



**Are Vaccines Safe? Let's dive in.**

## ***The National Childhood Vaccine Injury Act of 1986***

Vaccines were not given to Moses on Mount Sinai, they are just products like cars or peanut butter. These manufacturers were making products so unsafe that it wasn't profitable. But, instead of prioritizing safety, they lobbied Congress to give them immunity from product liability, meaning they couldn't be sued for injuring their customers. However, Congress added that they must disclose the safety data in the packet insert.







# Post-Licensure Safety

Federal law says package inserts should include “**Only those adverse events for which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.**” 21 CFR 201.57

A **serious adverse event** according to the FDA is something that is very, very serious.

Medical intervention is required to prevent permanent “impairment of a body function” or “permanent damage to a body structure,” other life threatening events, and death.

# Let's now look at the Hepatitis B packet insert



**Hepatitis B is given  
the first day of life**

This is a list of the Post-Marketing serious adverse events (events that are causal after FDA approval), Section 6.2 of Engerix given to birth to 19 years: herpes zoster, meningitis, thrombocytopenia, anaphylaxis, hypersensitivity syndrome, arthralgia, arthritis, urticaria, erythema multiforme, ecchymoses, erythema nodosum, encephalitis, encephalopathy, multiple sclerosis, neuritis, hypoesthesia, paresthesia, Guillain-Barre syndrome, Bell's palsy, optic neuritis, paralysis, paresis, seizures, syncope transverse myelitis, conjunctivitis, keratitis, earache, tinnitus, vertigo, tachycardia, vasculitis, apnea, bronchospasm, dyspepsia, alopecia, angioedema, eczema, erythema multiforme including Stevens-Johnson syndrome, erythema nodosum, lichen planus, and purpura.

**If all those events happened after approval,  
what did the clinical trials find?**





## 6.1 Clinical trials need:

1. **Power** – how many participants to pick up adverse events
2. **Time** – how long participants are observed
3. **Control** – a group to compare the positive or negative outcomes to

# Clinical Trial Comparison

## Hep B

Patients: 147 infants and  
children up to 10 years

Time: Monitored for 5 days

Placebo: No

[Recombivax Info](#)

## NexGard for Dogs

Patients: 615 dogs

Time: 90 days

Placebo: Yes

[Dog Vaccine Info](#)

## Dengue

Patients: 35,000+

Time: 28 days - 72 months

Placebo: Yes

[Dengvaxia Info](#)

# A placebo is important for a proper comparison

## Do seatbelts and airbags work?

It's easy to see which is safer when presented a side by side comparison of a car crash with and without seatbelts and airbags. But, without knowing the relative risk from a placebo, there isn't a good way to determine if something works or if it instead causes more harm than it is trying to prevent.

If instead the video had shown the heads decapitating in 3% of crashes when people wore seatbelts, that may change the risk analysis of the safety of seatbelts for some people who chose to wear them.





# Let's try a risk analysis without a placebo control

Trial P3T06 was used in both ActHib (HiB) and Pentacel (DTaP). In ActHib, it was the main trial, and in Pentacel it was the control. So, let's use that trial to assess the relative risk to the disease.

## ActHib:

50 serious adverse events out of 1,455 participants (3.4%) or 3,400/100,000

The US averages 50 cases per year or 1.67/100,000

From this trial, you are 2,035x more likely to have a serious adverse event taking ActHib than actually getting HiB. And, of course, not everyone who gets HiB dies.

## Pentacel:

19 serious adverse events out of 484 participants (3.9%) or 3,900/100,000

In 2019, the CDC reported the US had 6,121 cases of children under 6 years old. That's 204/100,000. Of those 204 cases, there were 7 deaths or .23/100,000

What is interesting is that of the known vaccination records, only 443 of those cases were unvaccinated. 1,955 of the cases were partially or completely vaccinated. So, if we extrapolate from the CDC's data, only 9.5% of total cases are unvaccinated, the real risk would be 20/100,000.

Getting vaccinated you assume the totality of the serious adverse events from the trial, 3,900/100k + 184/100k of the vaccinated cases. It doesn't seem like getting this vaccine is a good trade off.

Wait a tick? I thought you couldn't  
get Pertussis if you were vaccinated.





# Consensus Paper:

The leading pertussis experts in the world all agree, DTaP does not prevent transmission of infection.

"aPVs [pertussis vaccine]...cannot avoid infection and transmission...aPV pertussis vaccines do not prevent colonization. Consequently, they do not reduce the circulation of B. Pertussis and do not exert any herd immunity effect."

## From the CDC:

Another study that calculated Tdap vaccine effectiveness among adolescents found that, **within the first year** after vaccination, **effectiveness was 68.8%** (95% CI = 59.7%–75.9%); **by  $\geq 4$  years** after vaccination, vaccine **effectiveness was 8.9%** (95% CI = -30.6%–36.4%)



Now it makes sense why in the 2019 CDC report that so many more vaccinated kids reported pertussis.

\*DTaP is the full dose used in infants. Tdap is a smaller dose "a booster" given to kids 6 and older. Both have the pertussis vaccine, which is what is at issue.

**Reported DTaP Vaccine Status of Children with Pertussis,  
Ages 6 months through 6 years**

Age	Vaccine History Unknown	Unvaccinated	Undervaccinated (1-2 doses)	Completed Primary DTaP Series (3+ doses)	Total
	No. (%)	No. (%)	No. (%)	No. (%)	No.
6-11 mo	399 (50.8)	70 (8.9)	97 (12.4)	219 (27.9)	785
1-4 yrs	1417 (49.5)	297 (10.4)	103 (3.6)	1048 (36.6)	2865
5-6 yrs	460 (44.9)	76 (7.4)	34 (3.3)	454 (44.3)	1024
<b>Total*</b>	<b>2276 (48.7)</b>	<b>443 (9.5)</b>	<b>234 (5.0)</b>	<b>1721 (36.8)</b>	<b>4674</b>



Does the vaccines not causing autism  
hold water?

The CDC and HRSA paid the Institute of Medicine to review what they said were the **158 most common serious injuries claimed from vaccines**

## Results:

**18** - the evidence **supported** a causal relationship

**5** - the evidence **rejected** a causal relationship

**135** - the evidence was **insufficient** to reach a conclusion

Wait a minute. 135 commonly claimed serious injuries caused by vaccines, they say they don't know?! No one has done the studies?

Is somebody lying? Someone has to be lying.

[Read the book](#)

# Adverse Effects of Vaccines

## Evidence and Causality



Vaccination

Febrile Seizures

Guillain-Barre  
Syndrome

Multiple  
Vaccinations at  
Once

## Vaccines do not cause autism.

Some people have had concerns that ASD might be linked to the vaccines children receive, but studies have shown that there is no link between receiving vaccines and developing ASD. The National Academy of Medicine, formerly known as Institute of Medicine, reviewed the safety of 8 vaccines to children and adults. The review found that with rare exceptions, these vaccines are very safe.

**Source:** [Adverse Effects of Vaccines: Evidence and Causality \[Institute of Medicine. 2012\]](#) 

It says on the [CDC website](#) that vaccines do not cause autism. But, like any good scientist, they site a source. What does the source say?

Source

If they are lying about the association of autism and pertussis, what else are they lying about?

545 (574 of 895) Automatic Zoom

## AUTISM

### Epidemiologic Evidence

The committee reviewed one study to evaluate the risk of autism after the administration of DTaP vaccine. This one study (Geier and Geier, 2004) was not considered in the weight of epidemiologic evidence because it provided data from a passive surveillance system and lacked an unvaccinated comparison population.

### *Weight of Epidemiologic Evidence*

*The epidemiologic evidence is insufficient or absent to assess an association between diphtheria toxoid-, tetanus toxoid-, or acellular pertussis-containing vaccine and autism.*

The headline on the CDC webpage says it does not cause autism, but the source they site says the “evidence is **insufficient or absent** to assess an association between” the pertussis vaccine and autism.

# Is it safe?

1. The CDC's own data contradicts the advertised effectiveness of many of the vaccines
2. The CDC's own data contradicts the safety of many of the vaccines
3. Many FDA approved vaccines have less robust clinical trials than vaccines for dogs

**This is what informed consent is. It is your decision.**



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