



## **Vaccine Safety Has Not Been Established** by Ted Kuntz

What you discover when you examine the vaccine safety literature is that the safety of the vaccine program **has not been established** using sound, rigorous, independent science.

When public officials make the unqualified statement that vaccines are “safe and effective”, they are either mis-informed or are not being openly transparent about the status of vaccine safety science.

Given that vaccines are a product **given to healthy children**, the level of safety testing ought to be even *more* rigorous than is required with all other pharmaceutical products. This is not the case. The safety testing of vaccine products is **less rigorous, incomplete, and protocols appear to have been designed to obscure identifying long-term adverse effects** of vaccines.

A **product can be effective and not safe**. Our history is replete with examples of this:

- **DDT** was effective and not safe
- **Thalidomide** was effective and not safe
- **Asbestos** was effective and not safe
- **Glyphosate** was effective and not safe
- **OxyContin** was effective and not safe
- **Vioxx** was effective and not safe

There is evidence that vaccines can be effective in reducing the incidence and symptoms of infections like measles and mumps, and thus I recognize the desire of government and public health to want to increase the use of vaccine products. There is also evidence that **vaccines can cause harm** as it did to my son and to many other families. My concern is that governments and the medical industry have a **tendency to over-simplify** what is really a very complex matter. This over-simplification and allegiance to an ideology puts us all at risk.

I wish to bring to your attention five issues pertaining to vaccine safety.

### **1. Vaccines Do Not Undergo the Same Level of Safety Testing As Other Medical Products**

Most people, including doctors, nurses, politicians and public health officials, are not aware that vaccines are **not tested for safety** to the same standards required for all other medical products. Vaccines have been classified as ‘*biologics*’ and are exempted from the extensive safety testing required for all drugs.

The result is that **no childhood vaccine product** licensed for use in Canada has been tested for safety using the standards required of all other medical products. In other words, vaccines are not subjected to the

**long-term, double blind, placebo-controlled studies** that are conducted on all other drugs prior to licensing. Instead, vaccines are released to the public with sub-standard safety testing.

The medical industry uses the monitoring of adverse events following vaccination as the primary method to evaluate safety. This means that our children are injected with products whose safety is determined by the amount of injury or death reported after vaccination.

This method to evaluate safety is grossly inadequate given that medical professionals are neither trained to recognize and diagnose vaccine injury, nor are there legal consequences for failing to report vaccine injury. Parents who report adverse events following vaccination are routinely told that adverse events are either normal or merely a “*coincidence*” and could not have been caused by the vaccine.

A 2011 study conducted at **Harvard Pilgrim Hospitals** for Health and Human Services in the US concluded that “*fewer than 1% of vaccine adverse events are reported.*” This means that 99% of vaccine adverse reactions may go unreported and unacknowledged.<sup>1</sup>

## **2. Vaccine products are not evaluated against a neutral placebo**

On examining the vaccine safety science, what an informed parent discovers is that **none of the vaccines on Health Canada’s recommended childhood vaccination schedule** were tested against a neutral placebo. The reason this is so critically important is that without such a comparison study, **no valid claims can be made** about any vaccine’s safety or efficacy, nor the safety of any combination of vaccines. This standard of safety testing is required for all pharmaceutical products . . . **excepting vaccines.**

This fact was recently confirmed by the **Informed Consent Action Network (ICAN)**,<sup>2</sup> which analyzed all the scientific evidence on which the US Department of Health and Human Services rests its claim of vaccine safety. ICAN reviewed *every single study* provided by HHS and which is the basis on which the FDA and by extension Health Canada licenses vaccines. The lack of proper placebo controlled comparator groups for safety-based studies should concern every parent committed to the health and safety of their children.

## **3. Pre-licensure testing period is too short to evaluate long-term safety**

Another concern is the unacceptably short time period for pre-licensing safety testing of vaccines. While pharmaceutical products are tested for safety for *years* prior to licensure, childhood vaccines undergo pre-licensing safety monitoring of **a few days to a maximum of a few weeks.**

This brief pre-licensing monitoring is not long enough to reveal whether vaccines cause autoimmune, neurological or developmental disorders like autism, learning disabilities, attention deficit hyperactivity disorder, life threatening allergies, asthma and other disorders. These disorders will only become apparent after the child is a few years of age.

Safety testing of childhood vaccines is conducted on a small sample, which *may or may not* include infants and children; is not compared against a control group receiving an *inert placebo*; and the period of testing

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<sup>1</sup> <https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system>

<sup>2</sup> <https://icandev.wpengine.com/wp-content/uploads/2019/08/ICAN-Reply.pdf>

ranges from as short as 48 hours to as long as 6 weeks. Here is an example of the duration of safety monitoring for various vaccine products licensed in Canada: <sup>3 4</sup>

<b>Hep B (Merck)</b> - 5 days	<b>Hep B (GSK)</b> - 4 days
<b>DTap</b> - 8 days	<b>MMR</b> - 42 days
<b>Polio</b> - 3 days	<b>Hib</b> - 3 days
<b>Pneumococcus</b> - 7 days	<b>Rotavirus</b> - 8 days
<b>Menningicoccal</b> - 7 days	<b>Influenza</b> - 4 days
<b>COVID-19</b> – available before safety trials completed	

Health Canada claims that it “conducts rigorous scientific review and testing of vaccines to assess their quality, safety, and efficacy before they are approved for use.” I contacted Dr. Teresa Tam, Canada’s Chief Medical Officer in 2018 to request evidence of the vaccine safety testing conducted by Health Canada. To date, Health Canada has **failed to provide** any evidence to support their claim of “rigorous scientific testing before they are approved for use.”

#### 4. The Safety of the Vaccine Program Has Not Been Established

Our public health officials claim that the ‘artificial stimulation of the immune system’ with injected ingredients (vaccination) is “the safest, most effective and best way to protect our children and communities.” This opinion is not, however, supported by robust scientific evidence.

The fact is, we don’t know the safety of the current vaccination program because **the science has not been done** to the level that would support this conclusion. This is not my opinion, but rather the finding of the **Institute of Medicine** (IOM) which found that the safety of the current childhood vaccine schedule **has never been proven** in large, long-term clinical trials. They state:

*“Few studies have attempted more global assessment of entire sequence of immunizations or variations in the overall immunization schedule and categories of health outcomes, and . . . **none has compared entirely unimmunized populations with those fully immunized for the health outcomes of concern to stakeholders.**” <sup>5</sup>*

In 2011, the IOM reviewed 155 health conditions associated with the varicella, tetanus, hepatitis B & MMR vaccines. In 134 cases the IOM deemed there were **too few scientifically sound studies** published in the medical literature to determine whether more serious brain and immune system problems *are or are not caused by the vaccines*, including multiple sclerosis, arthritis, lupus, stroke, SIDS, autism and asthma.

In 2012, the Cochrane collaboration declared: “The design and reporting of safety outcomes in MMR vaccine studies, both pre- and post-marketing, are largely inadequate.” <sup>6</sup>

If you read the vaccine information inserts provided by the manufacturer, and you should, they clearly state that vaccines **have not been tested** for their ability to cause cancer; their ability to damage an organism; their ability to damage genetic information within a cell; their ability to change the genetic information of an organism; their ability to impair fertility; or for long-term adverse reactions.

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<sup>3</sup> <https://www.vaccine101.ca/single-post/2018/02/07/Vaccine-Approval-Is-Fast-Tracked---Part-2>

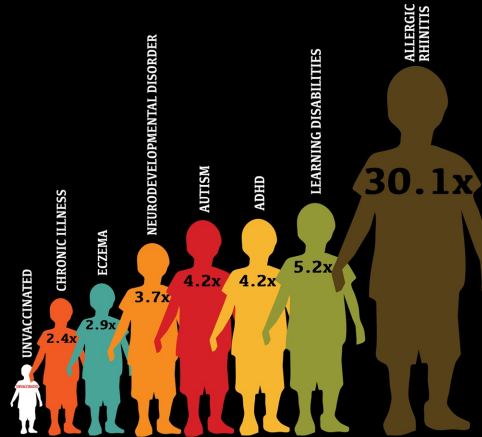
<sup>4</sup> <https://icandev.wpengine.com/wp-content/uploads/2019/08/ICAN-Reply.pdf>

<sup>5</sup> <https://www.ncbi.nlm.nih.gov/books/NBK206940/>

<sup>6</sup> [https://www.cochrane.org/CD004407/ARI\\_using-combined-vaccine-protection-children-against-measles-mumps-and-rubella](https://www.cochrane.org/CD004407/ARI_using-combined-vaccine-protection-children-against-measles-mumps-and-rubella)

## Truth in numbers: who is healthier?

An independent survey comparing the overall health of vaccinated and unvaccinated 6-12 year old children in the U.S. found that vaccinated children have higher odds of developing the following conditions:



<https://info.cnn.com/blog/first-of-its-kind-survey-shows-vaccinated-children-get-sicker>

In 1987, Congress mandated that Health and Human Services continuously improve the safety of vaccine products and report on their progress every two years. In 2018, in response to a Freedom of Information request, HHS admitted that it has **failed to file even a single report** over the 30 year period.

### 5. Legal Immunity Puts All of Us At Risk

Even more disconcerting is that vaccine manufacturers have been granted legal immunity for any harm or deaths caused by their products.

Think about this for a moment. Vaccines are the only product, medical or otherwise, where a manufacturer is not legally responsible for injury and death caused by their products. The result of this legal immunity is that **no one is held accountable** when injuries and deaths occur. Would you accept this lack of accountability with any other product? Why do we permit this lack of accountability with something as important as childhood vaccines? And finally, if vaccines are as safe as claimed, why do vaccine manufacturers need immunity?

A consequence of this legal immunity is that there is **no legal or financial incentive** for the medical industry to make their products safer, even when there is clear evidence that vaccines *can* be made safer.

*We and our children have been and are the victims of a carefully orchestrated, programmed propaganda campaign in which maximum publicity is repeatedly given to rare complications from one of the childhood diseases while actively suppressing the cases of morbidity and death caused by vaccines.*

~ Dr. Thomas Stone, MD