# Science Day Presentation for Gardasil

VIDEO TRANSCRIPT ROBERT F. KENNEDY, JR.





#### Introduction

Hi, I'm Robert F. Kennedy, Jr. and I'm making this video for the sake of parents who are trying to make an informed decision of whether or not to give their child, their boy or girl, the Gardasil vaccine.

I'm also making this video as a tool for pediatricians who are trying to understand how this vaccine, if it's actually causing all of these problems with young girls, could have been approved by FDA and then mandated by CDC.

Virtually all of the things that I'm going to talk about in this video are available to the public on public documents, as I'm going to show.

Finally, I want to say this about Merck, which is the company that makes the Gardasil vaccine.

Many of the things that I'm going to say today would be slanderous if they were not true. And if they're not true, then Merck should sue me. But Merck won't do that, and they won't do it because in the United States, truth is an absolute defense to slander. And second of all, Merck knows that if they sue me, I'm going to immediately file a discovery request, and many, many more documents are going to emerge that illustrate even more fraud by this company on the American public and the people all over the world.

Finally, as a footnote, I'm not going to talk today about the specific biological mechanisms that allow this vaccine to cause harm in human beings. That information is out there, it's in dozens of peer-reviewed, published scientific documents. Many of these are described on our website, and I urge people to go to the <a href="Children's Health-Defense">Children's Health-Defense</a> website to educate themselves on those issues.

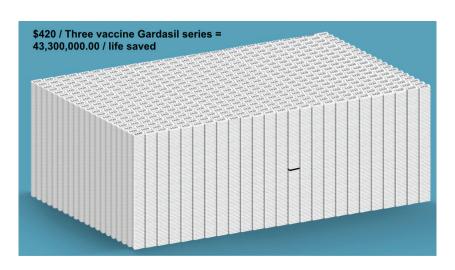
Today we're going to talk about the clinical trial—about Merck's fraud in that process. And this is Merck's claim:

The HPV vaccine will "eliminate cervical cancers and other HPV-associated cancers."

The danger of dying from HPV cancer in this country is 1 death in 43,500 people.

Imagine you have a deck of cards but instead of 50 cards, there [are] 43,500 on a big, big table, and one of those cards is a black card. If you get that, you die.

So, Merck's deal is that it's going to remove that black card from the deck. But in order to play the game and make sure that Merck removes the



black card, everybody who participates has to put in \$420 because that's the cost of the threedose Gardasil vaccine.

So, here's Gardasil by the numbers. So, the cost of the three-jab series averages about \$420. There are 76 million children who essentially have been mandated by CDC to receive these vaccines. This is a blockbuster product for Merck, and the global revenues from this vaccine today are about \$2.3 billion dollars. It's the third largest product in the company's inventory.

The cost of saving one American life is \$18.3 million dollars. People can argue whether or not that's a reasonable value of a human life, what I would say is that the criteria that we should use for evaluating reasonableness is, is there a cheaper way to save more lives, and many people would argue that Pap smears are the most effective way—that 80 percent of cervical cancer deaths have already been eliminated by Pap smears, and this is the most effective technology.

Incidentally, in another context, HHS has already put a value on human life, and the value is \$250,000. That is the maximum number that the Vaccine [Injury] Compensation Program will pay for killing an American citizen.

Prior to marketing a vaccine, the FDA licenses the vaccine. And in that licensing process, Merck

had to show that the [Gardasil] vaccine was safe. According to Federal regulations, "The word safety means the relative freedom from harmful effects...taking into consideration the character of the product in relationship to the condition of the recipient at the time."

So, what is the condition of the recipients—of the target group—for this vaccine? One is this vaccine targets millions of preteens and teens, for whom the risk of dying from cervical cancer is practically zero. Cervical cancer's median age of death is 58. It is first diagnosed at age 50 (median).

A teenage girl or boy has zero chance of dying of this illness, which means the threshold for giving this medication is very, very high.

Secondly, [the vaccine] is mandated in some jurisdictions, so the government is actually—government officials are actually coming in and ordering people to take this medical intervention. So, we have to be sure that the threshold for risk, "the risk profile" for that medical intervention should be very, very low.

Third, unlike other medical interventions, Gardasil recipients are perfectly healthy. So, when you give medication to a healthy individual, you have to make sure that the risk profile is practically zero. And in order to determine risk,

there is a standardized protocol, and it's called "double-blind placebo studies." What does that mean?

It means that the drug company that's trying to license this product gives the medication to one group of people, maybe 5,000 or 10,000 people, and gives a placebo, an inert placebo, either an identical-looking pill that is inert—it's either saline or sugar—to a

# DEATHS AND SERIOUS INJURIES FROM PREVENTATIVE MEDICINE ARE INTOLERABLE

21 CFR 600.3(p):

"The word *safety* means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time."

#### Tolerance for vaccine-associated risks should have been very low.

- Target population of millions of pre-teens, teens and young adults.
- Mandated in some jurisdictions, available elsewhere w/o parental consent
- Unlike other medical interventions, Gardasil recipients are healthy individuals
- Target individuals have low risk (effectively zero) of cervical cancer

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similarly situated group of 5,000 or 10,000 people, and it's "double-blind," meaning that neither the patients nor the researchers knew who got the placebo and who got the actual medication.

And you can see here, here's what the NIH (the National Institutes of Health) says about it: "A placebo is an inactive substance that looks like the drug."

So, here are typical examples:

Lipitor was given during its study phase to about 17,000 subjects. Half of them received Lipitor, half of them received a sugar pill that looked identical to Lipitor, and then they were observed and studied for up to 3.3 years.

Why for so long? Because many of the injuries that are caused by medication are latent—they don't show up for two or three or four or five years. Cancer, for example, may not show up for four or five years after the exposure. Autoimmune diseases and allergies and these kinds of things take a long time to diagnose. Enbrel, for that reason, was studied for 6.6 years and against

a control group that received a saline injection.

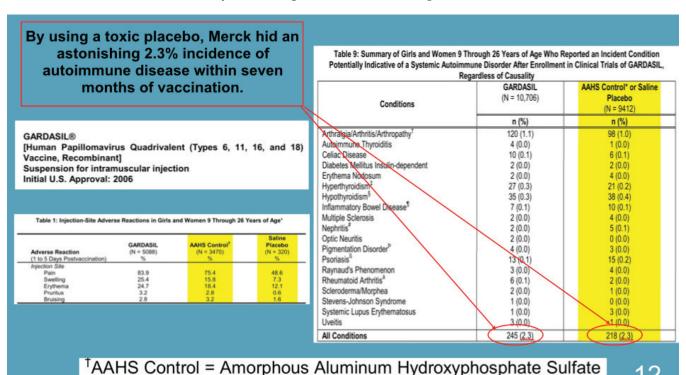
Botox—there was a national emergency to get Botox to market so people could get their wrinkles cured—was studied for 51 weeks, and it was studied against a saline injection.

Now I'm going to show you one of the really outrageous frauds that Merck committed during the clinical trials. This is an insert that is part of every vaccine package. And you can go on the Internet right now and look up that Merck product and search and find these two tables.

In the initial table, you can see there are three columns. This is a table that just looks at injuries at the vaccine site for redness and itching and bruising and pain at the vaccine site.

One, there were 5,000 girls—5,088 girls—who got the Gardasil vaccine.

Number two, there were 3,470 girls who got the AAHS control. What is that? That is the adjuvant in the vaccine. That is a toxic neurotoxin that's put in the vaccine to make it more



long-lasting, to provoke an immune response in the subject of the vaccine.

And most people believe that it is that aluminum adjuvant that is causing all of these injuries in the girls who are getting the vaccine. And there were 3,470 people who received just the neurotoxin with no antigens and no other vaccine components.

And you have a third group, which is the placebo group. What I want you to look at is at these numbers—that in the Gardasil and AAHS control, there is virtually the same number of injuries.

And when you get to the saline placebo, that injury rate is cut in half.

Now, let's go to the table where they talk about real systemic injuries—autoimmune diseases. And instead of showing us real science, which is to show us what happened to the saline group, they hide the saline group as a way of fooling you, your pediatrician and the regulatory agency by compressing it into the aluminum group. And they never tell us. They say, this is a combination of the aluminum adjuvant and the saline placebo. They don't tell us how many in each category were compressed there.

The real thing that you need to watch here is what happened.

These are all very, very serious injuries.
These are injuries that, in some cases, people would feel were worse than death—and that affect people and debilitate people for a lifetime in many cases.

In Ma Direct

And if you look at the bottom of the Gardasil group, an astonishing 2.3 percent of the girls in the clinical study who received the Gardasil vaccine got ill from autoimmune diseases, many within seven months of taking the vaccine.

And look what happened in the aluminum group—the same number exactly: 2.3 percent.

Nobody—no parent—would allow their daughter to take a substance that had a one-in-40 chance of giving them a lifetime disability.

The World Health Organization says that using a spiked placebo—or a faux-cebo—as Merck did with Gardasil puts you at a methodological disadvantage in that "it may be difficult or impossible to assess vaccine safety."

Dr. Stanley Plotkin, who developed the polio vaccine, who developed the pertussis vaccine, who developed the rotavirus vaccine—the Stanley Plotkin award is the Nobel Prize of vaccinology, it's given to the top vaccinologist every year—and what he says is:

Unless you have a true control group, you are in LA-LA LAND.

Finally, the American Medical Association says, the absence of double-blind placebo testing and short-term studies of chronic disease are "the indicia of marketing masquerading as science."

And that's what Merck gave us.

The Cochrane Collaboration—thirty thousand scientists from all over the world who came together to create an independent assessment of medical protocols, which they saw as being increasingly controlled by the industry—the

### MASKING GARDASIL INJURIES

In May of 2016, **Thomas Jefferson**, **Peter Gotzsche**, and Deputy Director **Karsten Juhl Jorgensen** of the **Nordic Cochrane Center** in Denmark, filed an unofficial complaint against the European Medical Agency for mal-administration and bias in its assessment of the possible serious neurological harm caused by the HPV vaccine.

"The use of active comparators probably increased the occurrence of harms in the comparator group, thereby masking harms caused by the HPV vaccine."

-Peter Gotzche, Cochrane Center

Cochrane Collaboration said, "The use of active comparators probably increased the occurrence of harms in the comparator group, thereby masking harms caused by the HPV vaccine."

And that indeed was Merck's point: to hide those harms.

So, if you do the math, women are 100 times more likely to suffer serious adverse events from the Gardasil vaccine than they are to be protected from cervical

So now we have a very different bargain in this card game that we're playing with Merck.

We have 43,000 cards, and the black card—the death card—is gone, but now, there are 1,000 blue cards, which if you pick one of those by mistake, you have a good chance of getting

an autoimmune disease. Nobody would take that bargain.

So, in order to get the FDA license to market this vaccine, Merck did a number of studies, which it called "protocols." We don't know how many they did because they're not telling us—they never disclosed it.

The one we're most concerned with is protocol 18. The reason protocol 18 is critical is because that was the basis for FDA giving Merck the license to produce and market the vaccine.

Why is that? Because protocol 18 is the only one in which the target audience for this vaccine—11- and 12-year-old girls—was actually tested and had a control group. The other ones that looked at big cohorts of women were [in] 16- to 25-year-old and 16- to 26-year-old women.

Protocol 18 looked at girls and boys from ages 9 to 15. It was a total of 1,200 children and almost 600 controls. That is a very, very tiny group of people to study in order to determine the safety of a product that is going to be marketed to billions of children around the world.

Now I'm going to show you one of the key fraudulent flimflams that Merck used to get this license. FDA said they approved Gardasil based on protocol 18 because protocol 18 was of particular interest—because it's the only protocol in which Merck used a true saline placebo instead of the aluminum adjuvant as a control.

#### PROTOCOL-18

Critically important for Merck in licensing Gardasil.

- First:

  ➤ FDA's Basis for approving vaccine for use in children under 16
- > Only study that included the Gardasil target population, eleven and twelve year-old boys and
- > Protocol-18 included 1062 nine to twelve year-old boys and girls, with 370 of them as the
- Tiny number for a drug intended for billions of children across the planet.

That's what Merck told FDA and the CDC, but Merck was lying. It actually did not use a true saline placebo. It used what Merck called the "carrier solution," which is all of the components of the vaccine except for the aluminum and the viral particles—the antigen.

Among the compounds that we know were in the carrier solution are:

- Polysorbate 80—we have no idea what the safety profile is because it's never been tested for safety independently in vaccines.
- Sodium borate, which is borax, which is banned by FDA in food products—in all food products in the United States—and is banned altogether in Europe.
- Genetically modified yeast (there's no safety test ever been done on it in vaccines).
- L-histidine, the same.
- And possibly, DNA fragments.

I say "possibly" because we know there are DNA fragments in the final vaccine, we don't know how they got there. And Merck has lied about the DNA fragments from the outset.

And despite these potentially toxic components of compounds that are in the vaccine, the 596 children that were given the carrier solution fared much better than any other cohort in the study. The girls and boys who received the carrier solution were the only significant cohorts with no serious adverse events for the first 15 days.

And here's another one of the gravamen of the fraud that Merck committed in its Gardasil trials. It turns out, in the protocol 18 study, it appears Merck cut the amount of aluminum that was given to the vaccine group in half. They tested a completely different formulation. If true, we theorize that they took the aluminum out to reduce the number of injuries and to mask the really bad safety profile of this vaccine.

And since the protocol 18 data are not based on the Gardasil vaccine formulation, the trial itself constitutes rank scientific fraud.

Here's another bag of tricks that was used by Merck in order to skew the clinical trial results in favor of Gardasil.

Merck and its researchers used what they call "exclusion criteria"—for example, people who had severe allergies, people who had prior genital infections were thrown out of the clinical trials. People who had over four sex partners in their entire lives were excluded from the trials. Anybody who had a history of immunological or nervous system disorders, people with chronic illnesses and seizure disorders, people with other medical conditions, people who had reactions to vaccine ingredients—including the aluminum, yeast and the benzonase—or anybody with a history of alcohol and drug abuse.

If you really wanted to know whether the vaccine was helping people—if it was effective—wouldn't you want those people in your study? Wouldn't you want people who had a genetic vulnerability to cancer in your study, to see if it actually was capable of preventing cancer?

Then Merck had one catch-all exclusion category, which was "Any condition which in the opinion of the investigator might interfere with

#### **AAHS DOSING IN PROTOCOL 18:** ANOTHER DECEPTION 225 mcg of AAHS TABLE 210 per mL = 112.5Protocol 018: Vaccine Products Used mcg per 0.5 mL Formulation Clinical Material Package and Storage Number Dosage 40/80/80/40 mcg plus 225 mcg Quadrivalent HPV (Types 6, V501 VAI025T004 aluminum 0.75-mL single dose vial 11, 16, 18) L1 VLP Vaccine adjuvant/mL 0.5 mL Placebo for Quadrivalent HPV Carrier Solution (Types 6, 11, 16, 18) L1 VLP PV501 VAI036P001 0.75-mL single dose vial Only /0.5 mL Vaccine HPV = Human papillomavirus; VLP = Virus-like particles.

#### UNLIMITED DISCRETION TO EXCLUDE

In addition, investigators could exclude anyone simply based on:

"Any condition which in the opinion of the investigator might interfere with the evaluation of the study objectives."

the evaluation of the study objectives." Well, that gave Merck and its paid investigators complete control to throw people out of the study who they thought might make the study look not successful. All of these exclusionary categories gave Merck the ability to limit the study to people who were like an elite club of superheroes. The people who [now] get the vaccine are not the same people they tested it on. They tested it on the Avengers. They didn't test it on, you know, Joe Bag-of-Donuts, the people who are actually receiving this vaccine in dayto-day life. And by doing that, they were able to mask whatever injuries might show up in a larger, more vulnerable population who are actually receiving the vaccine.

Next, Merck used an arsenal of sloppy protocols to, again, hide vaccine injuries. Among these, Merck gave report cards—the daily journal report cards—to only 10 percent of the people who they tested the vaccine on, and it told those people to only make reports for 14 days after the injection. And the report cards were only

designed to collect jab site information—so, redness, itching, bruising, fever.

And they ignored altogether the autoimmune diseases and menstrual cycle problems and fertility problems and pain and dizziness and seizures and all of the other things that we've now seen are associated with the vaccine. In fact, there are numerous girls who report that they were injured, that they attempted to report those injuries to Merck and that Merck rebuffed them.

Furthermore, Merck gave extraordinary discretion to its researchers to determine what was a vaccine injury

and what was not a vaccine injury. And because there was no inert placebo, it was completely within their discretion, if a girl came back with seizures or autoimmune disease or menstrual cycle problems, they could just say to the girl, "well, that's not related to the vaccine."

In some cases, we know that Merck actively covered up and lied about injuries that it had a duty to report to the Vaccine Adverse Event Reporting System (VAERS). For example, in the case of Christina Tarsell, a Maryland girl who died from the Gardasil vaccine, Merck lied about that death in its official reports to the Vaccine Adverse Event Reporting System. It told the system that Christina's doctor had told Merck that her death was the result of a virus.

And the doctor adamantly denies that. Merck has refused to remove that misinformation from the VAERS system.

Furthermore, Merck lied to the girls who participated in these studies, telling them, num-

## **UNREPORTED DEATHS**

In order to conceal Gardasil's link to the death of teenagers, Merck submitted fraudulent reports to VAERS, and posted fraudulent and misleading statements on its Worldwide Adverse Experience System attributing the death of specific children to viral infections for which there was no evidence, but were invented by Merck.

For example, Merck later claimed that it had reported the death of a Maryland child, Christina Tarsell. Merck, however, submitted <u>fraudulent</u> information about Chris' death to its Worldwide Adverse Experience System, and lied to the VAERS system. Merck claimed that Chris' gynecologist had told the company that her death was due to viral infection. Chris' gynecologist denies that she ever gave this information to Merck. To this day, Merck has refused to change its false entry on its own reporting system.

ber one, that the placebo was saline and that it contained no other ingredients. And number two, that the study in which they were participating was not a safety study. They were told that there had already been safety studies and that the vaccine had been proven safe.

What did this do for Merck? It made it so the girls were less likely to report injuries as associated with the vaccine—because they believed that the vaccine that they were receiving had already been proven safe and that any injuries that they did experience maybe a month or two months or three months after the vaccine must be simply coincidental and had nothing to do with the vaccine.

But in spite of all these efforts by Merck to discourage girls from reporting vaccine injuries during the clinical trials, half of the girls in the Gardasil group and half of them in the aluminum adjuvant group reported serious injuries after receiving the vaccine. In order to conceal the link between these injuries and the vaccine, Merck invented a brand new medical metric that had never been heard of before called "new medical conditions," and it dismissed all of these new injuries—which affected 50 percent of the girls who received the vaccine and the adjuvant—as "new medical conditions" unrelated to the vaccines, simply sad coincidences.

Many of these diseases were serious diseases—blood and lymphatic diseases, anemia, endocrine diseases, autoimmune diseases, gastrointestinal, Crohn's disease, ulcerative colitis, vaginal infections, musculoskeletal injuries, arthritis, neoplasm, Hodgkin's disease, neurological diseases, psychiatric diseases, depression, reproductive and breast disorders, menstrual irregularities and pain. Over 3 percent of the girls—1 in 30—in both groups required surgical and medical procedures.

So, this card game that we're playing with Merck has now become a really bad bet.

## "NEW MEDICAL CONDITIONS"

- Merck classified many illnesses/diseases including very serious ones –
   "new medical conditions" rather than adverse events or adverse reactions.
- At the time of approval, half of the participants in both vaccine and control arms reported NMCs.
- No rigorous investigation of NMCs.

# TABLE 303 Protocols 007, 013, 015, 016 and 018: New Medical Conditions after Month 7 in the Safety Population

Subjects in analysis population

Gardasil N=10452 Placebo N=9385

Subjects with new medical history

5178 (49.5%) 4883 (52.0%)

Merck has removed the one black card, but you now have a 1-in-40 chance of drawing a blue card and getting an autoimmune disease that may afflict you for the rest of your life—and you have a 1-in-2 chance of having some other serious medical condition.

So now let's look at Merck's central claim, which is that the Gardasil vaccine will prevent cervical cancer.

50% of study participants reported serious adverse events that Merck characterized as "NEW MEDICAL CONDITIONS"

Merck's in a sweet position here, let's face it, because the target group for this vaccine is 11-year olds, and the median age of death for cervical cancer is age 58.

So, Merck essentially is making this bargain:

It's telling the 11-year old girl, "If you take our vaccine, 47 years from now you won't die of cervical cancer." And of course, the truth is, you can't make a vaccine that proves that it's going to prevent cancer 47 years from now. There's no way to test for that.

So, Merck used a shortcut. It said, we're going to prove that it prevents what Merck called "surrogate end points." So the best thing that Merck could come up with was CIN2 and CIN3 lesions, which it called "precancerous" lesions, even though most of those lesions never mature into cancer.

So how can you call something "precancerous" when it was never going to turn into cancer?

And here's what a study published in the *American Journal of Epidemiology* said about Merck's scheme: "CIN3 is an imperfect diagnosis of precancer and an intermediate surrogate for cancer."

Their own attorneys told them, "For these

products, the indication is the surrogate, not the ultimate, endpoint. Promotion cannot make any claim vis-a-vis the ultimate end point," based upon the fate of a surrogate endpoint.

Merck has another problem.
Recent peer-reviewed
scientific studies indicate that perhaps only a
third of cervical cancer
cases are even associated
with the HPV virus. That
would completely put the

lie to Merck's claims that Gardasil is going to eliminate cervical cancer altogether.

So now we have a really dubious deal because we need to put that black card back in the deck. Because now, we have doubts about whether or not this vaccine can prevent cervical cancer at all.

But the news gets worse. Gardasil may actually cause cancer. Gardasil's insert states, "Gardasil has not been evaluated for potential to cause carcinogenicity or genotoxicity." And Gardasil's ingredients include possible carcinogens, including human DNA.

And look at this. This is Merck's own preclinical trial records, and those records show that girls or women who already had HPV—had been exposed at some point in their life to it—actually had a negative efficacy of 44.6 percent.

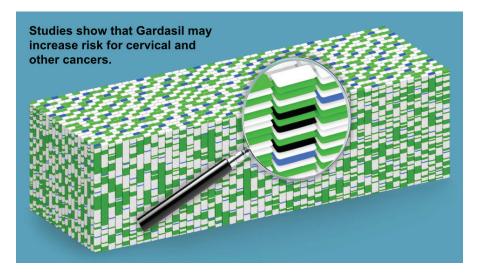
What is "negative efficacy"? It means those girls had a 44.6 increased risk of getting those precancerous lesions. To make things even worse, there are recent scientific studies that suggest a phenomenon of what is known as type replacement. There are some 200 different strains of HPV. Some of them are more cancerous than others, and the current HPV vaccine goes after 9 of those 200 viral types. What these studies indicate is, by eliminating those particular strains of the

virus, [the vaccine] opens up an ecological niche in the woman so that more lethal and virulent viruses can actually colonize that spot and dramatically increase the risk of cervical cancer.

So now Merck's deal is looking really grim. Not only do we have a 1-in-40 chance of getting an autoimmune disease and a 50 percent chance of getting some serious medical condition, but now, the cancer risk has been reinserted and actually amplified.

And now, let's look at some of the non-cancer injuries that Merck found in its preclinical studies.

The miscarriage rate in the preclinical studies—after Gardasil—doubled the background rate.
The birth defects in the Gardasil group were five



#### **DEATHS**

Cervical Cancer v. Gardasil

Annual Deaths from Cervical Cancer in US for women of all ages:

Death Rate in Gardasii Clinical Trials from all causes:

2.3/100,000 [NCI, study evaluating 2

Death risk from Vaccine is 37 TIMES the risk of Dying from Cervical Cancer

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times the rate of birth defects from the control group. As to reproductive disorders, an astonishing 10.9 percent of the women in the pooled group reported reproductive disorders within seven months of receiving Gardasil, compared to 1.2 percent in the placebo group. The death rate in the Gardasil group in the clinical trials was 8.5 per 10,000.

The death risk from this vaccine, according to Merck's own studies, is 37 times the risk of dying from cervical cancer.

So now look at the deal that Merck has offered us: they've actually increased our risk of dying by 37 times.

So now, let's look at post-licensing surveillance. So, Merck can argue that, "We might have missed something in our pre-licensing studies

but surely if there were any injuries being caused by this vaccine, we would see them in post-licensing surveillance."

And the problem with that is that the post-licensing surveillance system, the principal one, is called the Vaccine Adverse Event Reporting System. The system is a voluntary system that simply does not work. It's broken. In fact, in 2010, HHS hired

another federal agency, the Agency for Healthcare Research Quality, and a group of Harvard researchers to study the Vaccine Adverse Event Reporting System, and those researchers found that fewer than 1 percent of adverse events from vaccines are ever reported.

But even under that system, Gardasil has distinguished itself as the most dangerous vaccine ever invented.

In fact, when you compare it to Menactra, which is a meningitis vaccine that's given to the same age group—teenagers—Gardasil had 8.5 times more emergency room visits, 12.5 times more hospitalizations, 10 times more life-threatening events and 26.5 times more disabilities than Menactra.

The "vaccine court" which is within HHS has made awards for numerous deaths and very serious injuries from the Gardasil vaccine. So, HHS itself admits that this vaccine kills people, and it's given compensation to the families that were injured.

The same wave of serious injuries and deaths has been seen in nations around the globe when they adopt mandates for the Gardasil vaccine. Even Gardasil's own insert, the package insert that the company provides, acknowledges that the injuries that can be caused by this vaccine include death, pancreatitis, fatigue, malaise, immune system disorders, autoimmune diseases, anaphylaxis, musculoskeletal and connective tissue disorders, nervous system disorders, acute disseminated encephalomyelitis—that's brain injuries—Guillain-Barré syndrome, motor neuron diseases, paralysis, seizures, transverse myelitis and vascular disorders.

In Australia, in 2015, the Australian Department of Health Therapeutic Goods Administration reported that the adverse rate in girls is 17 times the incidental rate for cervical cancer throughout their lifespan. The study only looked at a handful of conditions but excluded demyelinating disorders, complex regional pain syndrome and premature ovarian failure. The study restricted its view to anaphylaxis, fainting, allergic reactions and other conditions that required hospitalization.

## **VAERS**

Grant Final Keport
Grant ID: R18 HS 017045

Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

Principal Investigator: Lazarus, Ross, MBBS, MPH, MMed, GDCompSci

Team members: Michael Klompas, MD, MPH

Performing Organization: Harvard Pilgrim Health Care, Inc

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Submitted to:
The Agency for Healthcare Research and Quality (AHRQ)
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
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Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

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India suspended its Gardasil trials after numerous deaths and serious injuries.

The South Asian Journal of Cancer found that "a healthy 16-year old is at zero immediate risk of dying from cervical cancer but is faced with a small, but real risk of death or serious disability from a vaccine that has yet to prevent a single case of cervical cancer."

Japan de-recommended Gardasil three months after it had added the vaccine to the immunization schedule. Japan's health ministry discovered adverse events reported after Gardasil's approval were many times higher than other vaccines on the recommended schedule—these included seizures, severe headaches, partial paralysis, complex regional pain syndrome and "an undeniable causal relationship between persistent pain and the vaccination."

Japanese researchers found that the adverse event rate for the HPV vaccine was as high as 9 percent and that pregnant women injected with the vaccine aborted or miscarried 30 percent of their babies.

In 2015, the Japanese Association for Medical Sciences issued official guidelines for managing symptoms of injuries caused by the Gardasil vaccine, and the Association announced that there was no proof that this vaccine even prevents cervical cancer.

Alarmingly, Merck's own studies indicate that the Gardasil vaccine may disproportionately impact Asian women. For example, in protocol 19, there were 8 deaths among 3800 women, and 7 of those were Asians. That was 87 percent for Asian women, while only 31 percent of study participants were Asian.

Denmark, in 2015, announced the opening of five new HPV clinics to treat women who were injured by the Gardasil vaccine. The day that they announced that opening, there were 1300 applicants for treatment in those clinics.



#### **DENMARK**

In March 2015, Denmark announced the opening of five new "HPV clinics" to treat children injured by Gardasil vaccines. Over 1300 cases flooded the HPV clinics shortly after opening.

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In Colombia in 2014, 800 girls in the town of Carmen de Bolivar were grievously injured by the Gardasil vaccine. Protests erupted all

over Columbia. The attorney general of Colombia ordered the National Health Service of that country to immediately begin treating girls who were injured by the Gardasil vaccine. In 2017, Colombia's highest constitutional court ruled that the HPV vaccine would no longer be considered mandatory in Colombia and ordered that girls who showed symptoms after receiving the vaccine be given appropriate medical care.

## **JAPAN**

Japanese researchers found that the adverse events rate of the HPV vaccine was as high as 9%, and that pregnant women injected with the vaccine aborted or miscarried 30% of their babies.

In late 2016, Japanese industry watch-dog, MedWatchJapan, issued a scathing letter to the World Health Organization, for failing to acknowledge the growing body of science demonstrating high risk of devastating side effects.



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Pompilio Martinez, who now teaches at the National University of Colombia, described the HPV vaccine as "a crime against humanity."

And recent studies have shown that in nations with robust HPV vaccination programs and heavily vaccinated populations—in the UK, in Sweden, in Australia—we're actually seeing dramatic

upticks—rises—in the rate of cervical cancer rather than the downtrends that Merck promised everybody.

Now I'm going to show you some of the reasons why your pediatrician is insisting—despite all of this evidence—that your daughter or son get the HPV vaccine. And the reason is, the pediatrician is getting his information from agencies that have been compromised through financial entanglements with Merck.

This is what the FDA is telling the public about vaccine safety: it says that vaccines are regulated by FDA and "undergo a rigorous review of laboratory and clinical data to ensure the safety, efficacy, purity and potency of these products."

But this is a very different story the FDA is acknowledging in-house—and this comes from a 2007 document (this is the year that Gardasil got its license from the FDA): "FDA's inability to keep up with scientific advances means that American lives are at risk. FDA's evaluation methods have remained largely unchanged over the last half century. The world looks to FDA as a leader. Today, not only can the Agency not lead, it cannot even keep up with the advances in science."

## FDA's Vaccine and Related Biological **Products Advisory Committee ("VRBPAC")**

2000 Investigation by U.S. House Government Reform Committee into VRBPAC:

- "The overwhelming majority of members, both voting members and consultants, have substantial ties to the pharmaceutical industry."
- . "conflict of interest rules employed by the FDA... have been weak, enforcement has been lax, and committee members with substantial ties to pharmaceutical companies have given waivers to participate in committee proceedings... In many cases, significant conflicts of interest are not deemed to be conflicts at all."

But the most troubling problem at FDA is—it has nothing to do with incompetence—it has to do with corruption. The panel within FDA that licenses new vaccines and anoints them as safe is called the Vaccines and Related Biological Products Advisory Committee; the acronym is VRBPAC. And in 2000, Congress investigated VRBPAC because of charges of corruption from outside the agency.

What FDA Tells the Public About Vaccine Safety Testing E ... ♥ ☆ Q 1) A https://www.fda.gov/biologicsbloodvaccines/vaccines/default.htm U.S. FOOD & DRUG 
 ■ Home
 Food
 Drugs
 Medical Devices
 Radiation-Emitting Products
 Vaccines, Blood & Biologics
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 Vaccines, Blood & Biologics Home > Vaccines, Blood & Biologics > Vac review of laboratory and clinical data to ensure the safety, efficacy, put and potency of these products. Vaccines approved for marketing may also be required to undergo additional studies to further evaluate the vaccine and often to address specific questions about the vaccine's · Consumers (Biologics) 90

safety, effectiveness or possible side effects.

And here's what the congressional committee found: "The overwhelming majority of [VRBPAC] members, both voting members and consultants, have substantial ties to the pharmaceutical industry."

In addition, "Conflict of interest rules employed by FDA have been weak, enforcement has been lax, and committee members with substantial ties to

Healthcare Providers (Biologics

pharmaceutical companies have [been] given waivers to participate in committee proceedings. In many cases, significant conflicts of interest are not deemed to be conflicts at all."

And here, says Congress, are some specific examples of the conflicts of the advisory committee that approves vaccines:

- Three out of five FDA advisory committee members who voted to approve the rotavirus vaccine in December of 1997 had financial ties to the pharmaceutical companies that were developing different versions of the vaccine.
- One of the five voting members had a 9-plus million dollar contract for a rotavirus vaccine.
- One of the five voting members was the principal investigator for a Merck grant to develop the rotavirus vaccine.
- One of the five voting members received approximately a million dollars from vaccine manufacturers toward vaccine development.

Once they get by FDA, vaccine companies then go to CDC, where another committee, which is called ACIP—Advisory Committee on Immunization Practices—will then take that vaccine that FDA has licensed, and they will put it on the recommended list, which means it becomes essentially mandatory for 76 million American children.

A listing on CDC's recommended list is the Holy Grail for vaccine companies. It means a bonanza of wealth for those companies. If ACIP votes to add your vaccine to the recommended list, it means:

- Mandating the vaccine to millions of American children, and half of those [vaccines] are paid for by the government;
- Immunity from liability for the manufacturers so nobody can sue them—no matter how dangerous that vaccine is, no matter how toxic its components, no matter how grievous your injury, you cannot sue that vaccine manufacturer for damages or liability;
- Inclusion in the Vaccines for Children Program, which is a program that guarantees
  that half the vaccines that you manufacture
  are going to be purchased by the CDC—at
  full cost.

This means billions of dollars for companies that are fortunate enough to get their vaccines listed on this recommended list. It means that you're going to sell 76 million vaccines to people who have no choice—you have no marketing costs, you have no advertising costs, you have limited testing expenses and you have no liability for injuries caused by your vaccine.

In 2006 and 2007, while Gardasil was getting its approvals, ACIP did not pretend to base its recommendations on scientific evidence. It only

adopted evidence-based standards in 2011.

So, what did it base its recommendation on? It turns out it was mainly just friendships and money. The conflicts at ACIP are as bad as the conflicts within the FDA.

This is from the same year-2000 investigation by Congress: "The CDC grants blanket waivers to the ACIP members each year that allow them to deliberate on any subject, regardless of

# ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES ("ACIP")

After FDA (VRBPAC)
licenses new vaccines,
CDC'S ACIP adds them to
the "recommended"
schedule.



their conflicts, for the entire year. ACIP members are allowed to vote on vaccine recommendations, even when they have financial ties to the drug companies developing related or similar vaccines."

And, "The ACIP's prolific use of working groups to track vaccine policy recommendations outside the specter of public scrutiny opens the door to special interest access." ACIP's policy of allowing government employees to vote "encourages a system where government officials make crucial decisions affecting American children without advice or consent of the governed."

Here is a typical committee panel that approved Merck's rotavirus vaccine. The majority of ACIP's members "were conflicted in their most recent vote." Again, these are Congress's words, not mine.

- The chairman served on Merck's Immunization Advisory Board.
- Another member who shared the patent on a vaccine under development for the same disease had a \$350,000 grant from Merck to develop this vaccine and was a consultant for Merck.

- Another member was under contract with the Merck Vaccine Division.
- Another member received salary from Merck and other payments.
- Another member was participating in vaccine studies with Merck.
- And another member received grants from Merck.

And unfortunately, that congressional investigation had virtually no impact on the way CDC does and continues to do business. For example, a 2009 report by the Inspector General of HHS found the same conditions existed—"CDC had a systematic lack of oversight." Ninety-seven percent of committee members' conflict disclosures had omissions, 58 percent had at least one unidentified potential conflict and 32 percent of the committee members had at least one conflict that remained unresolved. And the CDC continues to grant waivers.

So this shows that CDC is really just an arm of the vaccine industry. It shouldn't be regulating the industry—it's part of it.

## More from Congress's 2000 report . . .

The majority of the eight ACIP members were conflicted in their most recent vote:

- (1) the chairman served on Merck's Immunization Advisory Board,
- (2) another member shares the patent on a vaccine under development for the very same disease, had a \$350,000 grant from Merck to develop this vaccine, and was a consultant for Merck,
- (3) another member was under contract with the Merck Vaccine Division, received funds from various vaccine manufacturers including Pasteur, and was under contract as a principal investigator for SmithKline,
- (4) another member received a salary from Merck as well as other payments from Merck,
- (5) another member was participating in vaccine studies with Merck, Wyeth, and SmithKline, and
- (6) another member received grants from Merck and SmithKline.

This is CDC's entire budget, \$11.5 billion, and almost half of that—almost \$5 billion—goes to purchasing and promoting vaccines. And this little sliver here is the Immunization Safety Office.

That's how much money—less than 1 percent of the total—goes to vaccine safety.

Not only that, but Merck exercises control over CDC through the CDC Foundation. Merck contributes millions of dollars every year to the CDC Foundation. The CDC Foundation has received \$620 million from Merck and other pharmaceutical companies to pay for 824 programs at the CDC.

Merck representatives sit on the CDC Foundation Board and control the agency's activities.

## 45% OF FDA's BUDGET COMES FROM INDUSTRY

- Pharmaceutical companies pay billions of dollars in fees to the FDA to approve and fast-track new drugs.
- Between 2000 and 2010, pharmaceutical companies paid the FDA \$3.4 billion to gain drug approvals.



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companies paid \$3.4 billion to FDA to get drug approvals, and those payments by industry have caused FDA and CDC to treat the vaccine makers not as regulated entities but as partners and clients and friends.

According to Michael Carome, who is a for-

mer HHS employee, "Instead of a regulator and a regulated industry, we now have a partnership. That relationship has tilted the FDA away from [a] public health perspective to an industry-friendly perspective." And that's why your doctor does not know the truth about Gardasil.

# MERCK CONTROLS CDC BY PAYMENTS TO THE CDC FOUNDATION

- Merck contributes millions of dollars to the CDC foundation to control CDC decision-making.
- Through the CDC foundation, Merck places individuals to work at CDC, endows positions to CDC and funds projects at CDC.
- CDC foundation has received over \$620 million from Merck and other pharmaceutical companies to pay for 824 programs at CDC.
- Merck representatives sit on the CDC Foundation Board and control agency activities and policies, and can punish CDC by withholding funds from programs at any time.

"Most of us were shocked to learn the CDC takes funding from the industry... it is outrageous that industry apparently is allowed to punish the CDC if the agency conducts research hat has the potential to cut into profits."

-British Medical Journal (BMJ) (quoting UCLA Professor of Medicine Jerome R. Hoffman)

This is what the *British Medical Journal* said about those conflicts:

"Most of us were shocked to learn that the CDC takes funding from the industry. It is outrageous that industry apparently is allowed to punish the CDC if the agency conducts research that has the potential to cut into profits."

The corruption is systemic at FDA, too. Shockingly, 45 percent of FDA's budget comes from the industry. Pharmaceutical companies pay billions of dollars in fees annually to FDA to fast-track drugs. Between 2000-2010, pharmaceutical

This is another thing that your doctor probably doesn't know. The government agency NIH actually developed the key component for the Gardasil vaccine, and NIH owns part of the patent and receives royalties on it. Not only does NIH the agency receive millions and millions of dollars annually from the vaccine, but also the individual scientists who worked on the vaccine within the agency are entitled to make \$150,000 a year in royalty payments from Merck.

Every time your pediatrician sells one of those \$420 vaccines to your child—or you—NIH

# MERCK'S ROYALTY PAYMENTS COMPROMISE HHS REGULATORS



CDC or NIH Employees who worked on Gardasil vaccine patents can receive up to \$150k in licensing fees per year (in perpetuity) from Merck.

- Scientists at the National Institute of Health participated in the invention of HPV vaccines.
- NIH and it's employees receive tens of millions of dollars annually in Gardasil royalties from Merck.
- NIH and it's employees make money on every Gardasil vaccine sold.

scientists and HHS scientists and the agencies themselves are making money on that transaction. And that's why your doctor doesn't know what's happening—because he's getting his information or her information from those agencies.

There are many, many other shocking conflicts that I don't have time to talk about today between Merck and the other regulated vaccine makers and the industry that's supposed to be protecting the public from that regulated industry.

I just want to talk for a moment about one example. From 2002 to 2009, Julie Gerberding was the director of CDC, and she oversaw all of this crooked science that went into the approvals in 2006 and 2007 of Merck's Gardasil vaccine.

She was rewarded by Merck.

When she left the agency in 2009, she was hired by Merck as the president of its vaccine division and Merck gave her a salary of \$2.5 million a year, and \$38 million in stock options. And that kind of dough buys a lot of loyalty from regulators.

They know what's at the end of the line for them if they behave and if they do what Merck and

the other companies ask them to do. And these are the reasons that your pediatrician, who's giving your daughter that Gardasil vaccine believing that it may someday save her life, doesn't know about the risk and perils and the inefficacy that are attended to that vaccine, because the regulators from whom he's getting or she's getting her information have been corrupted by this company.

And most of you probably know—this is a difficult issue for people like myself who are concerned with vaccine injuries to address, because the press will not cover these issues because there's \$5.4 billion that go from these companies to advertising on TV and radio and newspapers and on the web every year, and nobody wants to lose that advertising revenue. And the Congress has been bought off, the regulatory agencies have been captured, and we can't use the courts because you cannot sue a vaccine maker for injuring yourself or your child.

But we've figured out ways around those laws, and we're going to sue Merck. And if you are Merck and you're listening to this tape:

#### We're going to come for you and we're going to get justice for these girls and these boys who you've injured because of your greed.

And if you're a mother or a father who are listening to this, we'd like your support. It's just a fact that the more monetary support the Children's Health Defense has, the more of these cases that we can bring, and we're going to get justice. And we're going to bring these cases and sue companies like Merck until we get that justice. So we want your money, and we want your support, and we want your membership.

But more than anything, we want you to protect your child from this vaccine and from other [vaccine] injuries—and for that reason we made this tape. Not only so that you can be informed about the science, but so you can ask the questions of your pediatrician, or you can give him a copy of this

video and ask him to watch it and respond to it.

And if you're a pediatrician, I would ask you to actually look at the science and not resort to appeals to authority. Because to say "Well, I know it's safe because CDC says it's safe" or "WHO [the World Health Organization] says it's safe" or "the AAP [American Academy of Pediatrics] says it's safe"—all of those agencies and organizations have been corrupted by pharmaceutical industry money.

You need to actually look at the science, and you need to read the science critically. And if you do that, you'll find that the things that I've talked about in this video are real, that these injuries are real, and that we have got to save our children from this cataclysm.

I want to thank you for listening to this video and urge you to join Children's Health Defense.

Robert F. Kennedy, Jr.'s reputation as a resolute defender of the environment stems from a litany of successful legal actions. Mr. Kennedy was named one of *Time* magazine's "Heroes for the Planet" for his success helping Riverkeeper lead the fight to restore the Hudson River.

The group's achievement helped spawn 300 Waterkeeper organizations across the globe. Mr. Kennedy serves as President of Waterkeeper Alliance and of counsel to Morgan & Morgan, a nationwide personal injury practice. He was previously Chief Prosecuting Attorney for the Hudson Riverkeeper, Senior Attorney for the Natural Resources Defense Council, and a Clinical Professor and Supervising Attorney at Pace University School of Law's Environmental Litigation Clinic. He is co-host of Ring of Fire on Air America Radio.

Earlier in his career he served as Assistant District Attorney in New York City. He has worked on environmental issues across the Americas and has assisted several indigenous tribes in Latin America and Canada in successfully negotiating treaties protecting traditional homelands. He is credited with leading the fight to protect New York City's water supply. The New York City watershed agreement, which he negotiated on behalf of environmentalists and New York City watershed consumers, is regarded as an international model in stakeholder consensus negotiations

and sustainable development.

Among Mr. Kennedy's published books are American Values: Lessons I Learned From My Fam-



ily, The New York Times' bestseller *Crimes Against* Nature (2004), The Riverkeepers (1997), and Judge Frank M. Johnson, Jr: A Biography (1977) and two children's books St. Francis of Assisi (2005), American Heroes: Joshua Chamberlain and the American Civil War and Robert Smalls: The Boat Thief (2008).

His articles have appeared in *The New York Times*, *Washington Post*, *Los Angeles Times*, *The Wall Street Journal*, *Newsweek*, *Rolling Stone*, *Atlantic Monthly*, *Esquire*, *The Nation*, *Outside Magazine*, *The Village Voice*, and many other publications. His award-winning articles have been included in anthologies of *America's Best Crime Writing*, *Best Political Writing* and *Best Science Writing*.

Mr. Kennedy is a graduate of Harvard University. He studied at the London School of Economics and received his law degree from the University of Virginia Law School. Following graduation he attended Pace University School of Law, where he was awarded a Masters Degree in Environmental Law.



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