containing” vaccine issues are:

1. The vaccine makers’ knowing and ongoing failure to prove Thimerosal, used as a preservative in vaccines, is safe to the established standard “**sufficiently nontoxic**,” a *legally binding CGMP safety minimum* since the late 1960s – as FDA officials have repeatedly testified before Congress.
2. The fact that the vaccine makers, *by willfully failing to comply with said established CGMP minimum for safety*, have knowingly manufactured and distributed Thimerosal-preserved vaccines that are plainly adulterated drugs under 21 U.S.C. 351(a)(2)(B).
3. The distribution of adulterated drugs – which subjects those vaccine makers who knowingly distributed and are still knowingly distributing these adulterated drugs to legal sanctions.
4. The independent epidemiological research studying the *in utero* and *post partum* links between Thimerosal exposure and neurodevelopmental disorders that have been published in peer-reviewed journals – which has clearly established a statistical link between Thimerosal exposure and the neurodevelopmental harm, even though the few, now seven, CDC-“directed” epidemiological studies of which the author speaks have found less-certain statistical evidence of a link between Thimerosal exposure and neurodevelopmental disorders.
5. All of the toxicity studies – which have clearly established that Thimerosal at the levels found in Thimerosal-preserved vaccines as well as at lower levels mercury poisons all who are administered such vaccines to some degree.
6. Several recent case studies – which have clearly established that many children

who have a diagnosed neurodevelopmental disorders and no major genetic defect tied to abnormal neurodevelopment (e.g., Downs, Reyes, and Fragile X) also have an unequivocal clinical diagnosis of mercury poisoning from the Thimerosal (49.6% mercury by weight) administered through serums (e.g., RhoGam) and Thimerosal-containing vaccines, ear drops, eye drops, and nasal sprays as well as mercury from other sources in some cases.

Given this reviewer's points **5** and **6**, Paul Howard's "*demanding scientists prove that thimerosal does not cause illness -- an impossible standard*" is true because science has already *unequivocally* established that Thimerosal, *at the levels found in vaccines*, causes clinical mercury poisoning, a recognized "*illness*," in susceptible individuals.

Since clinical mercury poisoning is a recognized illness, the alternative, *that Thimerosal does not cause mercury poisoning*, has been proven to scientifically impossible – hence, the author's "*an impossible standard*" remark.

Therefore, *based on: a) the body of published toxicological science and the published case studies and b) the vaccine makers' knowing failure to comply with the law*, the preceding facts have reduced the debate in any civil suit to determining the damages to be awarded for the knowing violative conduct by the vaccine makers when the damaged plaintiff(s) has proven that their child is mercury poisoned where Thimerosal-containing vaccines and other mercury-containing drugs given to the child are a source of the mercury that caused the mercury poisoning observed.

Because the vaccine makers of Thimerosal-containing vaccines and other drugs have: **a)** knowingly broken the law and **b)** continued to add an unnecessary²⁶ poison, Thimerosal, to their drug products without the required proofs of safety, the vaccine makers being tried should also be required to pay the maximum punitive damages that can be awarded and, *acting in their administrative capacities*, the judges should direct the appropriate attorneys general to initiate criminal proceedings against said vaccine makers.

"The very success of vaccines has become their downfall. As Dr. Offit writes in *Vaccinated*, 'When [vaccines] work, absolutely nothing happens; Parents go on with their lives, not once thinking that their child was saved.'"

Again, as Offit did, this author attempts to change the issue from Thimerosal-mercury poisoning to the "*success of vaccines*," the majority of which never contained Thimerosal.

At best, this tangential comment should simple be ignored.

"It is time to rescue vaccines from the witch hunts that go on when science fails to provide easy answers for complex diseases like autism."

²⁶ There is nothing in vaccine law that requires Thimerosal to be used as a preservative or, for that matter, requires any vaccine formulation to contain any preservative. At best, a preservative is only required for some vaccines when they are packaged in multiple-dose containers. Given the 1987 statutory mandate for the Secretary of HHS to safen vaccines (see 42 U.S.C. Sec. 300aa-27(a)) and the fact that any compound that is a preservative against bacterial and fungal contamination is also toxic to human cells, today, 20 years after this statute was enacted, all U.S. vaccines should only be packaged in unit-dose vials which require no preservative. Thus, the federal government, by not acting as mandated by statute, is also culpable.

Given the issue is Thimerosal-induced mercury poisoning and not vaccines, the “*easy*” answer is to ban all uses of Thimerosal and all other mercury compounds from medicine, recall and destroy all Thimerosal-containing doses, and, *thereby*, stop all mercury poisoning by medicine.

Based on the recent published case studies, the removal of Thimerosal from all of medicine would stop more than 85 % of the cases where a child has significant neurodevelopmental damage from being vaccinated or otherwise treated with drugs containing preservative and lower levels of Thimerosal or some other mercury compound.

Although the federal government and the makers of vaccines and other drugs continue to resist banning all uses of mercury or mercury compounds, banning Thimerosal is the simple, “precautionary principle” answer to questions about the safety of Thimerosal in vaccines and other drugs.

Like the Gordian knot, all we need do is cut off all uses of Thimerosal in medicine if we want an easy answer.

“First, policymakers should end the opt-out option for VICP. If society is going to mandate vaccines for school children and encourage companies to invest in their development, companies must be shielded from the volatile passions of the jury box.”

Apparently, the author has, like Dr. Offit and other vaccine apologists, failed to read Amendment VII to the Constitution of the United States of America, which clearly states:

“In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law.”

Thus, the author’s suggestion for changing the NVICP is clearly unconstitutional on its face and, hopefully, *after reading Amendment VII*, this author will publicly repudiate his remarks.

Why is it that this society, *supposedly a free-market democratic republic governed by the current constitution*, would want to: **a)** mandate vaccines, **b)** encourage companies to invest in developing vaccines, or **c)** shield vaccine makers from a trial by jury as the Constitution of the United States of America, as amended, clearly guarantees?

If vaccines were the wonders they are touted to be, there would be no need to mandate that we consume them.

If our society truly must coerce people into getting their children or themselves vaccinated, then we are implicitly admitting that vaccines are not the wondrous medicines they are touted to be, aren’t we?

If vaccines are the wondrous drugs they are touted to be, our society need not encourage companies to develop them more than we already are, the market (the number of people who would want to be vaccinated if a safe and effective vaccine were developed) should be more than enough to encourage vaccine developers.

Based on the author's remarks here, it appears that the author is a well-paid vaccine apologist who is shilling for the vaccine makers in this column.

“Second, and perhaps most importantly, policymakers must invest more in vaccine education, so that parents understand the benefits of vaccinations (along with their real, but very rare risks).”

Here, in principle, this reviewer agrees with the author.

However, unless

- Parents are told the truth that vaccines provide:
 1. Only theoretical benefits unless/until their child is exposed to the disease agent(s)
 2. In most cases, only limited-term immunity to said disease(s),
 3. No protection to some who are fully inoculated, and
 4. Some assurance of protection only for the diseases and disease strains covered by the vaccine;
- The vaccine makers and the federal government publish scientifically sound values for all of the actual benefit statistics for vaccines, including, in cases where the disease continues to occur, valid in-use vaccine effectiveness data (and not the projected *efficacy* numbers reported today);
- Our government acquires the data for and publishes all of the long-term and short-term risks, *including the risk of death (in most cases, the only “very rare” vaccine risk)*, along with their underascertainment-corrected incidence rates by age group, and, *where different*, by sex;
- Our government stops the problematic national chickenpox vaccination program and tells the American public that the chickenpox vaccine should only be given to seronegative children who have not had a documented case of chickenpox by age 10;
- Our government stops mandating its current ineffective influenza vaccination programs and only permits vaccination in a healthcare provider's facility in a manner that complies with the law (42 U.S.C. Sec. 300aa-25), and
- The government, vaccine makers, and their apologists stop claiming that “vaccines are the safest of drugs” without having any long-term safety studies to back up such claims,

this reviewer cannot support the author's “*policymakers must invest more in vaccine education*” because all that this course of action will do is result in an increase in vaccine propaganda.

“Vaccines may face an unappreciative audience within our own comfortable borders, but poor nations are in desperate need of them. Every year, for instance, 600,000 children die of rotavirus, a common childhood infection. Thankfully, in 2006 Merck got FDA approval for a vaccine to prevent it -- giving us 600,000 new reasons to reign in vaccine litigation.”

Again, the author closes by addressing a rotavirus vaccine²⁷ when the root issue is the

²⁷ While Merck's new rotavirus vaccine, RotaTeq, may be helpful in the third world, in the U.S. in less than a year of use in less than 2 million children, this rotavirus vaccine has already resulted in 28 VAERS-reported cases of intussusception (twisted intestines).

harm that Thimerosal-preserved vaccines is continuing to cause in the United States, where the maximum mercury exposure from Thimerosal in vaccines a child can receive, *when parents rigorously avoid giving their children any Thimerosal-containing vaccines*, can be less than 0.5 microgram of mercury, but, *If you fully vaccinate with all the recommended vaccines, including the Thimerosal-preserved flu shots*, that cumulative mercury dose can exceed 500 micrograms by the time that same child is 18,

Using the author's numbers analogy, every year that the use of Thimerosal is not banned from all of medicine, more than 4 million American babies are born into a country where they are at some risk of being unnecessarily mercury poisoned by Thimerosal in their vaccines and other drugs, unless their parents *continually* fight to make sure that all of their children's vaccines and other drugs are truly free of Thimerosal and other mercury compounds.

How many more tens of millions of American children do we have to put at risk of being mercury poisoned before we stop this unnecessary iatrogenic poisoning of our children?

How long before the government, vaccine makers and the healthcare establishment admits to the risk of mercury poisoning that every Thimerosal-containing vaccine presents and stops this genocidal maiming of not only our children but the children in all of the other nations who still allow Thimerosal-preserved vaccines and other Thimerosal-containing drugs to be given to their children because we have not banned the use of Thimerosal?

Until that day, writers like myself will continue to rebut the unsupported writings by the vaccine apologists like Paul Howard, who wrote this column, and others of his ilk, who continue to "spin" vaccination into a religion and increasingly use Orwellian doublespeak to mislead their readers for the benefit of the industry, which directly or indirectly compensates such writers.

"Paul Howard, Senior Fellow at the Manhattan Institute Center for Medical Progress, is Editor of the daily

Moreover, RotaTeq was found to increase the reported incidence of Kawasaki's disease, an often-lethal cardiovascular disease, by "5 times" the "reported" control-arm-rate found in Merck's Phase III clinical trial of RotaTeq. [See the FDA's 15 June 2007 notice, <http://www.fda.gov/cber/label/rotateqLBinfo.htm>, last visited on 15 October 2007.]

Therefore, *in the U.S.*, where rotavirus deaths are rare (20 – 60 per year), RotaTeq, a live-virus vaccine, *which gives everyone inoculated three cases of this mixture of human-cow hybrids rotaviruses*, may have already caused more harm than the native rotaviruses have, even though less than half of the annual candidate population has been inoculated.

Furthermore, current estimates indicate that, *for each American rotavirus death prevented*, the overall cost, including the cost of the vaccine's harm (intussusception, Kawasaki's disease and other serious adverse reactions), could be in excess of US\$ 60 million dollars.

Thus, only Merck and the healthcare establishment, and not the American public, are assured of benefiting from this rotavirus vaccine.

Moreover, no one knows what the long-term ramifications may be of introducing live human-cow hybrid rotavirus strains into the environment – especially in developing nations where sanitation is, at best, problematic.

Worst case, the RotaTeq rotavirus strains or "mutated" RotaTeq strains could amplify the disease's virulence and poor sanitation could spread these strains over the world.

Then, *like the current problem with the live polio vaccination*, instead of stopping disease, the vaccine-related "mutants" could spread variants of these artificial rotaviruses to everyone in developing countries where no one might have immunity – a problem that Nigeria is now experiencing with "mutant" vaccine-related polio.

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