

Facility Automation Management Engineering Systems (FAME Systems)

33A HOFFMAN AVENUE, LAKE HIAWATHA, NJ 07034-1922

Monday, 8 April 2013

Introduction

Following this introduction page are this commenter's remarks on an article posted with the titled, "Additional CDC data rule out vaccine-autism link", with a "commentary" titled, "**PERSPECTIVE**", by Dr. Paul A. Offit, which was downloaded from the Internet.

This commenter downloaded this Internet article from: <http://www.healio.com/pediatrics/vaccine-preventable-diseases/news/online/%7B80319B22-F42D-4F7D-AD6E-09E9C83FFDAB%7D/Additional-CDC-data-rule-out-vaccine-autism-link> on April 4, 2013.

FAIR USE NOTICE: The following review may contain quotations from copyrighted (©) material the use of which has not been specifically authorized by the copyright owner. Such material is made available for educational purposes, to advance reader's understanding of human rights, democracy, scientific, moral, ethical, social justice and other issues. It is thought that the quoted statements in such documents are a 'fair use' of this copyrighted material as provided for in Title 17 U.S.C. section 107 of the US intellectual property law. This material is being distributed without profit.

This analysis, titled "Comments about 13 April 2012 article posted on www.helio.com titled, "Additional CDC data rule out vaccine-autism link" with a "commentary" titled, "**PERSPECTIVE**", by Dr. Paul A. Offit", begins on the next page.

Introductory Remarks

First, when the comments address some specific sentence, clause, phrase, or word within the original article or Dr. Offit's comments, it is quoted in an *italicized "Times New Roman"* font.

Second, this commenter's remarks are written in a "Tahoma" font.

Third, when quoting or referencing other sources, the text is in an "Arial Narrow" font.

Finally, should anyone find any significant factual error in this review for which they have independent^[a], scientifically sound, peer-reviewed published substantiating documents, please submit that information to this reviewer so that he can improve his understanding of factual reality and, where appropriate, revise his views and this analysis.

Respectfully,

<S>

Paul G. King, PhD

Founder, **FAME Systems**

paulgkingphd@gmail.com

Tel. 1-973-997-1321, after 21:00 Eastern Time

[To whom all responses should be directed]

^[a] To qualify as an independent document, the study should be published by researchers who have no direct or indirect conflicts of interest from their ties to either those commercial entities who profit from the sale of vaccines or those entities, academic, commercial or governmental, who directly or indirectly, actively promote vaccines, the development of vaccines, and/or inoculation programs using vaccines.

Comments about 13 April 2012 article posted on www.helio.com titled, "Additional CDC data rule out vaccine-autism link", with a "commentary", titled, "PERSPECTIVE**", by Dr. Paul A. Offit**

by Paul G. King, PhD[1]

Lacking all of the raw data, study designs, models, exclusion criteria and statistical programs used, neither I nor other independent researchers can truly review the underlying article in *J. Pediatrics* [DeStefano F. *J Pediatr.* 2013;doi:10.1016/j.jpeds.2013.02.001] on which this posting is based.

Unfortunately, as other studies have shown, there are other differences[2] in vaccines that may have combined to give the reported "no difference" finding.

Further, because the Vaccine Safety Datalink (VSD) database is a MCOs' (Managed Care Organizations') treatment records database and the MCOs collaborating to provide data to the VSD do not have sufficient, if any, totally non-vaccinated children to use as true controls, any study that relies upon the VSD in this crude manner is problematic because almost all of the children are getting similar vaccination profiles.

Moreover, though the controls did not have an "autism" diagnosis, they apparently did have some of the symptoms used to diagnose "autism" – thus, the cases and controls both included children with symptoms indicative of neurodevelopmental, developmental and/or behavioral deficits.

As another individual put it, suppose you have a group of smokers that developed cancer and a group of smokers that did not develop cancer.

Both study cohorts were chosen so that they had the "same" exposure to cigarette smoke.

Does such a study prove smoking is not harmful?

No, this illustration and the cited DeStefano et al. (2013) study are but examples of studies with seriously flawed methodology.

Using Dr. Offit's game analogy, all this study is is another "stacked deck" card game where the desired outcome predetermined the deck to be used (the "hidden from public review" VSD database) and the cards from that deck (groups of fully vaccinated children having one of two diagnostic labels, "autism" and "not autism") that were to be dealt.

Thus, this paper is but another in a long line of biased studies where: **a)** all of the pertinent records are not open for independent review; **b)** the "autism link" study design is deliberately rigged to find no link between a diagnostic label "autism"; and **c)** in this instance, each group received the same number of antigens over several periods of time.

As one blatant example of a similarly distorted vaccination study, one need only look at the 2003 paper[3] in *Pediatrics*, where the published paper's Abstract reported, "The discontinuation of thimerosal-containing vaccines in Denmark in 1992 was followed by an increase in the incidence of autism", but an internal redacted e-mail between some of the authors and the CDC's liaison person, *speaking about the incidence and prevalence of autism after Thimerosal-preserved vaccines were completely removed from the Denmark program*, reported, "But the incidence and prevalence are still decreasing in 2001"[4].

Further, this 2013 paper is at odds with the reality that Merck's adding 1 antigen, the live varicella virus, to its M-M-R® II MMR vaccine to make its MMRV (Proquad®) vaccine markedly increased the actual post-approval adverse-events over the adverse events reported for giving the M-M-R® II and the Merck Varivax® (varicella) [MMR+V] in different locations on the same day to the point that the CDC's Advisory Committee on Immunization Practice (ACIP) withdrew[5] its previous recommendation to give the MMRV vaccine at 12 to 15 months[6].

Moreover, had the CDC researchers truly wanted to see the effect, *if any*, between the incidence of “autism” in fully vaccinated children and the incidence of “autism” in children who received a significant, lesser number of vaccines, then they would, at multiple age ranges, have compared a group of initially healthy, never-vaccinated, randomly chosen children [the “controls”] in, for example, Dr. Eisenstein's Chicago practice[7] with a matched group of vaccinated children in the MCOs' VSD data files who have an “autism” diagnosis [the “cases”].

If the rates for “autism” were, at every time interval, not significantly different, then the CDC could have validly stated that the vaccinations had no effect on the risk of an “autism” diagnosis.

Further, how can an author of a study, Dr. DeStefano, a federal employee whose job depends upon the continuing existence of vaccination programs or a commentator, like Dr. Offit[8], who has been enriched through development of a rotavirus vaccine report “*no relevant financial disclosures*” on a topic that specifically encourages health care professionals and the parents that they serve to increase childhood vaccination coverage?

Finally, Dr. Offit's “*First, Andrew Wakefield and coworkers claimed that the combination measles-mumps-rubella (MMR; M-M-R II, Merck) vaccine caused autism*” knowingly distorts reality because the first claim[9], *which has not been contested*, about a possible link between a vaccine and Kanner autism was published in 1976, more than two decades before the Wakefield A, et al. (1998) paper, a case study series that actually reported a possible link between a “new” childhood bowel disease found in some children with a diagnosis of pervasive development disorder [PDD] and the MMR vaccine doses previously administered in childhood[10].

Endnotes

- [1] Dr. King is a PhD Analytical Chemist, who does mostly uncompensated research into the safety and effectiveness of the vaccines approved by the U.S. FDA, and the effectiveness and cost-effectiveness of the current vaccination programs recommended by the U.S. CDC. [See, <http://dr-king.com>.]
- [2] Those differences include differences in the levels of antigens, the identities and levels of the other “inactive” components [e.g., surfactants], as well as the differences, if any, in the adjuvants and adjuvant levels and/or, for those vaccines that may contain Thimerosal [influenza] the differences in its levels of Thimerosal exposure.
- [3] Madsen KM, Lauritsen MB, Pedersen CB, Thorsen P, Plesner A-M, Andersen PH, Mortensen PB. Thimerosal and the Occurrence of Autism: Negative Ecological Evidence From Danish Population-Based Data. *Pediatrics* 2003; **112**: 604-606.
- [4] http://dr-king.com/docs/20120331_FalsusInUnoFalsusInOmnibusAThimerosalpreservedVaccineConundrum_b.pdf, “Inclusion 1” (last page).
- [5] “Shortly after completion of this study, ACIP withdrew its recommendation to administer MMRV preferentially as the first dose of MMR-containing vaccine in young children as a result of an increased incidence of febrile seizures following administration of MMRV compared with MMR+V.” <http://www.ajmc.com/articles/Impact-of-MMRV-Combination-Vaccine-on-Childhood-Vaccination-Compliance> and “□ MMRV was associated with a 2-fold increase in risk of fever and febrile seizures 7-10 days after MMRV compared with separately administered MMR+V among 12-23 month olds.” “• CDC recommended MMR+V unless parent/guardian prefers MMRV”, <http://www.healthandwelfare.idaho.gov/Portals/0/Health/Immunizations/2012-04.NIIW.Vaccine%20safety.pdf>.
- [6] http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5903a1.htm?s_cid=rr5903a1_e, Use of Combination Measles, Mumps, Rubella, and Varicella Vaccine – Recommendations of the Advisory Committee on Immunization Practices (ACIP), Recommendations and Reports, *MMWR* 2010 May 7; **59**(RR03):1-12.
- [7] Personal communication from Dr. Eisenstein to the listeners to the “Know Your Rights Hour” program <http://www.blogtalkradio.com> that his records show only about 1 instance of an autism diagnosis in a population of more than 50,000 never-vaccinated children.
- [8] <http://www.chop.edu/news/chop-vaccine-researcher-elected-to-institute-of-medicine.html>; <http://www.chop.edu/doctors/offit-paul-a.html>; and http://en.wikipedia.org/wiki/Paul_Offit.
- [9] Eggers C. [Autistic syndrome (Kanner) and vaccination against smallpox (author's transl)]. *Klin Padiatr.* 1976 Mar; **188**(2): 172-180, emphasis added:
“Abstract
3-4 weeks following an otherwise uncomplicated first vaccination against smallpox a boy, then aged 15 months and last seen at the age of 5 1/2 years, gradually developed a complete Kanner syndrome. The question whether vaccination and early infantile autism might be connected is being discussed. A causal relationship is considered extremely unlikely. *But vaccination is recognized as having a starter function for the onset of autism*”.
- [10] Wakefield AJ, Murch SH, Linnell AAJ, Casson DM, Malik M, Berelowitz M, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis and pervasive developmental disorder in children. *Lancet.* 1998; **351**: 637-641.