How the Pharmaceutical Companies Rig Their Studies To Hide Vaccine Dangers

Excerpt from *Vaccine Danger Quackery and Sin*

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The gold standard for a scientific study is a randomized controlled trial (RCT). In an RCT, the study participants are selected from the targeted population and randomly assigned to either a trial or control group. In a vaccine study, the trial group receives the vaccine being tested for efficacy and safety. The control group is supposed to receive a placebo injection, which should be an inert liquid like saline. The study participants and administrators should be kept blind as to which persons are in each group.

The control group is supposed to give the background base for determining adverse events. The adverse events in the trial group are compared to the adverse events in the control group to determine if the vaccine is safe. But pharmaceutical companies have a problem. They know their vaccines are unsafe and could never pass muster as safe and effective in a properly conducted RCT. They could fudge the data, but the problem with doing that is it's a crime and they don't want to go to jail.

The pharmaceutical companies have figured out a way to rig their vaccine studies to conceal the health dangers of their vaccines and, at the same time, avoid jail. Pharmaceutical companies use a trick to make their dangerous vaccines appear safe. They use a bioactive ingredient, which they falsely call a "placebo," to administer to the control group. The bioactive injections cause adverse events in the control group. This raises the background adverse events so that when the vaccine group is compared to the control group receiving the "placebo," the vaccine group's adverse events do not look so bad by comparison.

That is what Merck did when it tested Gardasil. Gardasil® is a quadrivalent human papillomavirus recombinant vaccine (qHPV) made by Merck, The 2006 Gardasil package insert describes used two placebos used in its testing.[1] One placebo was a inert saline injection given to 320 members of the control group and another was an injection containing amorphous aluminum hydroxyphosphate sulfate (AAHS) given to another 3,470 members of the control group. The total number of persons in the control group was 3,790 (3,470+320=3,790). When the total control group of 3,790 participants was listed they were described as receiving a "placebo." But AAHS cannot be truly described as a placebo. It is a bioactive ingredient that is formulated to cause the body to have an immune response.

A placebo is an innocuous, inactive substance that does not have a physiological effect on the body.[2] Some prefer to call such inert substances dummies.[3] Indeed, Merck acknowledges that a

placebo is supposed to be inert and inactive. “On its website, qHPV vaccine’s sponsor [Merck] defines a placebo as ‘an inactive pill, liquid, or powder that has no treatment value’. This definition is consistent with the decades old notion of placebos as pharmacologically inert substances used to obtain unbiased assessments in experimental research.”[4]

But when Merck sought FDA approval for Gardasil in 2006, it administered AAHS to the control group, while misleadingly calling it a placebo. Furthermore, Merck concealed the independent reporting of the systemic effect of the actual placebo (saline solution) on the control group. This was purposeful because Merck specifically broke out the different localized reactions to the injections site for the “"Aluminum-Containing Placebo" and the saline “placebo.” That is because it was expected that there would likely be some reaction to the injection site for anything injected into the body. But systemic reactions, like fever and nausea, are a whole other matter. Merck lumped the AAHS control group and the saline placebo control group together when reporting systemic reactions. This had the effect of elevating the systemic adverse events caused by the “placebo” injections. Merck reported the combined 3,790 members of the AAHS and saline control group as a single “placebo” group. It made it appear that the systemic adverse event rate of approximately 38.6% for the Gardasil test group was not so bad because the combined 3,790 members of the control group had 35.1% systemic adverse events. Merck purposely obscured that 92% of the control group received AAHS.

Even though 92% of the control group received a bioactive AAHS injection, Merck described the control group throughout the 15-page package insert as receiving a “placebo.” The first mention of an “Aluminum-Containing Placebo” appeared on page 6. But it was only in a chart heading. AAHS is not mentioned again until pages 10 and 12, where it is again listed as an "Aluminum-Containing Placebo," and only in a chart heading. But there was no explanation.

Interestingly, the insert explains: “Each 0.5-mL dose of the [Gardasil] vaccine contains approximately 225 mcg of aluminum (as amorphous aluminum hydroxyphosphate sulfate adjuvant) [AAHS]” among other ingredients. Thus, the test subjects and 92% of the control group were injected with AAHS. When you realize that the purpose of AAHS is to stimulate the immune response and that immune response is the catalyst for adverse events, you get an idea of the trick Merck was pulling. They wanted the control group’s immune system ramped up to have as many adverse events as possible to make the expected adverse events from Gardasil not look so bad by comparison to the “placebo” injected control group.

Once Merck received its 2006 FDA approval for Gardasil it slithered back and rewrote its package insert to explicitly describe the use of AAHS as the “placebo” in the control group.[5] In September 2008, Merck published a new Gardasil package insert that made 68 references to AAHS use in the control group. Suddenly the group of 3,790 people in the control group that was labeled in 2006 as receiving a “Placebo” was now listed as receiving “AAHS control or Saline Placebo.” Merck then explains in the package insert that “AAHS Control = Amorphous Aluminum Hydroxyphosphate Sulfate.” Once they obtained FDA approval and the coast was clear, Merck decided to go back and tidy up its package insert to reflect what was really happening in the trials.

Peter Doshi, Ph.D., is an Associate Professor of Practice, Sciences, and Health Outcomes Research at the University of Maryland School of Pharmacy. He wrote an article with other scientists exposing the fraud of vaccine researchers using bioactive placebos. In particular, he cited the example of the Merck Gardasil study using AAHS with Merck misleadingly calling it a "placebo." Dr. Doshi correctly identifies that practice as an ethical issue. Dr. Doshi describes the problem:

> [T]he efficacy and safety analyses of these five qHPV [Guaradasil] vaccine trials were conducted as if the trials were controlled with inert placebo when they were not. None of the key publications for these trials, which have been used to inform regulatory and health decision making, appear to discuss how AAHS-containing control could affect the interpretation of results.[6]

Doshi was troubled that Merck lied to the trial participants by telling them they would receive an inactive placebo. When in fact they were receiving a bioactive AAHS injection.

> We also consider that the use of the term 'placebo' to describe an active comparator like AAHS inaccurately describes the formulation that the control arm participants received, and constitutes an important error that requires correction. If trial participants were told they could receive 'placebo' (widely defined as referring to an 'inactive' or 'inert' substance) without being informed of all non-inert contents of the control arm injection, this raises ethical questions about trial conduct as well.[7]

Using a bioactive ingredient that is actually one of the adjuvants used in the Gardasil injection renders the study results almost useless. Dr. Doshi explains:

> With respect to adjuvants in vaccines, the FDA has noted that 'adjuvants have their own pharmacologic activity, which may affect both the immunogenicity and the safety of vaccines. Adverse reactions may include local reactions such as pain, swelling, injection site necrosis, and granulomas. Systemic reactions may include nausea, fever, arthritis, as well as potential immunotoxic reactions. Unexpected, rare events may also occur'.[8]

Dr. Doshi opined that the reasons given by Merck for using AAHS in the control arm were not credible. Merck claimed that it wanted to test only the HPV virus-like particles and therefore used the AAHS in the control group. But that appears to be a deceptive cover story that makes no sense. If that was Merck's objective, it could not accomplish it by only using AAHS. Merck should have included all other adjuvants that were in the Gardasil vaccine to inject in the control group. Dr. Doshi explains:

> According to qHPV vaccine's prescribing information, each dose of vaccine contains '9.56 mg of sodium chloride, 0.78 mg of L-histidine, 50 mcg of polysorbate 80, 35 mcg of sodium borate, <7 mcg yeast protein/dose and water', in addition to AAHS and HPV virus-like particles. To test HPV virus-like particles, as the manufacturer

> stated was its intention in using an AAHS control, the control would logically have also included these other ingredients in addition to AAHS.[9]

Finally, Dr. Doshi explains that the study would be irrelevant even if Merck included all other ingredients in the control group injection. To conduct such a study would be scientifically irrational. A vaccine trial aims to assess the safety and efficacy of the vaccine as manufactured and not just one component of the vaccine. That is because there is a synergism between the ingredients in the vaccine, and people are injected with all those ingredients, not just the antigen in the HPV virus-like particles.

> [T]he stated rationale of using AAHS control, to characterise the safety of the HPV virus-like particles, lacks clinical relevance. The clinically relevant question is what are the effects (benefits and harms) of qHPV vaccine—the whole product, not one of its components.[10]

Clearly, the real reason that Merck used AAHS and misleadingly labeled it as a "placebo" in its control group was to ramp up the adverse events in the control group to then show that the Gardasil vaccine was safe compared to the control group receiving a "placebo." Those reading the study will not realize that the "placebo" was not a placebo at all but an injection of a bioactive substance made up of amorphous aluminum hydroxyphosphate sulfate (AAHS).

Merck is not alone. All pharmaceutical companies making childhood vaccines use the same deceptive trick. An author of a book titled *Turtles All the Way Down* needed to remain anonymous to protect himself from backlash in the medical community. The anonymous author explains how the pharmaceutical companies rig the trials while staying out of jail:

> Vaccine trials in general, and childhood vaccine trials specifically, are purposely designed to obscure the true incidence of adverse events of the vaccine being tested. How do they do this? By using a two-step scheme: First, a new vaccine (one which does not have a predecessor), is always tested in a Phase 3 RCT in which the control group receives another vaccine (or a compound very similar to the experimental vaccine, see explanation below). A new pediatric vaccine is never tested during its formal approval process against a neutral solution (placebo). Comparing a trial group to a control group that was given a compound that is likely to cause a similar rate of adverse events facilitates the formation of a false safety profile.[11]

The pharmaceutical companies use the word "placebo" to describe the injection given to the control groups in their studies of childhood vaccines. But the "placebos" always contain bioactive ingredients that cause adverse events. Those adverse events in the control group are then used as the supposed background rate of adverse events to compare the tested vaccine's safety. The tested vaccine may be quite dangerous, but because it is often being compared to an equally dangerous bioactive "placebo" the pharmaceutical companies can announce that the vaccine is safe because it does not significantly increase the rate of adverse events as compared to the control group receiving

a “placebo.” Shocking as it may sound, it is a historical, scientific fact that no vaccine on the CDC childhood vaccine schedule was ever tested in a randomized controlled trial using an inert placebo for the control group.

The CDC has described the hepatitis A vaccine as “very safe.” The CDC recommends that children get a two-shot administration beginning as early as 12 months old.[12] Merck, in 1996, tested its hepatitis A vaccine (VAQTA®) against a control group that was given a “placebo” containing an aluminum diluent. Aluminum is a bioactive ingredient that not only stimulates the immune system but it is also neurotoxic. There are significant side effects to being injected with such a heavy metal. Merck described the placebo as (alum diluent). That means that the aluminum was a diluent. A diluent is a substance used to dilute other ingredients. That suggests the “placebo” carried other unspecified ingredients diluted in the aluminum carrier.

It is not surprising then to find that the 1996 Merck VAQTA® hepatitis A study showed systemic side effects for the control group receiving the ‘placebo” that in most instances were equal to or greater than those in the test group getting the VAQTA® vaccine. With that trick, Merck was able to say in their VAQTA® package insert that “[t]here were no significant differences in the rates of any adverse events or adverse reactions between vaccine and placebo recipients after Dose 1.”[13]

Another example of the "placebo" scam run by pharmaceutical companies is a 2002 safety trial study for a new DTaP (diphtheria, tetanus, and pertussis) vaccine. The CDC has concluded that “DTaP and Tdap vaccine [*sic*] are safe and effective at preventing diphtheria, tetanus, and pertussis.”[14] The CDC based its conclusion that the DTaP vaccine was safe on a rigged study.

In the DTaP study, the “control group” received the older DTP vaccine.[15] In that study, 1 in every 22 subjects in the experimental group became so ill that they were admitted to the hospital.[16] But a similar rate of hospitalization was also reported in the control group. The study thus reported that the “rates of vomiting, convulsions and hospitalizations ... were not significantly different between the two groups.”[17] The study showed that the new DTaP vaccine and the older DTP vaccine both have a high rate of adverse events, which caused many children to be hospitalized. But the point of the study was to measure the safety of the new vaccine against the older vaccine and not to measure the vaccine's safety in absolute terms. With the rigged criteria of relative safety, the FDA and the vaccine maker were able to announce a finding that the new vaccine was just as safe as the older vaccine because the rate of hospitalization was the same for both. But no rational person would ever say that a vaccine is safe that causes 1 out of every 22 children to be hospitalized. The trial showed that both the old and new vaccines were unsafe. But because the vaccine maker did not use an actual placebo there was no comparison to an inert (saline solution) the danger of the new DtaP was obscured.

The scam artists at the Pharmaceutical companies argue that when they have a childhood vaccine that has been proven effective, it is unethical not to administer that established vaccine to the control group. That is their cover story, but it is a provable lie. The testing of Prevnar® proves the lie. Prevnar® is supposed to guard against pneumococcus bacterium. Before Prevnar® there was

no established childhood vaccine against pneumococcus bacterium. And so, no ethical claim could be made not to use an inert saline solution for the control study group. Nonetheless, Pfizer chose not to test Prevnar® against a true control group using a saline solution. Instead, Pfizer used a bioactive meningococol bacterium "placebo."

It gets worse; the control "placebo" was an investigational vaccine. An investigational vaccine is an experimental vaccine that has only been tested in a laboratory and is approved by the FDA for use on persons for testing purposes only.[18] An investigational vaccine has not been shown to be safe or effective. That means the "placebo" vaccine given to the control group was an unproven and possibly unsafe vaccine that could cause unknown adverse events. The testers introduced an unknown variable into their test.

Pfizer went a step further in contaminating the test. Pfizer gave both the control group and the test group the DTaP vaccine. The Pfizer Prevnar® insert states:

> Efficacy was assessed in a randomized, double-blinded clinical trial in a multiethnic population at Northern California Kaiser Permanente (NCKP) from October 1995 through August 20, 1998, in which 37,816 infants were randomized to receive either Prevnar® or a control vaccine (an investigational meningococcal group C conjugate vaccine [MnCC]) at 2, 4, 6, and 12-15 months of age. Prevnar® was administered to 18,906 children and the control vaccine to 18,910 children. Routinely recommended vaccines were also administered which changed during the trial to reflect changing AAP and Advisory Committee on Immunization Practices (ACIP) recommendations.[19]

Pfizer did all it could to obscure the dangerousness of Prevnar. It was as though they knew that Prevnar would be shown in the study to be dangerous to children. The test did not disappoint. Sure enough, the study resulted in about 1,000 infants being hospitalized; that amounted to one out of every 35 infants in the study being hospitalized.[20] One out of every 16 children in the trial needed to be taken to the emergency room within 30 days of being vaccinated.

The study reported 5 cases of sudden infant death syndrome (SIDS) among the Prevnar test group and 8 cases of sudden infant death syndrome among the control group receiving the "placebo." Prevnar was shown to kill children, yet because they rigged the study to ramp up the control group's deaths by giving the control an experimental vaccine, they concluded that Prevnar was safe. Furthermore, the study authors stated: "The number of SIDS deaths in the efficacy study from October 1995 until April 20, 1999, was similar to or lower than the age and season-adjusted expected rate from the California State data from 1995-1997."[21] The study authors compared the SIDS data in the study to the SIDS data from a state that mandates childhood vaccinations and does not allow religious exemptions.

It is interesting that many of the childhood vaccine studies report SIDS data. But when people try to link SIDS to vaccines, they are considered conspiracy theorists or anti-vax wackos.

But Pfizer was not done. They must keep the poisons coming. Prevnar was purported to work against 7 strains of pneumococcus bacteria. In 2010, it updated its Prevnar vaccine to cover 13 pneumococcus bacterial strains. The new vaccine was branded Prevnar 13. How did they study the new vaccine for efficacy and safety? Well, they were not about to use an inert saline solution for the control group. So, they tested Prevnar 13 against the control group receiving the previously approved predecessor Prevnar vaccine.[22] What was the result? The Prevnar 13 package insert reveals:

> **Serious adverse events** reported following vaccination in infants and toddlers occurred in **8.2%** among Prevnar 13 recipients and **7.2%** among Prevnar recipients.[23]

You read that correctly. The FDA approved Prevnar 13 as safe even when **8.2% (one out of every 12 children) suffered a "serious adverse event"** from the vaccine. But because Prevnar 13 was compared to an equally dangerous predecessor vaccine, it was deemed by the FDA to be safe. There was a lot of money at stake with Prevnar and its successor vaccine, Prevnar 13. Reuters reported in 2014 that Prevnar and Prevnar 13 combined annual sales of almost $4.5 billion made them Pfizer's second-biggest franchise.[24]

This same scam is being run for adult vaccines. For example, Jeremy Howick revealed that "in the COVID-19 vaccine developed by the University of Oxford, the control group receives a meningitis and septicaemia vaccine as a placebo." [25] The Oxford COVID-19 vaccine is made by AstraZeneca and sold under the brand names Covishield and Vaxzevria.

On April 29, 2020, Pfizer-BioNTech announced the phases 1-2 studies (NCT04368728) of its COVID-19 vaccine.[26] The trial was described as "a Phase 1/2, randomized, **placebo-controlled**, observer-blind, dose-finding, and vaccine candidate-selection study in healthy adults."[27] One would naturally think that Pfizer-BioNTech would conduct the study using an inert saline solution. But you would be wrong.

The Informed Consent Action Network (ICAN) filed a Freedom of Information Act request with the FDA asking for the ingredients of the "placebo" used in the Pfizer-BioNTech studies. The FDA responded by denying the request. The FDA stated in pertinent part that information was a "trade secret" and thus "confidential commercial information."[28]

Dear reader, think about that. The placebo used in the control groups for the Pfizer-BioNTech COVID-19 vaccine trials is considered a confidential trade secret. We know from that alone that the placebo was not an inert substance like saline because saline is not and cannot be a trade secret. Thus, we know that the ingredients for the "placebo" were very likely bioactive. Pfizer-BioNTech likely used their usual procedure of administering a bioactive ingredient to the control group to set a very high level of adverse events against with which to measure the mRNA COVID-19 vaccine to make the mRNA COVID-19 falsely appear safe. We now know that their scheme worked because the Pfizer-BioNTech COVID-19 vaccine won emergency use authorization and immediately began injuring and killing people.

Endnotes

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