



How trustworthy are vaccine manufacturers?

By Lucija Tomljenovic, PhD

There is a growing number of reports of research misconduct, biased reporting, conflicts of interest, and outright fraudulent activity by pharmaceutical companies who produce the ever growing list of vaccines. This brings into question the accuracy of the vaccine manufacturers' claims of safety and efficacy.

For example **Merck & Co., Inc., the pharmaceutical company who produces the MMR (measles, mumps, and rubella) vaccine is currently accused in the U.S. of fraudulently lying about the efficacy of its mumps vaccine for the purpose of continuing to secure governmental contracts worth \$ millions.**

In 2012, two former Merck virologists, a group of doctors, and direct payers filed two whistleblower lawsuits in the Pennsylvania federal court. Merck's attorneys were unsuccessful in their attempts to block the case from going to trial with U.S. Federal District Judge C. Darnell Jones II, recently clearing the case for trial. Judge Jones ruled the whistleblowers and direct purchasers produced enough evidence to establish that false statements could have helped give Merck a monopoly.

A recent article from Pharma-based website fierce vaccines states:^[1]

*Merck has been the sole manufacturer with an FDA license to produce mumps vaccine since 1967, the news service points out, and **the company has long touted a 95% efficacy rate for the shot.** The drug maker brought in \$621 million on mumps vaccine sales last year, between its MMR2 vaccine and ProQuad, a pediatric combo jab.*

***But rather than using the "gold standard" approach and testing the vaccine against a wild-type mumps virus, Merck tested it against the attenuated virus strain that had created the vaccine in the 1960s--likely overstating the vaccine's effectiveness,** the whistleblowers claim, according to the judge's memorandum. And if Merck "fraudulently misled the government and omitted, concealed, and adulterated material information regarding the efficacy of its mumps vaccine" in violation of the False Claims Act, as they allege, it may have discouraged competition.*

"This decision brings us one step closer to shining a light on Merck's deceptive business practices so that new and more effective vaccines will ultimately be developed in the future," Robins Kaplan Miller & Ciresi lawyer Kellie Lerner said in a statement.

Furthermore, with regard to the studies which allegedly demonstrably show no link between autism and vaccines, it has to be emphasized that once such studies undergo proper expert scrutiny, the "evidence" against the link becomes rather flimsy.

In reviewing the published literature on measles-mumps-rubella (MMR) vaccine (139 studies), the respected Cochrane Collaboration review panel concluded that, **"The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate."** [emphasis added] ^[2]

Moreover, none of the 31 studies that were included in the review met the Cochrane Collaboration's methodological criteria.

More specifically, referring to the 2001 Fombonne and Chakrabarti study ^[3] which was widely regarded by medical health authorities as most *persuasive* in disproving the link between the MMR vaccine and autism, the

Cochrane Collaboration commented the following: "**The number and possible impact of biases in this study was so high that interpretation of the results is impossible.**" [2]

Although the Cochrane Review on the safety of MMR concluded that there was no credible link between MMR vaccination and autism and Crohn's disease, as pointed out earlier, the majority of the studies included in the evaluation were methodologically inadequate.

The question is: **What "credible" evidence can be derived from inadequate and/or methodologically flawed studies?**

How far can one trust vaccine manufacturers who consistently fail to provide scientifically credible evidence of safety and efficacy?

References:

1. Fierce Vaccines. *Lawsuits claiming Merck lied about mumps vaccine efficacy headed to trial.* <http://www.fiercevaccines.com/story/lawsuits-claiming-merck-lied-about-mumps-vaccine-efficacy-headed-trial/2014-09-09>
2. Demicheli, V., et al., *Vaccines for measles, mumps and rubella in children.* Cochrane Database Syst Rev, 2005(4): p. CD004407.
3. Fombonne, E. and S. Chakrabarti, *No evidence for a new variant of measles-mumps-rubella-induced autism.* Pediatrics, 2001. 108(4): p. E58.