Sound Choice Pharmaceutical Institute July 8, 2014

To Date: No studies refute the link between the use of human fetal manufactured vaccines and autism

(Sea, WA) A recent publication in the journal Pediatrics made news headlines across the US. The paper, authored in part by the Rand Corporation with Maglione as the first author, "Safety of Vaccines Used for Routine Immunization of US Children: A Systematic Review" (1) was touted by the media as debunking once and for all any link between MMR and autism.

However, in the Rand publication, **only ONE study considering the relationship between MMR and autism was actually reviewed**. The manner in which the Maglione Pediatrics paper is written is somewhat misleading, because unless one reads the entire paper one might be led to believe that over 20,000 papers were reviewed, when in fact only 67 papers were reviewed. Those 67 papers were written about MANY different vaccine associated adverse events, and only one paper included in the Pediatrics meta-analysis considered MMR and autism association. That paper, published by Uno in 2012 (2) , looked at children born in Japan between 1984 and 1992 who were vaccinated with an animal manufactured MMR made by Takeda (3) (4).

Thus, it is not surprising that they did not observe an association between MMR and autism when they review studies from Japan because it is only the human fetal manufactured MMR vaccine where we would expect to see a link to autism. The reviewers apparently do not know about animal versus human fetal vaccine manufacturing, and they do not account for this in their meta-analyses.

A similar Australian study also made news headlines this spring. Headlines read: **"**Study of over 1 million children finds no link between MMR vaccine and autism." Unfortunately for the general public and for our children, neither the reporters who carried the study nor the experts who discussed the study seem to have READ the paper critically, or even read the entire paper at all.

Like the RAND study, the authors identified 1,112 studies, but only included 10 in their meta-analysis. Unfortunately, they do not discuss this in their paper, so one must wonder how many publications were excluded from their final report that demonstrated a link between MMR and autism? Of the 10, only six studies had any data regarding MMR and autism.

The largest study included in the Australian meta-analysis, by Madsen et. al. (5), has been controversial since its first publication, and the authors of the Australian paper at least acknowledge that the study had a "moderate risk of bias". One of the senior authors of the Madsen paper, Thorsen, has been indicted for wire fraud and money laundering by a US federal grand jury (http://www.justice.gov/usao/gan/press/2011/04-13-11.html), yet there is no disclosure of this in the Australian paper.

In the 2002 Madsen paper included in the Australian meta-analysis the rate of autistic disorder for children vaccinated between 1991 and 1999 was 0.00061 (269 out of 440,655 children which is 1 child in every 1,638 children). Other studies such as a 2007 publication by Atladóttir (6) looking at similar time periods and extracting data from the same databases used by Madsen et. al. report autism prevalence at 0.0018 for children born between 1990 and 1999 ; 3 times higher than the number in the 2002 Madsen paper. This is a curious anomaly since the same databases and birth years were used in both studies.

It is also curious that the Madsen paper and the Atladóttir paper share some authors, particularly the indicted Thorsen. For the 2002 paper when they want to disprove any link

between MMR and autism, the autism rates they report are suspiciously low, and in the 2007 paper when they want to claim that removal of thimerosal did not reduce autism rates their reported autism rates are 3 times higher than their 2002 paper.

Which paper is correct? The 2007 paper at least is in agreement with other papers published considering the same time frame, and therefore, the 2002 Madsen paper may have missed or excluded a significant number of children with autism.

One of the studies included in the Australian meta-analysis, by Uchiyama et. al. (8), studied children in Yokohama district Japan born between 1976 and 1999. The MMR available in Japan that these children would have been vaccinated with was an animal based MMR made by Takeda (3) (4) . No other MMR vaccines were available in Japan during this time period. Therefore, including this study of an animal based MMR in the Australian met-analysis will certainly skew any results, since we would not expect an animal-based MMR to increase the risk of autism. The inclusion of this study would artificially lower the apparent risk of MMR and autism. In order to consider human fetal manufactured MMR and autism, all Japanese studies must be excluded from the analysis.

Another study included in the Australian meta-analysis compared the age of first MMR immunization for children who developed autism compared to children who did not develop autism (9). ALL children in this study received MMR, so this is not a comparison of children vaccinated with MMR versus children not vaccinated with MMR.

To conclude that MMR is not related to autism merely because not ALL children who are vaccinated with MMR at similar ages develop autism is like concluding that smoking does not contribute to lung cancer because not all smokers develop lung cancer or like concluding that sun exposure does not contribute to skin cancer because not everyone who gets sunburned gets skin cancer. That conclusion is illogical, unscientific and absurd.

These authors DID REPORT in their summary conclusions that vaccination before 36 months of age was "more common" among children with autism, supporting a link between autism and vaccination with human fetal manufactured MMR at an age when rapid brain development is in progress! Isn't it time for DENIAL to stop, and honest study to be undertaken examining the impact of human fetal manufactured vaccines, and the fetal contaminants that are contained in the final product, and autism. If there is a link, then prevention and treatments are within reach.

The prevention solution is so easy : don't use human fetal cells to make vaccines. Alternatives for the MMR and Hepatitis A could be commercially available within months – not years – if the public demanded them. For some of the fetal manufactured vaccines there are already alternatives available in the US, but people cannot choose the alternatives unless the manufacturing processes and contaminants are clearly disclosed, which they are not currently. For those who are already impacted by autism, treatments and cures are needed. If the fetal contaminants are linked to autism, then stem cell therapy becomes a top candidate for treatment of existing disease. The millions of dollars that have been spent to falsely debunk associations between vaccines and autism could already have brought animal manufactured alternatives to the US and could have funded rigorous, controlled stem cell trials for those already affected by autism. Isn't it time to start spending our tax payer dollars more wisely?

1. *Safety of Vaccines Used for Routine Immunization of US Children: A Systematic Review.* **Maglione, MA, Das, L, Raaen, L, Smith, , A, Chari, R, Newberry, S, Shanman, R, Perry, T, Goetz, MB and Gidengil, C.** July 1, 2014, Pediatrics, p. epub.

2. *The combined measles, mumps, and rubella vaccines and the total number of vaccines are not associated with development of autism spectrum disorder: the first case-control study in Asia.* **Uno Y, Uchiyama T, Kurosawa M, Aleksic B, Ozaki N.** 28, Jun 13, 2012, Vaccine. , Vol. 30, pp. 4292-4298.

3. *An epidemiological study on Japanese autism concerning routine childhood immunization history.* **Takahashi H, Suzumura S, Shirakizawa F, Wada N, Tanaka-Taya K, Arai S, Okabe N, Ichikawa H, Sato T.** 3, Jun 2003, Jpn J Infect Dis. , Vol. 56, pp. 114-117.
4. *New Japanese rubella vaccine: comparative trials.* **Best JM, Banatvala JE, Bowen JM.** 5925, Jul 27, 1974, Br Med J. , Vol. 3, pp. 221-224.
5. *A population-based study of measles, mumps, and rubella vaccination and autism.* **Madsen KM, Hviid A, Vestergaard M, Schendel D, Wohlfahrt J, Thorsen P, Olsen J, Melbye M.** 19, Nov 7, 2002, N Engl J Med. , Vol. 347, pp. 1477-1482.
6. *Time trends in reported diagnoses of childhood neuropsychiatric disorders: a Danish cohort study.* **Atladóttir HO, Parner ET, Schendel D, Dalsgaard S, Thomsen PH, Thorsen P.** 2, Feb 2007, Arch Pediatr Adolesc Med. , Vol. 161, pp. 193-198.
7. *MMR-vaccine and regression in autism spectrum disorders: negative results presented from Japan.* **Uchiyama T, Kurosawa M, Inaba Y.** 2, Feb 2007, J Autism Dev Disord. , Vol. 37, pp. 210-217.
8. *Age at first measles-mumps-rubella vaccination in children with autism and school-matched control subjects: a population-based study in metropolitan atlanta.* **DeStefano F, Bhasin TK, Thompson WW, Yeargin-Allsopp M, Boyle C.** 2, Feb 2004, Pediatrics. , Vol. 113, pp. 259-266.
9. *Validity of childhood autism in the Danish Psychiatric Central Register: findings from a cohort sample born 1990-1999.* **Lauritsen MB, Jørgensen M, Madsen KM, Lemcke S, Toft S, Grove J, Schendel DE, Thorsen P.** 2, Feb 2010, J Autism Dev Disord. , Vol. 40, pp. 139-148.