

Wednesday, 27 December 2006

Eddy A. Bresnitz, M.D., M.S.
Deputy Commissioner/State Epidemiologist
Department of Health and Senior Services
State of New Jersey
P.O. Box 360
Trenton, New Jersey 08625-0360

Dear Dr. Bresnitz:

The review that follows this introductory letter is a critical assessment of your letter dated “December 14, 2006,” which I received on Thursday 21 December 2006.

In general, to clearly differentiate between my assessment comments and those of the article, the article’s printed statements are quoted in an *italicized “Times New Roman”* font followed by this reviewer’s remarks in indented text written in a “**News Gothic MT**” font.

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

For those who have access to a color printer, this reviewer’s comments are made in a **blue** color.

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

Respectfully,



Paul G. King, PhD,
Science Advisor & New Jersey Representative
Tel.: 973-997-1321, 973-331-0131, 973-263-4843
Email: drking@gti.net or
Technical@Mercury-FreeDrugs.org

c: Jon S. Corzine, Governor of New Jersey
Office of the Governor
PO Box 001
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609-292-6000

Annotated (in blue News Gothic MT font) transcription of December 14, 2006 letter from Eddy A. Bresnitz, MD., M.S., Deputy Commissioner/State Epidemiologist, Department of Health and Senior Services, State of New Jersey, P.O. Box 300, Trenton, N.J. 08625-0360, www.nj.gov/health, Jon S. Corzine, Governor, Fred M. Jacobs, M.D., J.D., which was received by Dr. Paul G. King on 21 December 2006:

“December 14, 2006

Dr. Paul King
33 Hoffman Avenue
Lake Hiawatha, NJ 07034

Dear Dr. King:

Your letter to Governor Jon E. Corzine expressing concern over the efficacy and safety of influenza vaccinations has been referred to me for a response. I would like to take this opportunity to respond to your expressed concerns by providing you more information and another perspective on this important personal and public health intervention which helps reduce influenza disease incidence and its related hospitalizations or deaths.”

Contrary to the statement made here, all of the recent population studies reviewing the effectiveness of the human influenza vaccines, including those conducted by the Centers for Disease Control and Prevention on the elderly, have found that, *in general*, the influenza vaccines are much less effective than the claims made from the results of small clinical trials.

Factually, as the original article:

- David A. Geier, Paul G. King, and Mark R. Geier. Influenza Vaccine: Review of effectiveness of the U.S. immunization program, and policy considerations. ***JAP&S (Journal of American Physicians and Surgeons)*** 2006 Fall; **11**(3): 69-74 [1],

and a more recent article:

- Tom Jefferson (a world recognized vaccine researcher). Influenza vaccination: Policy versus evidence. ***BMJ (British Medical Journal)*** 2006 October 28; **333**: 912-915 [2],

have clearly established that the human influenza vaccines are *not* as effective as claimed in:

- Preventing those inoculated from getting influenza and/or
- Stopping the spread of influenza in the human population.

In addition, *as cited in Reference 1*, the following articles have found the influenza vaccines are *not* effective in preventing influenza in the elderly:

- a. Simonsen L, Reichert TA, Viboud C, *et al.* Impact of influenza vaccination on seasonal mortality in the US elderly population. ***Arch Intern Med*** 2005; **165**: 265-272.
- b. Cohen J. Study questions the benefits of vaccinating the elderly. ***Science*** 2005; **307**: 1026.

Furthermore, *as cited in Reference 1*, the following article has found the influenza vaccines was *not* effective in preventing influenza in young children:

- a. Maeda T, Shintani Y, Nakano K, Terashima K, Yamada Y. Failure of inactivated influenza A vaccine to protect healthy children aged 6-24 months. ***Pediatr Int*** 2004; **46**: 122-125.

“In the article you cited, the authors concluded that, ‘influenza vaccines are not effective at preventing influenza disease nor in stopping the spread of influenza’. While the results of one statistical analysis may be interesting and of some value, to rely on only one study to determine public health policy to the neglect of other studies done over time by other investigators with contrary and reaching different conclusions would be considered imprudent. In fact, studies done over several decades by other investigators and researchers seem to indicate that influenza vaccines do reduce illness, interrupt disease spread, and reduce those complications due to influenza which results in excess hospitalizations and deaths.”

First, the quotation provided is from my original letter, and *not* the article cited [1].

Factually, *among its statements*, that article stated, “Between 1979 and 2000, influenza vaccine was shown to have little or no effectiveness over the U.S. population for preventing influenza cases, deaths, or hospital admissions” at the beginning of the article’s “**Discussion**” section and, in the second paragraph of the article’s “**Conclusions**” section stated, “The current influenza vaccination program seems to be ineffective, ...”

Second, *as cited above*, the original article cited other prior articles that found the influenza vaccines were *not* effective in children, adults and/or the elderly, and, since Governor Corzine received my original communication, another article, written by a recognized vaccine expert [2], supports the conclusions reached in my original communication to Governor Corzine, “influenza vaccines are not effective at preventing influenza disease nor in stopping the spread of influenza.”

With respect to the writer’s “*studies done over several decades by other investigators and researchers seem to indicate that influenza vaccines do reduce illness, interrupt disease spread, and reduce those complications due to influenza,*” this reviewer asks the writer to please provide the references that both cover similarly sized populations (millions) and support his statement because this reviewer is *not* aware of any such studies.

“Your letter seems to imply that since the influenza vaccine is imperfect, it has little or no societal value to preventing disease. It is an accepted medical fact by your colleagues that the efficacy of influenza is dependent on such factors as the age of the vaccine recipient, and the similarity between the circulating influenza virus and those antigens found within the specific vaccine. In addition, when performing efficacy studies there are multiple outcomes that can be selected by the investigators as they seek to measure vaccine efficacy such as measuring influenza-like illnesses, confirmed influenza cases, seroconversion rates, disease clusters, hospitalizations, deaths, or other end points to demonstrate vaccine efficacy.

Contrary to the writer’s statement, “*Your letter seems to imply that since the influenza vaccine is imperfect, it has little or no societal value to preventing disease,*” the letter to which the writer refers clearly states the reality that the influenza vaccines are *not* effective and, *to use the writer’s generalization,* are ineffective in “*preventing disease.*”

Since the cited studies have clearly demonstrated the current human influenza vaccines are ineffective in preventing the human influenza disease, it should be obvious that they have “*little or no societal value to preventing disease.*”

Since vaccine effectiveness is judged by how well the vaccine protects those vaccinated from getting the disease in the population for which it is approved and the data clearly show that the current influenza vaccines are *not* effective using the most relevant measures of effectiveness, deaths, hospital admissions and influenza cases, this reviewer is at a loss to understand the reason the writer brings up “*efficacy*” rather than effectiveness.

Finally, this reviewer can assure the writer that, as scientists, my colleagues are more interested in the actual effectiveness of a given vaccine and less interested in the generalizations presented by the writer here.

“There is a general consensus in the medical community that vaccinated young children and adults have a higher rate of protection against the influenza illness that older persons with weaker immune systems. Influenza vaccines can be up to 90 percent effective at protecting adults and young children from influenza, but only up to 30-40 percent effective at preventing infection among the frail and elderly population. Preschool-aged children are also at a high risk of complications and have similar rates of hospitalization to the elderly.”

Contrary to the writer’s assertion about young children, a recent study has shown that the influenza vaccine inoculations are no more effective for children two years of age and younger than a placebo inoculation.

Thus, the writer’s assertions concerning the rate of protection for influenza in young children is *not* supported by the recent published studies.

Second, vaccine effectiveness statements couched in terms of “*can be up to*” are, *at best,* misleading because they do *not* reflect the level of effectiveness typically

expected but only report the maximum reported value in studies that typically involved less than 10,000 participants (often, less than 1,000).

Third, based on the reported number of annual flu-related deaths in children under fourteen years of age during the period from 1979 to 2001 [1], the average death rates from influenza vary from about 0.25 deaths per 100,000 children for children up 1 year of age to about 0.07 deaths per 100,000 children for children 1 to 4 years of age to about 0.04 deaths per 100,000 children for children 5 to 14 years of age.

Given these low death rates before the flu vaccine was first recommended for children 6 months to 23 months in 2002 and the lack of effectiveness of the influenza vaccines for young children, there is no scientific or economic justification, other than to line the pockets of the pediatricians who give these vaccines and the vaccine makers who produce them, for recommending that children 2 years of age and under should be vaccinated for influenza.

Finally, this reviewer is *not* aware of any nationwide study that supports the writer's claim that, "[p]reschool-aged children are also at a high risk of complications and have similar rates of hospitalization to the elderly," and asks the writer to provide supporting references to nationwide studies, *not* small-scale trials that lack any statistical validity for the population, which contain scientifically sound population-applicable data that clearly supports the writer's unsupported assertions here.

"These young children are considered to be among the most efficient incubators and transmitters of influenza disease to their families and those older persons they come in contact with."

Since this reviewer is *not* aware of any large-scale study that supports the writer's statement and the recent evidence is that influenza is primarily contacted and spread through the "workplace," this reviewer would again ask the writer to provide the independent (*not* underwritten by the vaccine maker or the CDC) peer-reviewed published population studies that support this view of the spread of influenza – after all, the epidemics seem to spread from Asia to the U.S. – indicating that travelers (airline workers and passengers) are the main transport vector.

"While protection against acquiring infection is less for the vaccinated elderly than for younger vaccinated persons, the vaccine is effective at preventing excess hospitalizations and deaths to this older population."

Based on the available U.S. data for the period from 1979 to 2000 that was published and evaluated in **Reference 1**, the writer's unsupported assertion, "*the vaccine is effective at preventing excess hospitalizations and deaths to this older population,*" is clearly at odds with the findings reported.

This reviewer would again ask the writer to provide published independent peer-reviewed articles that: **a)** evaluate nationwide data over some period of time and **b)** support the claims made by the writer.

“This fact prompted the New Jersey Department of Health and Senior Services to require all long term care facilities and hospitals, beginning in 1998 and 1999 respectively, offer an annual influenza vaccination to their residents or inpatients 65 years of age or older.”

Since the findings of the current published independent peer-reviewed articles are clearly at odds with this claimed “*fact*,” this reviewer finds that it would seem that the New Jersey Department of Health and Senior Services (NJDHSS) acted without any factual basis to justify its decision.

“In your letter, you call upon the State of New Jersey to cancel the flu vaccination program. This would be an impossible task to accomplish since the state does not operate or fund any public influenza clinics. Influenza vaccination services are only provided through private physicians, local health departments, employers, or some out-of-state for profit health service corporations which set up temporary ‘flu shot clinics’ at shopping malls, supermarkets, pharmacies, and retail discount or department stores using their private funds to purchase vaccine. The organizations or practitioners administering influenza vaccine to the public have been doing so for decades, and generally follow the vaccine recommendations of their professional organizations or national recommendations from the federal government.”

This reviewer notes that the writer’s statements here ignore the reality that the people of New Jersey look to the State of New Jersey to provide them with unbiased information on the safety and effectiveness of vaccines to guide them in making informed health decisions and in giving and/or withholding their informed consent for themselves and their dependents.

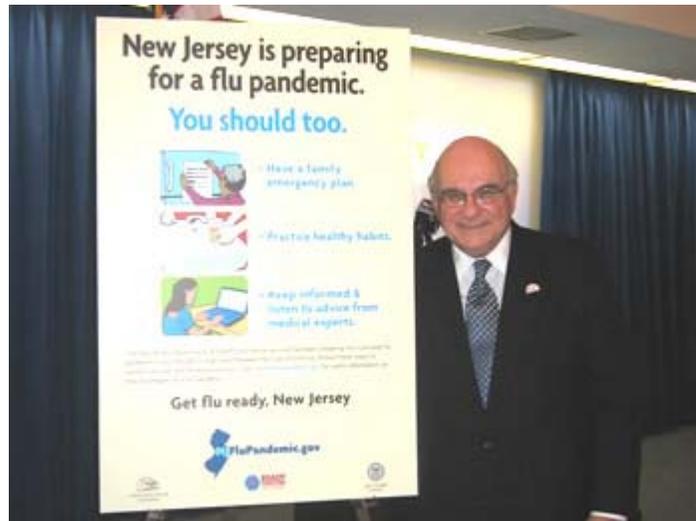
In addition, the reviewer notes that the State of New Jersey through the NJDHSS is currently promoting flu vaccination even though the federal government’s published historical data records clearly indicate that the current influenza vaccines are *not* effective.

Thus, to “*stop*” a influenza vaccination program that is *not* effective, all the NJDHSS would need to do is launch a statewide public awareness campaign (like the one the have already launched [see **Figure 1**, insets from <http://www.nj.gov/health>, on the next page]) that would simply alert the people of New Jersey to the reality that the influenza vaccines may *not* be effective.

In addition, this reviewer notes that the NJDHSS is currently supporting amending New Jersey law to, among other things:

- “A new rule at N.J.A.C. 8:57-4.19 would require children attending child care centers and preschools that are six to 59 months of age to receive one annual dose of influenza vaccine.”

that, based on scientific reality, the NJDHSS should immediately withdraw.



Get Flu Ready New Jersey: Commissioner Fred M. Jacobs, M.D., J.D. advises residents to prepare for a possible flu pandemic. The Department launched a statewide public awareness campaign during a press conference. For more information go to: www.njflupandemic.gov

Figure 1

Hopefully, if the writer and the NJDHSS persist in ignoring these scientifically sound and valid findings that the influenza vaccines are *not* effective, when the people of New Jersey do find out the truth about the ineffectiveness of the influenza vaccines and the reality of the mercury poisoning of those who receive Thimerosal-containing influenza vaccines, they will hold the writer of this letter and the other responsible NJDHSS personnel to account for their failure to inform them of the facts about the effectiveness, or lack thereof, of the influenza vaccines as well as the mercury poisoning that Thimerosal-containing vaccines provides.

Moreover, since 2005, when federal law was changed to add all influenza vaccines to the list of vaccines covered by the National Vaccine Injury Compensation program, this reviewer finds that many of these clinics are now operating outside of the federal statutory requirements for the administration of a covered vaccine including the records review, follow-up and recordskeeping requirements in **42 U.S.C. Sec. 300aa-25**.

“Your expressed concern around the issue of the preservative, thimerosal in influenza vaccines is similar to concerns raised by others. Without going into extensive detail at this time, I will restate the current position that there is no published scientific evidence that thimerosal in influenza vaccine causes severe adverse effects to persons.”

Without going into extensive detail, this reviewer finds that the writer’s statement is knowingly false on its face because Thimerosal, at the levels (0.003% to 0.01%) used in vaccines claiming it as a preservative, is known to

cause anaphylactic shock in those who are severely allergic to it, as some are, as well as severe allergic reactions.

Since the writer is a medical doctor, this reviewer hopes that he would agree that anaphylactic shock and other severe allergic reactions are recognized “*severe adverse effects*” that medicines can have.

In addition, this reviewer notes that the writer has failed to observe that, by law (**21 CFR Sec. 610.15(a)**) *since 1973*, Thimerosal used as a preservative in a vaccine formulation has been required to be proven to “**be sufficiently nontoxic so that the amount present in the recommended dose of the product will not be toxic to the recipient**” and, *as far as this reviewer can ascertain and as government and industry officials have repeatedly testified before the U.S. Congress and elsewhere*, the requisite toxicity studies required to satisfy this law have *not* been conducted.

Thus, this reviewer challenges the writer to provide the scientifically sound and appropriate, peer-reviewed, published toxicity studies for Thimerosal that prove that it is “**sufficiently nontoxic ...**,” to the degree required by **21 CFR Sec. 610.15(a)**, at any level, with an appropriate safety factor of at least 100X since Thimerosal (49.55% mercury by weight) is a bioaccumulative mercury poison that is also a proven human teratogen, immunogen, carcinogen, and autoimmunogen at Thimerosal levels below 1 part per million (ppm; 0.0001%) with proven lethal toxicity to developing human neurons at Thimerosal levels below 1 part per billion (ppb; 0.000001%) [Parran et al., 2005]¹.

Since **21 CFR Sec. 610.15(a)** falls within the current good manufacturing practice (CGMP) minimums for drugs and drug products (as these are set forth in **21 CFR Parts 210 and 211**), knowing failure to comply with any clear CGMP minimum, *as clearly seems to be the case here*, renders the drugs that do *not* comply adulterated under **21 U.S.C. Sec. 351(a)(2)(B)** and, *since 1988*, when the U.S. Supreme Court unanimously ruled that no FDA administrator has the legal authority to ignore any clear policy, law, or statute that requires an action be taken, it is clear that all Thimerosal-preserved vaccines and other drugs are, *by statute*, adulterated drugs under **21 U.S.C. Sec. 351(a)(2)(B)**.

“As you are undoubtedly aware a physician may choose to order, then offer and administer available thimerosal-free influenza vaccines to their patient. (Attachment 1) The pharmaceutical companies are working to expand their production capacities to manufacture more preservative-free vaccine each year. There are additional references and resources for more information about influenza vaccine, thimerosal, and other topics which may interest you and are accessible at www.immunize.org or www.cdc.gov/nip/.”

First, only Sanofi-Aventis currently makes a “no Thimerosal” inactivated-influenza vaccine and, *though they have claimed they could make as much as*

¹ Parran DK, Barker A, Ehrich M. Effects of thimerosal on NGF signal transduction and cell death in neuroblastoma cells. Toxicol Sci. 2005 Jul; **86**(1): 132-140. Epub 2005 Apr 20.

needed if the federal government required them to, less than 20% of the doses they reported releasing this year were made without the use of Thimerosal.

The other major inactivated-influenza vaccine makers with vaccines licensed for use in the U.S, Novartis (formerly Chiron-Evans) and GlaxoSmithKline (GSK), have *not* yet provided any “no Thimerosal” vaccine doses though both do make “reduced Thimerosal” vaccines that are claimed to be preservative-free, but only Novartis’ vaccines are licensed for use in children (age 4 and up).

Moreover, this year GSK acquired another Canadian flu vaccine maker and licensed its “Thimerosal-preserved” vaccine, FluLaval, for use in the U.S. – so that they government actually increased the capacity of vaccine makers to provide “Thimerosal-preserved” doses to the U.S. market.

Novartis’ actions are more difficult to judge because, *depending upon whose “press release” you read*, they either shipped “no Thimerosal-preserved” vaccine doses (Novartis’ press release) or “no reduced Thimerosal” doses (the CDC/CBER view) to the U.S. this season (2006/2007) after shipping only “Thimerosal-preserved” doses in the 2005/2006 “flu season” and being shuttered by the British health ministry in 2004 because of contamination of the finished packaged vaccine doses with viable *Serratia* species.

The problems with MedImmune’s live-virus influenza vaccine, FluMist, are that it:

- Exposes those inoculated with it to three strains of influenza,
- Gives some of those immunized with it an active cases of influenza, and
- Makes some of those inoculated into “Typhoid Mary” spreaders of those strains influenza and any variants created in the inoculee to those who have *not* been inoculated with those strains or the variants generated from them, or are otherwise not protected from contracting influenza.

[Note: Even the FluMist package insert recommends a 21-day quarantine of those inoculated from those who may be susceptible to contracting influenza. In the worst reported incident of which this reviewer is aware, an entire pre-school class contracted influenza from an aide who was inoculated with FluMist and did *not* quarantine herself from the class for 21 days. Moreover, at least two of those children had cases severe enough to require them to be hospitalized for several days.]

If the reader of this review wishes to further evaluate the level of this reviewer’s understanding of the influenza vaccines and Thimerosal (49.55% mercury by weight), the current most common U.S. trade name for sodium ethylmercurithiosalicylate (originally, Merthiolate was the most common trade name for this mercury compound), then he or she should read the documents posted on <http://www.Mercury-FreeDrugs.org> that critically review seminal publications in these areas, including those by the U.S. Centers for Disease Control and Prevention (CDC), the U.S. FDA’s Center for Biologics Evaluation

and Research (CBER), and recognized pro-vaccine researchers (e.g., Dr. Eric Fombonne) and vaccine apologists (e.g., Dr. Steve Novella).

“While I cannot comment on the statistical accuracy or robustness of the study you cited, it would appear that the findings of those investigators are contrary to the current policies, practices, and recommendations of such notable professional organizations as the American Academy of Pediatrics, American Academy of Family Physicians, American College of Obstetrics and Gynecology, the national Advisory Committee on Immunization Practices, American Medical Association, the federal Centers for Disease Control and Prevention, American College of Physicians, American Lung Association, and the Medicare Program.”

First, since the writer is a “*State Epidemiologist*” and all of the raw data (and its sources) needed to reevaluate the statistical accuracy and robustness of the study cited is provided in the “**Reference 1**” article (unlike the epidemiology studies published by those whose positions seem to have a pro-vaccine bias), this reviewer is surprised that the writer “*cannot comment on the statistical accuracy or robustness of the study ... cited.*”

Unless the findings reported are *not* valid (and the writer has provided no references that contradict them), the “*current policies, practices, and recommendations of such notable professional organizations as the American Academy of Pediatrics, American Academy of Family Physicians, American College of Obstetrics and Gynecology, the national Advisory Committee on Immunization Practices, American Medical Association, the federal Centers for Disease Control and Prevention, American College of Physicians, American Lung Association, and the Medicare Program*”:

- Are *not* relevant to the issues of ineffectiveness and/or lack of the legally required proof of safety raised by this reviewer and
- Clearly indicate that these organizations need to change these policies, practices and recommendations because there are no scientifically sound U.S. population studies, *as far as this reviewer can ascertain*, that are at odds with the cited article’s findings and the findings are supported by the published findings of other researchers including those cited in this review of the writer’s remarks.

“It is to organizations such as these that your medical colleagues and public health departments refer to for guidance and recommendations within a greater body of knowledge on this subject, rather than a single study published in a peer-reviewed journal which seems in its findings and conclusions to contradict other published studies.”

First, this reviewer’s medical colleagues, who are researchers in this area, do *not* refer to such organizations for guidance and recommendations when that guidance and recommendations are clearly at odds with sound science.

Second, since the other recent article [2] cited in this review and the applicable reference articles, including those published by CDC researchers, cited in both

references [1, 2] clearly support the conclusions reached, this reviewer is at a loss to explain the writer's "single study" rhetoric unless the writer did *not* even read the abstracts to the applicable references cited in that "single study."

Third, IF, as Dr. Jefferson noted in his "**Reference 2**" article's "**Summary Points**" box included on the next page (with **bolding** added for emphasis), "systematic reviews of large datasets from several decades provide the best information on vaccine performance," THEN this reviewer notes that the systematic decades-spanning review of the published information on **a)** U.S. population and **b)** influenza: **1)** inoculation levels and rates, **2)** disease levels and rates, **3)** death levels and rates, and **4)** hospital discharge levels and rates where Influenza is the first listed reason for admission, the Geier et al. article [1] is, by far, the largest systematic "several decade" population study of which this reviewer is aware.

Reference 2's "Summary Points":

"Summary points

Public policy worldwide recommends the use of inactivated influenza vaccines to prevent seasonal outbreaks

Because viral circulation and antigenic match vary each year and non-randomised studies predominate, **systematic reviews of large datasets from several decades provide the best information on vaccine performance**

Evidence from systematic reviews shows that inactivated vaccines have little or no effect on the effects measured

Most studies are of poor methodological quality and the impact of confounders is high

Little comparative evidence exists on the safety of these vaccines

Reasons for the current gap between policy and evidence are unclear, but given the huge resources involved, a re-evaluation should be urgently undertaken"

In addition, Dr. Jefferson's "[e]vidence from systematic reviews shows that inactivated vaccines have little or no effect on the effects measured" [2] clearly supports the findings by Geier *et al* [1].

Hopefully, *after studying Dr. Jefferson's paper and re reading the paper by Geier et al.*, the writer of this letter will understand that there is no scientifically sound proof that any of the current influenza vaccines are truly effective in the U.S population as a whole.

"Thank you for taking the time to express your concerns and perspective on this important personal and public health issue. I hope my responses addressed some, if not all, of your expressed concerns.

Sincerely,

(signature of Eddy A. Bresnitz)

Eddy A. Bresnitz, M.D., M.S.

Deputy Commissioner/State Epidemiologist"

First, this reviewer sincerely thanks the writer for recognizing:

- Each of this reviewer's concerns are an "*important personal and public health issue*" and
- The time spent by this reviewer in expressing his "*concerns and perspective on this important personal and public health issue*" in the letter Governor Corzine received.

Second, this reviewer hopes that this review of the writer's letter has clarified the issues and, *to some degree*, helped both the writer and any other reader to understand the difference between sound science and "*current policies, practices, and recommendations of such notable professional organizations*" when it comes to the ineffectiveness for all of the current influenza vaccines (since a recent paper reported the inactivated-influenza vaccines were more effective than the live-virus influenza vaccines) and the current lack of the requisite toxicological proof of safety for any of the current Thimerosal-containing influenza vaccines.

In addition, though some of his colleagues and fellow researchers are physicians, this reviewer is:

- ❖ A Ph.D. Analytical Chemist and
- ❖ A thorough analytical researcher in the area of mercury poisoning by:
 - Thimerosal, a highly toxic mercury compound used in vaccines and other drug products as a manufacturing sterilant and/or preservative, and
 - Other mercury compounds that are or, *in the case of Calomel*, have been used in medicine without, *as those in the government and healthcare establishment, who have testified on this issue before Congress, have repeatedly admitted*, the requisite toxicological proofs of safety.²

Finally, to aid you in your study, this reviewer has attached copies from ".pdf" files for the cited Geier *et al.*, Jefferson, and Parran *et al.* articles.

² As all who study the safety of medicines know, only scientifically sound and appropriate toxicity studies can prove drug safety. At best, epidemiological studies can only estimate the probability, at some confidence level, that there is a possible causal link between some that level of exposure to a toxic substance (e.g., micrograms of Thimerosal injected) and the degree of risk of various negative clinical disease outcomes (e.g., Alzheimer's Disease, asthma, diabetes, leukemia, MS, neurodevelopmental disorders including autism, obesity, seizures, and tics).