"Vaccines Are Safe And Effective" . . .

so why should anyone be concerned about safety?

https://dickatlee.com/vaccines/maine/vaccine_safety_problems_da.html (also PDF)

version: 14 April 2019

A. History and Process

1. **Early lawsuits** — By the mid-1980s, vaccine manufacturers were being so heavily sued for damages caused by their vaccines (especially the DPT) that they told the federal government that without indemnity from damages they would cease producing vaccines.
2. **National Childhood Vaccine Injury Act** (NCVIA, 1986) — The resulting law immunized from legal liability for damages both the manufacturers and those who give the vaccines. Their liability was replaced with the National Vaccine Injury Compensation Program (NVICP, or "Vaccine Court" — section E, below), under which injured parties were to sue the Secretary of Health and Human Services (HHS).
3. **Supreme Court 2011: Bruesewitz** — removed liability related to design defects, and eliminated availability of state lawsuits in the aftermath of a loss in Vaccine Court.
4. **Incentives: absence of liability = removal of incentive to improve safety** — the fact that removing liability from manufacturers would remove any incentive on their part for vaccine safety was clearly recognized at the time. Unlike the industry's other drugs, vaccines were now characterized by

   a. **no legal costs**;
   b. **no necessity of advertising**;
   c. **a potential captive audience of tens of millions of customers**, guaranteed, once mandates appeared;

   The industry has often explicitly acknowledged this financial bonanza as being where its future lies: not drugs, but vaccines — more of them (now over 270 in the pipeline) and faster development/approval. Safety was no longer part of their equation.
5. **HHS responsibility for safety abrogated** — To address the loss of safety incentives, the NCVIA explicitly required HHS to (a) actively pursue improving vaccine safety and to (b) report to Congress on its efforts every two years. However, a 2018 lawsuit forced HHS to acknowledge that **it had never done either of these**, over the entire 30+ year span since the law took effect.
6. **The four vaccine post-development steps** — Each is accompanied by conflicts of interest and/or perverse incentives:

   a. **FDA approval** after supposed testing for safety and efficacy, which then permits marketing
   b. **CDC's ACIP** (section C3, below) **adding it to the vaccine schedule**. This **activates liability immunity**. It is also an implicit suggestion to states to adopt a requirement, and promotes media pressure. The resulting financial bonanza can amount to over a billion dollars in a single year.
   c. **Administration** by doctors and healthcare-provider organizations and pharmacies
   d. **Injury/death redress** sought from the Vaccine "Court" (section E, below)

7. **Conflicts of interest and perverse incentives for doctors/providers** — taking these first, dealing with the FDA and CDC below:
   a. **Doctors/nurses** — who lack detailed knowledge about vaccine efficacy and adverse reactions
      1. **Payments in kind** from industry (drug samples, dinners, "educational" materials)
      2. **Hidden incentives** from healthcare-providing organizations and insurers in the form of higher reimbursement rates for practices that are up-to-schedule
      3. **Direct subsidies** to medical practices from the government or insurance companies depend on the percentage of the practice's patients that are fully up-to-schedule
   b. **Hospitals** — in many years, federal reimbursement rates depend on how fully patients and staff are flu- and pneumonia-inoculated during their stays
   c. **Insurance companies** — government rating of the up-to-schedule status of the doctors they insure affects their financial relationship with the government

B. The FDA

1. **The regulator** — Vaccines cannot be sold until approved by the Vaccines and Related Biological Products Advisory Committee (VRBPAC)

2. **FDA regulatory-capture corruption**
   a. VRBPAC has a long-standing reputation for serious conflict-of-interest and rotating-door relationships of its members with the pharmaceutical industry.
   b. Numerous instances have been revealed of the FDA withholding from the public serious safety issues that show up in safety trials, until too many deaths occur.
   c. Sometimes the manufacturers withhold from the FDA data which indicates lack of safety.

3. **Vaccines ≠ Drugs** — VRBPAC's name exemplifies the problem: the FDA considers vaccines "biological products," distinct from drugs, and thus their safety testing does not require the rigor demanded of pharmaceutical drug testing.

4. **No Effective Safety Testing** — Vaccine safety testing violates the gold-standard "double-blind placebo-controlled" protocol of scientific research:

   a. **"Fast Track" short term testing** — Instead of years, testing often lasts only days, in at least one case only hours, despite the fact that research uncovering the mechanisms of vaccine-constituent effects on the body is revealing the existence of inherent biological latency (delays) in the appearance of adverse effects — often weeks, months, or years.
   b. **No inert placebo** — Vaccine safety tests submitted to the FDA have almost never used an inert placebo (saline injection). Instead, what is used is either an earlier "approved" vaccine or the vaccine's *adjuvant* (section F1 below: used to provoke the immune system to respond), neither of which has ever itself been tested against an inert placebo. Use of such "fauxcebos" is scientifically indefensible, in that it is virtually guaranteed to hide any safety problems in the vaccine being tested.
   c. **Never an inert placebo** — In 2016 the research study guidelines of the World Health Organization (WHO) were changed to **explicitly reject inert placebos**: "study participants in the control group must receive an established effective intervention" — i.e., another approved vaccine. Under this guideline, any study following the gold-standard rule of scientific research would be automatically considered invalid.

d. **Inappropriate test subjects** — Generally, only healthy children are enrolled in these tests, yet in actual practice the vaccine is recommended for — and in mandatory situations given to — all children, who have never been tested.
e. **Removal of problem subjects** — Subjects drop out: some for inconvenience, some who have side effects, some die. Of these latter two cases, the report often simply says the researchers determined the events were "not due to the vaccine," while citing no evidence.
f. **No synergy testing** — The CDC's vaccine schedule calls for several vaccines to be given during one visit. Yet safety testing of vaccines has not included seeing how they interact with other vaccines, and there has never been a human study on the effects of the whole vaccine schedule, nor of multivalent (more than one antigen) vaccines.
g. **No carcinogenicity nor multigenerational safety testing** has been done on vaccines, at least in recent years.

C. The CDC

1. **Conflicted mission** — The CDC is tasked with both promoting vaccines and deciding whether those vaccines should go/stay on its schedule, two inherently conflicting roles. It spends about $4 billion a year purchasing vaccines which it gives to vaccine dispensers. Any evidence leading to removal of a vaccine from the schedule would leave the CDC with a chunk of unusable inventory.

2. G**eneral conflicts of interest** — The CDC's immunization section has been found by four different government investigations to be rife with both conflicts of interest and failure of individuals to declare such conflicts.

3. **The Advisory Committee on Immunization Practices (ACIP)** —
   a. **Role** — ACIP meets four times a year to decide which of the vaccines that have applied to be on the schedule should be added to it, resulting in $ billions in profit for the applicant.
   b. **Conflict-of-interest waivers** — The CDC routinely grants conflict-of-interest waivers to ACIP members, various of whom have notoriously voted to add to the CDC schedule vaccines in which they had a direct interest (even patents), upon which they then made tens of millions of dollars.
   c. **Incompetence** — ACIP meetings are public, with online videos available. Now that members of the public are attending these meetings and focusing attention on them, the lack of adherence to scientific reasoning — and failure to acknowledge data or lack thereof — in many decisions has been remarkable, even sunning.

4. **Research fraud** — examples of the CDC covering up the link between vaccines and autism by means of fraudulent research:
   a. **Verstraeten study** on neurological damage from thimerosal (ethyl mercury) — continually altered data until the 11-fold risk disappeared.
   b. **DeStefano study** on the MMR and autism — destroyed data and altered protocols to hide a strong autism link with black boys, and also with kids having non-mental-retardation autism (which is most of them), as revealed by the main researcher in the documentary *Vaxxed*.
   c. **Madsen study** on neurological damage from thimerosal — Paul Thorsen, the primary researcher, designed the study to hide the connection; he is now HHS's most-wanted fugitive, for embezzlement and other crimes.

5. **Failure to study safety** — The 1986 NCVIA tasked the Institute of Medicine with issuing reports on vaccine injury. In each of the IOM reports on injury causality, the IOM has decried the lack of research that would clarify where safety issues need to be resolved. The following is the list of the IOM's conclusions on the causality (or not) of significantly-frequently reported adverse events for the vaccine(s) being considered:
   a. 1991 — vaccine = DTP →
      result: 6 causal, 4 non-causal, *12 insufficient research to judge*
   b. 1994 — vaccines = diptheria, tetanus, measles, mumps, polio, hepatitis-b, hib →
      result: 12 causal, 4 non-causal, *38 insufficient research to judge*
      (also insufficient to judge risks of multi-antigen vaccine)
   c. 2011 — vaccines = varicella, hepatitis-b, tetanus, measles, mumps, rubella →
      result: 18 causal, 5 non-causal, ***135** insufficient research to judge*
   d. In 1994 —and in each subsequent report — the IOM called for the CDC to research which children are at risk of vaccine injury. As of the 2011 report, the CDC had failed to do so.

D. Lack of Effective Post-Marketing Safety Follow-up

1. **VAERS** — The CDC's **Vaccine Adverse Events Reporting System**
   a. A **"passive" system** that depends on doctors (or patients) reporting adverse events.
   b. Most doctors surveyed are **unaware of the system**, and thus don't use it.
   c. Most doctors **do not know how to recognize a vaccine adverse event**, and when presented with one — even one acknowledged in HHS's Vaccine Injury Table (E5, below) or on the manufacturers' package inserts — they generally deny it is vaccine connected.
   d. As a result, an HHS-sponsored Harvard study found that only **about 1% of adverse events are entered in VAERS**
   e. Despite this, each year around about 11,000 reports are received:10-15% involve hospitalization, permanent disability or are considered life-threatening, about 2% involve deaths.
   f. An HHS sponsored program to try **automating VAERS reporting** succeeded in its pilot, at which point the CDC suddenly cut off communications with the developers, killing the program.

2. **VSD** — The CDC's **Vaccine Safety Datalink**
   a. A database of all the health-related information of millions of members of several HMOs.
   b. It's ideal for doing studies of both vaccine safety and vaccine effects on overall health.
   c. However, the CDC **severely restricts researchers' access** to the data, and
   d. the CDC **refuses to do the ultimate vaccinated-vs-unvaccinated study** that Congress has called for it to do, for which the VSD would be ideal.

3. **World Health Organization** — In July 2018 the WHO proposed revising its guidelines for classifying Adverse Events Following Immunization (AEFI):
   a. **Only reactions occurring during initial trials** can be considered vaccine-related, thus denying the known biological mechanisms of damage that involve latency
   b. **If any another explanation is possible, an event is defined as not vaccine-related**, though many adverse events and deaths are exacerbations of an existing problem that, by this definition, constitutes that "other explanation."
   c. It should be noted that internal WHO presentations are available in which its Third World

vaccine program is described as a "business," with significant employment security.

E. The Vaccine "Court"
(National Vaccine Injury Compensation Program: NVICP)

1. Set up by the 1986 NCVI Act as a **replacement for industry liability**
2. **Victims (or their families) sue the HHS Secretary**, who is defended by the Dept. of Justice; obvious conflict of interest, since HHS is supposed to promote the use of vaccine safety, and yet any admission of lack of safety will go against them in "court."
3. NCVIA-stated intent is a **non-adversarial process** to compensate "quickly," "easily," and "generously;" in practice has proved to be exactly the opposite
4. Separate system, unlike civil courts: **no jury, and vitally important: no discovery**
5. **Vaccine Injury Table**
   (https://www.hrsa.gov/sites/default/files/vaccinecompensation/vaccineinjurytable.pdf)
   If injury/death is on HRSA's official "list" of adverse events for the given vaccine, the government is not supposed to contest the claim. But if not on the table, the **victim must prove causation**, which is virtually impossible without discovery from the manufacturer.
6. **Statute of limitations for filing a claim is short** — most people have never heard of the "court," or don't find out about the link with the vaccine until too late.
7. Only about **a third of cases are settled favorably**.
8. And yet, so far, **over $4 billion** has been paid out in restitution.
9. **Omnibus Autism Proceeding** — in 2007, with 5000 autism claimants, an agreement was reached to try 7 cases. If in any one of these autism cases was found to have been caused by a vaccine, all 5000 would be compensated. DoJ lawyers concealed and misstated the statements of their main medical witness, who had acknowledged to them the autism possibility, and as a result, all but one of the 5000 cases were dismissed. The one exception was settled out of court with a permanent gag order.
10. **Loss of access to state courts** — Prior to 2011, losing in the NVICP permitted going next to civilian courts. This option was removed by the 2011 Bruesewitz Supreme Court decision.

F. The Problem of Vaccine Excipients: a few examples
(Excipients: the other contents of vaccines beyond the targeting antigen)
https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf

1. **Adjuvants** — the substances used to force the immune system to respond to the vaccine, without which the vaccine wouldn't work, particularly in an infant's dialed-back immune system.
   Example: ***aluminum***
   a. **The go-to adjuvant** — used for decades, and grandfathered in as presumed safe, but never tested, and now in a nanoparticle form of aluminum hydroxyphosphate sulfate.
   b. **Bio-kinetics** — ingested or intravenous aluminum is very quickly excreted, but injected aluminum stays in the body for long periods, sometimes many years.
   c. **Potent neurotoxin**
   d. **Carried to the brain** — recent research shows that macrophages arrive at the injection site, ingest the aluminum particles, and carry them all over the body, but particularly to the brain, where, with macrophages not designed to digest metals, they stay indefinitely, creating brain

inflammation.

e. **Heavy load** — the aluminum load from the CDC schedule is far beyond that considered "safe" by the FDA.

2. **Preservatives**
   Example: ***thimerosal***
   a. **50 times more toxic to neurons than the methyl mercury** we all avoid in fish, and injected directly rather than eaten.
   b. **Removed from most vaccines** after the CDC discovered (but hid) significant neurodegenerative effects, but existing stocks were allowed to be exhausted over several years.
   c. **Still in the multi-dose vial of flu vaccine**, which tends to be less expensive for the dispenser, and can deliver a major dose of mercury if not shaken each time (about which few are aware).
   d. CDC-sponsored research published recently indicated a **significant increase in miscarriages among pregnant women receiving a flu shot;** CDC tried to distance itself from this result.
3. **Attenuators** — chemicals intended to weaken virulent viruses, such as formaldehyde, a known carcinogen.
4. **Emulsifiers** — e.g., polysorbates, known to facilitate crossing of the blood-brain barrier
5. **Human DNA**
   a. From (aborted) embryonic cell lines used in the creation/growing of vaccines
   b. Obviously a problem for some from a religious standpoint.
   c. CDC dismiss health concerns, since the DNA is in small broken fragments, but research has demonstrated that just such fragments can incorporate into the recipients DNA, and some of it is in a configuration that can't be broken down by the usual enzymes.
6. **Undocumented non-excipient contaminants** — a wide variety of metals and fragments presumably resulting from the manufacturing process and poor quality control.

G. The Broader Issues

1. **Informed consent —** sufficient information to make possible an informed decision
   a. Both the **Nuremburg Code** and the **United Nations Universal Declaration on Bioethics and Human Rights** — to both of which the U.S. is a signatory — specify the necessity of informed consent for medical treatment based on adequate information.
   b. **Requirement of Consent** — violated by
      1. **Mandatory vaccination laws** — elimination of exemptions
      2. **Prerequisite for receipt of public services** (a civil rights issue)
      3. **Child Protective Services** threats/actions to remove children (and forcibly vaccinate them)
   c. **Inadequate information**
      1. **Doctors are untrained** and uninformed/unaware of the necessary information.
      2. **CDC handouts** don't provide adequate information.
      3. **Vaccine package inserts**
         a. Never shown to patients
         b. Doctors don't have time to study what's on them — excipient list or known adverse events

c. Information requirements are gradually being removed — e.g. the mathematical risk of each of the listed adverse effects.

2. **The over-arching problem**
   a. **One size fits all** — Vaccine mandates contradict basic tenets of medical science — e.g.,
      1. **Dose** must be appropriate to size
      2. **Contraindicatio**n situations must be known and honored.
   b. **Risk-benefit** — The framework essential for determining the appropriateness of each vaccine (for society and each individual's biological state). Examples:
      1. The recently-approved **Japanese encephalitis** vaccine has serious side effects, and will cost society huge sums of money, and yet in the last 50 years only 25 people have gotten (not even died from) the disease.
      2. The **Hepatitis-B** vaccine (to prevent a disease only obtained from promiscuous sex and drug needles) involves serious brain inflammation risks, and yet is given immediately after birth. It might be appropriate for children of infected mothers, but mothers are almost never screened.
      3. One of the foremost proponents of vaccines in the Third World, Dr. Peter Aaby, did a retrospective study of his use of the DPT (diphtheria-pertussis-tetanus) vaccine in Africa in the 1980's, and discovered that **10 times as many of the vaccinated children died** from causes unrelated to the vaccine-related diseases as were saved from deaths caused by those diseases, leading to the likely conclusion that their immune systems had been damaged.

3. **In a nutshell** — Attack with a needle is assault; include a vaccine and it's immunization.