



## Is Vaccine Safety Evidence “Rock Solid”?

By Lucija Tomljenovic, PhD

Despite the widespread notion that vaccines are largely safe and serious adverse complications are extremely rare, a close scrutiny of the scientific literature does not support this view. <sup>[1-3]</sup> Indeed, it is often *assumed* that vaccines face a tougher safety standard than most pharmaceutical products.

However, according to the U.S. Food and Drug Administration (FDA) transcript of the 2002 Workshop on non-clinical safety evaluation of preventative vaccines: recent advances and regulatory considerations <sup>[4]</sup>:

*Historically, the non-clinical safety assessment for preventive vaccines has often not included toxicity studies in animal models. This is because vaccines have not been viewed as inherently toxic.*

*In contrast to most drugs and biological products that are predominantly developed to treat ill patients, vaccines primarily are given to large numbers of healthy people, oftentimes predominantly healthy infants and children. **And this places significant emphasis on their safety.** [emphasis added]*

This is a startling admission from an Agency which according to its own mission statement is:

*responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs<sup>[5]</sup>.*

Essentially, what the FDA workshop<sup>[4]</sup> revealed is that not only are vaccines not adequately evaluated for toxicity but also, that the reason for such an oversight rested on a belief rather than scientific evidence.

Moreover, **it is mind-boggling that inadequately tested products on whose safety FDA “places significant emphasis” are actually licensed by the same Agency for mass use.**

Furthermore, erroneous assumptions of safety in the absence of actual experimental data are not only dangerous but have historically hampered serious scrutiny of potential vaccine harms.

For example, in responding to numerous criticisms of their study *Unexplained cases of sudden infant death shortly after hexavalent vaccination* <sup>[6]</sup> Zinka et al. (2006) noted <sup>[7]</sup>:

*(ad 6) The main problem is that vaccination specialists have failed for decades to establish any tests or other criteria to find out if adverse events are linked to vaccinations or not. To our knowledge they did not even try hard—why?!*

*(1) A precise description of the mechanism leading to serious adverse events after hexavalent vaccination is not the task of forensic pathology. This would be the job of vaccination specialists, and actually this job should have been done before phase 1 and phase 2 studies in order to get valid data on the drug safety.*

Similarly, in 2006, Ottaviani et al. <sup>[8]</sup> in reporting a case of a 3-month-old female infant who died shortly after being given a hexavalent vaccination noted that:

- ***This case offers a unique insight into the possible role of hexavalent vaccine in triggering a lethal outcome in a vulnerable baby. Any case of sudden unexpected death occurring perinatally and in infancy, especially soon after a vaccination, should always undergo a full necropsy study according to our guidelines...The identification of a possible pathological basis of reflexogenic mechanisms in sudden, unexpected infant death necessarily requires examination of the brainstem nuclei and of the cardiac conduction system on serial sections.***

The senior author of this study, Professor Luigi Maturri, is a member of the European Medicines Agency (EMA) Pathologists Panel for evaluation of SUD (sudden unexpected death) cases reported for hexavalent vaccines. Although a review by EMA cited in the study concluded that the causes of death following hexavalent vaccination remained unexplained, the following was also emphasized:

*However, to the best of our knowledge, during the mentioned post-mortem investigations, little, if any, attention was paid to examination of the brainstem and the cardiac conduction systems on serial sections, nor was the possibility of a triggering role of the vaccine in the lethal outcome considered [8].*

Some of the likely reasons explaining why causality is rarely established by scientific investigations of vaccine-related serious adverse reactions are:

- it is assumed that vaccines cannot cause such reactions (as implied by the FDA workshop) and;
- studies are not designed to detect them [13]

We have also noted that too often clinical trials of new vaccines conducted by drug companies are fast tracked to licensure but:

- 1) fail to use inactive placebos as controls;
- 2) include too few children in the age group that will be targeted for universal use;
- 3) have inadequate periods of time for follow up of safety and effectiveness;
- 4) only study healthy children without personal or family histories of vaccine reactions, autoimmunity, allergy, neurological disease or concurrent illness (although children with these medical histories are specifically targeted for vaccination post-licensure with very few medical contraindications listed to guide physicians);
- 5) fail to study large numbers of children given the experimental vaccine simultaneously with all other vaccines routinely administered simultaneously to children in that age group;
- 6) dismiss serious health problems, injuries and deaths occurring during the trial as not related to the experimental vaccine without adequate research evidence-based support;
- 7) use questionable surrogate endpoints to demonstrate vaccine effectiveness; and 8) lack adequate post-licensure follow-up [9-12].

**The pushing of poorly tested drugs on most vulnerable populations (i.e., infants and children) can hardly be viewed as ethical.**

**Unfortunately it is a frequent occurrence in medical practice when it comes to vaccination.**

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